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Saudi Food & Drug Authority

MDS – REQ 1

Requirements for Medical Devices Marketing Authorization

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements obtaining medical devices marketing authorization (MDMA) for the purpose of making available in return for payment or free of charge of a medical device, with a view to distribution and/or use within the KSA, In addition to risk classification rules for medical devices.

Scope

This document applies to manufacturers of medical devices for the purpose of making available with the KSA, and their authorized representatives.

Background

SFDA has issued this document in reference to the following:

- Article Eight, Nine and Ten of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H
- "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H
- Following SFDA/MDS announcements:
    - Announcement number (2/13/MDS-AN012) regarding marketing authorization renew & update fees and review times, and Announcement number (MDS-01-01-21) dated 13/1/2021 supplementary to the announcement number (2/13/MDS-AN012)
    - Announcement (8) 8/2019 regarding Updated timeframe for deleting medical device marketing authorization (MDMA) applications

Requirements

General	1	Medical device may be made available in return for payment or free of charge, with a view to distribution and/or use within the KSA only if it is registered at SFDA and obtaining medical devices marketing authorization (MDMA).
	2	Medical device shall comply with the "Essential Principles of Safety and Performance" specified in Annex (1) and Annex (2).
	3	Medical device manufacture shall: – Prepare, hold and update the "Medical Device Technical Documentation" and/or "IVD Technical Documentation" that confirm to "Essential Principles of Safety and Performance" specified in Annex (3) and Annex (4) – Establish, document and maintain an effective quality management system (QMS) according to the international ISO standard (ISO 13485:2016) or any identical adopted standard for the same issue/version.
Submitting to SFDA	4	– Application shall be submitted by a local manufacturer, an overseas manufacturer or the AR of the overseas manufacturer if overseas manufacturer wishes, after they obtain the following: • Local Manufactures: License of medical devices manufacture through the "GHAD System - Licensing Services" • Authorized Representative: License of authorized representative through the "GHAD System - Licensing Services" – Applicant shall submit the "Application Form for Medical Devices Marketing Authorization" electronically via "GHAD System - Marketing Authorization Services" and provide required documents specified in the application form. – In regard of low-risk medical devices (except IVDs, sterile, having measuring function, reusable surgical instruments, and novel), the following shall be submitted in accordance to "Technical Documentation" in Annex (3): 1. Device Description and Specification 2. Information to be Provided by The Manufacturer 3. Essential Principles Checklist 4. Evidence of Compliance with the Applicable Essential Principles

		5. Risk Management File 6. Post-Market Surveillance Plan and Report SFDA has the right to request all "Technical Documentation" if necessary, even after obtaining the MDMA, and they shall be provided within (10) days of its request Notes 1. Manufacture shall classify the medical device according to the "Risk Classification Rules for Medical Devices" specified in Annex (5). 2. Innovative medical devices are exempted from some of the requirements specified in Annex (3) and Annex (4) when verifying the eligibility of the exception after submitting "Innovative Medical Device Summary Form" in Annex (11). - Applicant shall pay fees specified in Annex (12). - Medical devices may be bundled/grouped within one MDMA application based on the criteria mentioned in Annex (15). - Once satisfied, SFDA will issue MDMA including the information specified in Annex (13).
Post submitting	5	SFDA shall be informed, via the electronic system, within (10) days of the occurrence any significant change to the relevant information or (30) non-significant changes. For more information, see guidance on variations.
	6	The MDMA certificate shall be renewed before its expiration date, and the updated documents, if necessary, shall be submitted through the electronic system, and a renewal request can be submitted 90 days before its expiry date.

Annexes

The requirements stated in the annexes are
harmonized with international regulatory requirements

Annex (1) Essential Principles of Safety and Performance for Medical Devices other than In-Vitro Medical Device

General Requirements	
1.	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
2.	The requirement in this annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.
3.	Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall: a) Establish and document a risk management plan for each device; b) Identify and analyse the known and foreseeable hazards associated with each device; c) Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; d) Eliminate or control the risks referred to in point (c) in accordance with the requirements of Essential Principle (4); e) Evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and f) Based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Essential Principle (4).

4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: a) Eliminate or reduce risks as far as possible through safe design and manufacture; b) Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and c) Provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.
5.	In eliminating or reducing risks related to use error, the manufacturer shall: a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.
7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer. The environmental and/or conditions of use that may be encountered within the KSA shall be considered and addressed.
8.	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

9.	For the devices which do not have medical intended purpose but shall be treated as medical devices, that are listed in table (1) of Annex (5), the general safety requirements set out in Essential Principle (1) and Essential Principle (8) shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.
Requirements Regarding Design and Manufacture	
10.	Chemical, physical and biological properties
10.1.	Devices shall be designed and manufactured in such a way as to ensure that the general characteristics and performance requirements are fulfilled. Particular attention shall be paid to: a) The choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability; b) The compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion; c) The compatibility between the different parts of a device which consists of more than one implantable part; d) The impact of processes on material properties; e) Where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; f) The mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; g) Surface properties; and h) The confirmation that the device meets any defined chemical and/or physical specifications.
10.2.	Devices shall be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the devices. Particular attention shall be paid to tissues exposed those contaminants and residues and to the duration and frequency of exposure.

10.3.	The devices shall be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.
10.4.	Substances
10.4.1.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues that may be released from the device.
10.4.2.	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance shall be verified, taking account of the intended purpose of the device.
10.5.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.
10.6.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.
11.	Infection and microbial contamination
11.1.	The devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible and appropriate the risk of infection to patients, users and, where applicable, other persons. The design shall: a) Reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, b) Allow easy and safe handling, c) Reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use, and d) Prevent microbial contamination of the device or its content such as specimen or fluids.
11.2.	Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilization

11.3.	Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.
11.4.	Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.
11.5.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilized by means of appropriate, validated methods.
11.6.	Devices intended to be sterilized shall be manufactured and packaged in appropriate and controlled conditions and facilities.
11.7.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilization indicated by the manufacturer.
11.8.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.
12.	Devices which, if used separately, would be considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.
12.1.	In the case of devices which incorporate, as an integral part, a substance which, if used separately, would be considered to be a medicinal product, shall be verified by reference to SFDA requirements for medicinal products.
12.2.	Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply with the state of the art for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for the occurrence of adverse events.
13.	Devices incorporating materials of biological origin

13.1.	For devices manufactured utilizing derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable the following shall apply: a) Donation, procurement and testing of the tissues and cells shall be done in accordance with the state of the art; b) Processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; c) The traceability system for those devices shall be complementary and compatible with state of the art traceability and data protection.
13.2.	For devices manufactured utilizing tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: a) Where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; b) Sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; c) In the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, state of the art controls shall be put in place.
13.3.	For devices manufactured utilizing non-viable biological substances other than those referred to in Essential Principle (13.1) and Essential Principle (13.2), the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.
14.	Construction of devices and interaction with their environment.

14.1.	If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.
14.2.	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: a) The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; b) Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; c) The risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; d) The risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; e) The risks of accidental ingress of substances into the device; f) The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and g) Risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.
14.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.
14.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.
14.5.	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

14.6.	Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.
14.7.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.
15.	Devices with a diagnostic or measuring function
15.1.	Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.
15.2.	The measurements made by devices with a measuring function shall be expressed in the International System of Units (SI) according to the Law of Measurement and Calibration
16.	Protection against radiation
16.1.	General: a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

16.2.	Intended radiation a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.
16.3.	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.
16.4.	Ionizing radiation a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the state of the art safety standards for protection against the dangers arising from exposure to ionising radiation. b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.
16.5.	Imaging medical devices shall be capable of automatically recording dose, protocol data, and patient information such as age, gender and weight in standardized formats.
17.	Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.
17.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.
17.3.	Software referred to in this Essential Principle that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).
17.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.
18.	Active devices and devices connected to them
18.1.	For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.
18.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.
18.3.	Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.
18.4.	Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
18.5.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

18.6.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.
18.7.	Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.
18.8.	Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorized access that could hamper the device from functioning as intended.
18.9.	Where the electrical medical device is intended to be connected to an alternating current (AC) power supply, the device shall be: a) designed to operate with a 60 Hertz supply at nominal values of either 230 or 400 volts, and b) fitted with the appropriate AC power connector in accordance with part 401 of SBC and the Saudi standard entitled "Plugs and socket-outlets for household and similar purposes- safety requirements and test methods 250 V/13 A (SASO-2203)".
18.10.	For electrical medical devices, colours of conductors' insulators shall be in accordance with the Saudi Building Code –Electrical Requirements part 401 of SBC.
19.	Particular requirements for active implantable devices

19.1.	Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: a) Risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, b) Risks connected with medical treatment, in particular those resulting from the use of defibrillators or high frequency surgical equipment, and c) Risks which may arise where maintenance and calibration are impossible, including: – Excessive increase of leakage currents, – Ageing of the materials used, – Excess heat generated by the device, – Decreased accuracy of any measuring or control mechanism.
19.2.	Active implantable devices shall be designed and manufactured in such a way as to ensure – if applicable, the compatibility of the devices with the substances they are intended to administer, and – the reliability of the source of energy
19.3.	Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.
19.4.	Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.
20.	Protection against mechanical and thermal risks
20.1.	Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

20.2.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance
20.3.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.
20.4.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.
20.5.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.
20.6.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.
21.	Protection against the risks posed to the patient or user by devices supplying energy or substances
21.1.	Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.
21.2.	Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.
21.3.	The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

22.	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons
22.1.	Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the layperson's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply. The user interface of the electronic system shall be in both the Arabic and English languages.
22.2.	Devices for use by lay persons shall be designed and manufactured in such a way as to: – Ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information, – Reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and – Reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.
22.3.	Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: – can verify that, at the time of use, the device will perform as intended by the manufacturer, and – if applicable, is warned if the device has failed to provide a valid result.
Requirements Regarding Information Supplied with the Device	
23.	Label and instructions for use

23.1. General requirements regarding the information supplied by the manufacturer.

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Information supplied by the manufacturer for devices for use by lay persons shall be in both the Arabic and English languages.

b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

c) Labels shall be provided in a human-readable format and shall be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class A and class B devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Essential Principle.

e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) and shall meet eIFU requirements set out in Annex (10).

g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the recognized standards

i) Labelling shall not include the SFDA logo, but may include the Medical Device National Listing Number.

23.2. Information on the label

The label shall bear all of the following particulars:

a) The name or trade name of the device, and Arabic name as it is pronounced in English for devices for use by lay persons;

b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;

c) The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

d) Where applicable, an indication that the device contains or incorporates:

- A medicinal substance, including a human blood or plasma derivative, or
- Tissues or cells, or their derivatives, of human origin, or
- Tissues or cells of animal origin, or their derivatives,

e) Contains substances which are carcinogenic, mutagenic or toxic to reproduction or substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health in a concentration above 0,1 % weight by weight (w/w) shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging

f) The UDI carrier.

g) The lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

h) An unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;

i) Where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

j) An indication of any special storage and/or handling condition that applies;

k) If the device is supplied sterile, an indication of its sterile state and the sterilisation method;

l) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

m) If the device is intended for single use, an indication of that fact.

n) If the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;

o) If the device is custom-made, the words ‘custom-made device’;

p) An indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation’;

q) In the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;

r) For active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.

s) If the device is intended for non-clinical research, presentation, demonstration, teaching or testing purposes only, an indication of that fact.

23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

The following particulars shall appear on the sterile packaging:

a) An indication permitting the sterile packaging to be recognised as such,

b) A declaration that the device is in a sterile condition,

c) The method of sterilisation,

d) The name and address of the manufacturer,

e) A description of the device,

f) If the device is intended for clinical investigations, the words 'exclusively for clinical investigations',

g) If the device is custom-made, the words 'custom-made device',

h) The month and year of manufacture,

i) An unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and

j) An instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

23.4. Information in the instructions for use

The instructions for use shall contain all of the following particulars:

a) The particulars referred to in points (a), (c), (d), (e), (j), (k), (m) and (q) of Essential Principle (23.2);

b) The device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;

c) Where applicable, a specification of the clinical benefits to be expected.

d) Where applicable, links to the summary of safety and clinical performance referred to in Annex (9);

e) The performance characteristics of the device;

f) Where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;

g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;

h) Specifications the user requires to use the device appropriately, e.g. If the device has a measuring function, the degree of accuracy claimed for it;

i) Details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;

j) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;

k) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,
- identification of any consumable components and how to replace them,
- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and
- methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;

l) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;

m) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;

n) If the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation information shall be provided to identify when the device shall no longer be reused, e.g. Signs of material degradation or the maximum number of allowable reuses;

o) An indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential principals of safety and performance;

p) If the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Essential Principle (23.1) no instructions for use are required, this information shall be made available to the user upon request;

q) For devices intended for use together with other devices and/or general purpose equipment:

- Information to identify such devices or equipment, in order to obtain a safe combination, and/or
- Information on any known restrictions to combinations of devices and equipment;

r) If the device emits radiation for medical purposes:

- Detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,
- The means of protecting the patient, user, or other person from unintended radiation during use of the device;

s) Information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,
- warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

- warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,
- if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered and identification of their origins,
- warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and
- precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;

t) In the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side-effects and risks relating to overdose;

u) In the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;

v) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:

— infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and

— physical hazards such as from sharps. If no instructions for use are required, this information shall be made available to the user upon request;

w) For devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;

x) For devices to be treated as medical devices but which are not medical devices, that are listed in table (1) of Annex (5), information regarding the absence of a clinical benefit and the risks related to use of the device;

y) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;

z) A notice to the user and/or patient that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the Saudi Food and Drug Authority;

aa) Information to be supplied to the patient with an implanted device in accordance with Annex (8).

bb) For devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

cc) For devices for use by lay persons, contacts information for the canter(s) within the KSA providing technical assistance for users.

Annex (2): Essential Principles of Safety and Performance for In-Vitro Medical Devices

General Requirements	
1.	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art
2.	The requirement in this annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.
3.	Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall: a) Establish and document a risk management plan for each device; b) Identify and analyse the known and foreseeable hazards associated with each device; c) Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; d) Eliminate or control the risks referred to in point (c) in accordance with the requirements of Essential Principle (4); e) Evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and f) Based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Essential Principle (4).

4.	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: a) Eliminate or reduce risks as far as possible through safe design and manufacture; b) Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and c) Provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.
5.	In eliminating or reducing risks related to use error, the manufacturer shall: a) Reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and b) Give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
6.	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.
7.	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer. The environmental and/or conditions of use that may be encountered within the KSA shall be considered and addressed.
8.	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.
Requirements Regarding Performance, Design and Manufacture	

9.	Performance characteristics
9.1.	Devices shall be designed and manufactured in such a way that they are suitable for the purposes for the purposes referred to in the IVD definition, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable: a) The analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and b) The clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.
9.2.	The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.
9.3.	Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.
9.4.	The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions: a) For devices for self-testing, performances obtained by laypersons; b) For devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).
10.	Chemical, physical and biological properties

10.1.	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in General Requirements are fulfilled. Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.
10.2.	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.
10.3.	Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR') and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health.
10.4.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.
11.	Infection and microbial contamination
11.1.	Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall: a) Allow easy and safe handling; b) Reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; And, where necessary c) Prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen
11.2.	Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.

11.3.	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.
11.4.	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.
11.5.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.
11.6.	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.
12.	Devices incorporating materials of biological origin
	Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person. In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.
13.	Construction of devices and interaction with their environment
13.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.

13.2.	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: a) The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; b) Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; c) The risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; d) The risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; e) The risks of accidental ingress of substances into the device; f) The risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character coding on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended; g) The risks of any foreseeable interference with other devices.
13.3.	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.
13.4.	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.
13.5.	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.
13.6.	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

13.7.	The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.
14.	Devices with a measuring function
14.1.	Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Essential Principle (9.1), taking into account the intended purpose of the device.
14.2.	The measurements made by devices with a measuring function shall be expressed in the International System of Units (SI) according to the Law of Measurement and Calibration
15.	Protection against radiation
15.1.	Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.
15.2.	When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be: a) Designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and b) Fitted with visual displays and/or audible warnings of such emissions.
15.3.	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.
16.	Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

16.1.	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.
16.2.	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.
16.3.	Software referred to in this Essential Principle that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).
16.4.	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.
17.	Devices connected to or equipped with an energy source
17.1.	For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.
17.2.	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.
17.3.	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.
17.4.	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.
17.5.	Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

17.6.	Where the electrical medical device is intended to be connected to an alternating current (AC) power supply, the device shall be: a) designed to operate with a 60 Hertz supply at nominal values of either 230 or 400 volts; and b) fitted with the appropriate AC power connector in accordance with part 401 of SBC and the Saudi standard entitled "Plugs and socket-outlets for household and similar purposes- safety requirements and test methods 250 V/13 A (SASO-2203)".
17.7.	For electrical medical devices, colours of conductors' insulators shall be in accordance with the Saudi Building Code –Electrical Requirements part 401 of SBC.
18.	Protection against mechanical and thermal risks
18.1.	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.
18.2.	Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.
18.3.	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated. Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.
18.4.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.
18.5.	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

18.6.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.
18.7.	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.
18.8.	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.
19.	Protection against the risks posed by devices intended for self-testing or near-patient testing
19.1.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user. In the case of self-testing, the user interface of the electronic system shall be in both the Arabic and English languages.
19.2.	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to: a) Ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and b) Reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.
19.3.	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user: a) Can verify that, at the time of use, the device will perform as intended by the manufacturer; and b) Be warned if the device has failed to provide a valid result.

Requirements Regarding Information Supplied with the Device	
20.	Label and instructions for use
20.1.	General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Information supplied by the manufacturer for devices intended for self-testing shall be in both the Arabic and English languages.

b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.

c) Labels shall be provided in a human-readable format and shall be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

d) Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.

e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic) in accordance with eIFU requirements set out in Annex (10), except when the device is intended for near-patient testing.

g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the recognized standards. In areas for which no recognized standards exist, the symbols and colours shall be described in the documentation supplied with the device.

i) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements

shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other safety information shall be given in the instructions for use.

j) If there is a safety data sheet it shall be made available, unless all relevant information, as appropriate, is already made available in the instructions for use.

k) Labelling shall not include the SFDA logo, but may include the Medical Device National Listing Number.

20.2. Information on the label

The label shall bear all of the following particulars:

a) The name or trade name of the device, and Arabic name as it is pronounced in English for devices intended for self-testing;

b) The details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;

c) The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

d) An indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;

e) The LOT NUMBER or the SERIAL NUMBER of the device preceded by the words lot number or serial number or an equivalent symbol, as appropriate;

f) The UDI carrier;

g) An unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;

h) Where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

i) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;

j) An indication of any special storage and/or handling condition that applies;

k) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;

l) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

m) If the instructions for use are not provided in paper form in accordance with point (f) of Essential Principle (20.1), a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;

n) Where applicable, any particular operating instructions;

o) If the device is intended for single use, an indication of that fact.

p) If the device is intended for self-testing or near-patient testing, an indication of that fact;

q) Where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;

r) Where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Essential Principle and with the requirements of Medical Devices Law;

s) The devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;

t) The label for devices for self-testing shall bear the following particulars:

i. the type of specimen(s) required to perform the test (e.g. blood, urine or saliva);

ii. the need for additional materials for the test to function properly;

iii. contact details for further advice and assistance.

The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.

u) If the device is intended for non-clinical research, presentation, demonstration, teaching or testing purposes only, an indication of that fact.

20.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging'):

	The following particulars shall appear on the sterile packaging: a) An indication permitting the sterile packaging to be recognised as such, b) A declaration that the device is in a sterile condition, c) The method of sterilization, d) The name and address of the manufacturer, e) A description of the device, f) The month and year of manufacture, g) An unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order, h) An instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use
20.4.	Information in the instructions for use

20.4.1. The instructions for use shall contain all of the following particulars:

a) The name or trade name of the device, and Arabic name as it is pronounced in English for devices intended for self-testing;

b) The details strictly necessary for the user to uniquely identify the device;

c) The device's intended purpose:

i. what is detected and/or measured;

ii. its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);

iii. the specific information that is intended to be provided in the context of:

- a physiological or pathological state;
- congenital physical or mental impairments;
- the predisposition to a medical condition or a disease;
- the determination of the safety and compatibility with potential recipients;
- the prediction of treatment response or reactions;
- the definition or monitoring of therapeutic measures;

iv. whether it is automated or not;

v. whether it is qualitative, semi-quantitative or quantitative;

vi. the type of specimen(s) required;

vii. where applicable, the testing population; and

viii. for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.

d) An indication that the device is an *in vitro* diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;

e) The intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);

f) The test principle;

g) A description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);

h) A description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;

i) A list of materials provided and a list of special materials required but not provided;

j) For devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:

   i. information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or

   ii. information on any known restrictions to combinations of devices and equipment.

k) An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;

l) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;

m) If the device is supplied as sterile, an indication of its sterile state, the sterilization method and instructions in the event of the sterile packaging being damaged before use;

n) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate:

   i. warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,

   ii. warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

   iii. warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

   iv. precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitization or an allergic reaction by the patient or user,

v. if the device is intended for single use, an indication of that fact.

vi. if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses;

o) Any warnings and/or precautions related to potentially infectious material that is included in the device;

p) Where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;

q) Conditions for collection, handling, and preparation of the specimen;

r) Details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;

s) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

i. details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;

ii. identification of any consumable components and how to replace them;

iii. information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;

iv. methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.

t) Where applicable, recommendations for quality control procedures;

u) The metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;

v) Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;

w) Analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed

for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;

x) Clinical performance characteristics as defined in Essential Principle (9.1) of this annex;

y) The mathematical approach upon which the calculation of the analytical result is made;

z) Where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;

aa) Where relevant, reference intervals in normal and affected populations;

bb) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;

cc) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:

i. infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;

ii. environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);

iii. physical hazards such as explosion.

dd) The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;

ee) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;

ff) A notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the Saudi Food and Drug Authority;

gg) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Essential Principle and with the requirements of Medical Devices Law;

hh) For devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.

20.4.2. In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:

a) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;

b) Specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;

c) The device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;

d) The results shall be expressed and presented in a way that is readily understood by the intended user;

e) Information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;

f) The information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, further advice such as national helplines, websites;

g) For devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

h) Contacts information for the center(s) within the KSA providing technical assistance for users.

Annex (3) Medical Device Technical Documentation

The technical documentation shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the below elements:

1) Device Description and Specification, Including Variants and Accessories

This section defines the device and any accessories. The following points shall be documented and shall include information relating to the variants and accessories covered by the technical documentation:

a) Product or trade name of the device (list all products or variants that are covered by the technical file, including any accessories).

b) Clear identification of device by product code, model number, catalogue number or other unambiguous means.

c) Description of the device and any accessories, including:
   i) Physical description (i.e. what the device looks like)
   ii) Details about components, parts, spares, and accessories
   iii) Materials and which of these have direct or indirect contact with the human body (i.e. what it is made of)
   iv) Principles of operation/mode of action (i.e. how it works/operates)
   v) Any specific performance characteristics it has (and how they different between models)
   vi) Options/configurations/sizes (i.e. detail what options/configurations/sizes are available for the market if applicable)

d) Picture or drawing of the device which should be detailed enough to aid understanding of the device operation and include sufficient explanation to understand the drawing

e) Intended purpose of the device, including:
   i) Key indications
   ii) Medical conditions
   iii) Patient populations
   iv) Contraindications (e.g. age, gender, parts of the body, if suffering from another disease, pregnant or breast feeding etc.)

f) Intended users of the device
   i) Patient/Clinician/Carer
   ii) Any user restrictions.

g) Rationale of the qualification of the device (i.e. why is it being regulated as a medical device – this applies also to devices which do not have medical intended purpose but shall be treated as medical devices, that are listed in table (1) of Annex (5))

h) Classification of the device in accordance with the classification rules. This should include the class of device and all the applicable rules with a justification of the chosen class/rule for both the device and any accessories.

i) An explanation of any novel features (examples of novel features include new to market technology, new types of materials used or new application of existing technology)

j) Description of any devices required to operate the device that are not included (e.g. IT infrastructure, laptop, mobile 'smart' phone)

k) Device history (i.e. provide an overview of the previous generation or generations of the device if applicable)

l) Device market position (i.e. are there similar devices in KSA or other international markets)

m) Declarations (i.e. does the device require any specific declarations to be made such as containing animal tissue/medicines/human blood derivatives)

2) Information to be provided by the Manufacturer

Information provided by the manufacturer conveys information to the user or clinician and is a key part of the technical documentation. The Technical Documentation shall include a full set of labels for the device and packaging which includes the instructions for use (IFU) and any promotional material as applicable. Information provided by the manufacturer shall fulfill the Essential Principles of Safety and Performance requirements set out in Annex (1).

Specific considerations shall be considered for:

a) Where the manufacturer has placed information on their website, this shall also be identified.

b) When instructions for use are provided to the user in non-paper format (e.g. electronic), the risks associated with doing so should be considered, e.g. security against modification.

c) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to SFDA.MD/ ISO 15223-1 that provides examples of appropriate symbols, and any symbols not defined in internationally recognized standards shall be explained in the instructions for use (IFU).

d) Promotional material must not contain claims that exceed those in the instructions for use, clinical evaluation or technical documentation. For devices for use by lay persons, the advertising and marketing material shall be provided in both languages (Arabic and English).

e) Manufacturer's instructions for handling, storage, transportation, installation, maintenance (including service manuals), and disposal of the medical devices shall be made available to the SFDA or any relevant party in English and, when requested, in Arabic.

3) Design and Manufacturing Information

This section provides details on the device design and how it is manufactured. This section shall include:

a) Full device description
   i) Technical drawings (clearly labelled and explained)
   ii) Bill of materials
   iii) Information to describe the function and assembly of the device

b) Applied parts
   i) Explanation of which parts of the device contact the human body either directly or indirectly
   ii) Identification of the contact materials

c) Technical specifications (as applicable)

i) Device features
ii) Dimensions
iii) Performance attributes
iv) Voltages
v) Output
vi) Temperatures
vii) Flows
viii) Weight
ix) Speed
x) Other specifications

d) Requirements documentation
i) User requirements
ii) Product requirements
iii) Software requirements
iv) Hardware requirements
v) Other requirements

e) Design Traceability
i) Traceability matrix to show how user requirements have been validated and product/design requirements have been verified.

f) Design Stages
i) Reference to design procedure
ii) Description of design stages
iii) Confirmation of the verification and validation conducted on the device

g) Manufacturing processes
i) Manufacturing information to include:
ii) Manufacturing process flow
iii) Manufacturing specifications including in process testing
iv) Final inspection and acceptance criteria
v) Manufacturing validation

h) Manufacturing structure
i) Name and address of place where design was carried out (all sites and subcontractors)
ii) Name and address of place where manufacturing is carried out (all sites and subcontractors)
iii) Detail of suppliers including identification of critical suppliers
iv) Confirmation of subcontractor contracts (if applicable)

4) Essential Principles of Safety and Performance

This section within the technical documentation is intended to demonstrate how the manufacturer has met the essential principles of safety and performance set out in Annex (1), taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The Essential Principles checklists shall be used to demonstrate this and should form this section of the technical documentation. The demonstration of conformity shall also include:

a) The essential principles requirements that apply to the device and an explanation as to why others do not apply;

b) The method or methods used to demonstrate conformity with each applicable essential principles requirement;

c) Any standards, or other solutions applied;

d) The precise identity of the controlled documents offering evidence of conformity with each standard, or other method applied to demonstrate conformity with the essential principles requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5) Benefit-Risk Analysis and Risk Management

This section of the technical documentation documents the benefit to risk assessment and demonstrates that the device is considered safe. This section may directly refer to the device risk assessment or the clinical evaluation (or both). A risk/benefit statement should appear in these documents and this may be repeated here, or reference made to it.

a) Risk management should be documented and should contain as a minimum:
   i) Procedure
   ii) Risk Management Plan
   iii) Risk Analysis
   iv) Risk Management Report

   Evidence of these documents shall appear within the technical documentation. The Risk Management Plan, Analysis and Report could be combined into one document or separate documents, as long as each part meets the requirements for planning, analysis and reporting.

   Risks should be controlled to ensure they are ‘as low as possible’ and the risk analysis criteria should be either referenced or explained.

b) The risk management procedure should ensure required elements are addressed:
   i) Risk Analysis
   ii) Risk Evaluation
   iii) Risk Control
   iv) Production & Post-production information

   Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. SFDA.MD/ ISO 14971 provides direction and further information for conducting Risk Management activities.

c) Risk management plan shall include:
   i) Assignment of responsibilities and authorities
   ii) Requirements for review of risk management activities
   iii) Criteria for risk acceptability, based on the manufacturer’s policy for determining acceptable risk
   iv) Verification activities
   v) Activities related to collection and review of relevant production and post-production information

d) Risk management analysis shall include:
   i) A description and identification of the medical device that was analyzed
   ii) A picture or diagram if appropriate
   iii) A description of the intended purpose from a functional point of view

iv) Identification of the persons who conducted the risk analysis] – (Risk analysis should be conducted using a multi-disciplinary team (high risk devices should have more focused experts involved))
v) Scope and date of the analysis
vi) Analysis of findings:
(1) Ensure the risk scale make sense, are the severities and occurrences in the analysis similar to what is expected for the device?
(2) Ensure the risks re-calculated after risk reductions have been put in place
(3) Ensure that instructions for use are not being employed as risk mitigation
(4) Ensure that risk mitigations that do not design out a hazard do not reduce severities (electrocution does not reduce in severity when the probability of occurrence is reduced)
(5) Consider the risk mitigations that are listed and their effects on the risk are similar to what is expected for the device
(6) Ensure the overall acceptability of each risk has been stated
(7) Possible relevant hazards to consider:
(a) Usability, including foreseeable misuse (not reading instructions for use (IFU), home use, reuse, local language)
(b) Mechanical hazards (pinch, traps, trips)
(c) Electrical hazards (leakage, fire, burn, ingress, power limitation, accidental disconnect/shutdown)
(d) Biological hazards (cleaning, sterility, leaching, toxic materials, includes user and patient)
(e) Software hazards (safety, security, confidentiality, utility over lifetime)

e) Risk Management report shall include:
i) Confirmation that the risk management activities have been carried out as planned
ii) Overall Residual Risks are discussed and is acceptable
iii) Post-market information (evidence that ensure the control of post-market information)

6) Product Verification and Validation

This section of the technical documentation lists the methods and standards used to verify and validate the product. The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of Medical Devices Law and in particular the applicable Essential Principles of Safety and Performance.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service.

a) Pre-clinical data and clinical data

i) A list of standards to which compliance is claimed

ii) Results of tests, such as engineering, laboratory, simulated use and animal tests, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications

iii) Detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:
   (1) The biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user
   (2) Physical, chemical and microbiological characterisation
   (3) Electrical safety and electromagnetic compatibility (if applicable)
   (4) Software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer)
   (5) Life of product, Stability, including shelf life
   (6) Performance and safety

iv) The clinical evaluation report and its updates and the clinical evaluation plan, according to Annex (6).

v) The Post-Market Clinical Follow-up (PMCF) plan and PMCF evaluation report or a justification when a PMCF is not applicable, according to Annex (6).

b) Additional information required in specific cases:

i) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Medicinal Products Law in KSA, including a medicinal product derived from human blood or human plasma, a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device

ii) Where a device is manufactured utilizing tissues or cells of human or animal origin, or their derivatives, and is covered by Medical Devices Law, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by Medical Devices Law, a statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Essential Principle (13.1) or Essential Principle (13.2), respectively, of the essential principals of safety and performance set out in Annex (1).

iii) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:
   (1) Absorption, distribution, metabolism and excretion
   (2) Possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions
   (3) Local tolerance

(4) Toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.

(5) In the absence of such studies, a justification shall be provided.

iv) In the case of devices containing substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) or endocrine-disrupting substances referred to in Essential Principle (10.4.1) of the Essential Principles of Safety and Performance set out in Annex (1), the justification referred to in Essential Principle (10.4.2) of the Essential Principles of Safety and Performance set out in Annex (1).

v) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilization and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

vi) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

vii) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the essential principals of safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

viii) Specific cases that may involve additional clinical scrutiny may also include total and partial joint prosthesis, cardiovascular devices, implantable pulse generators, supportive devices such as meshes.

7) Post Market Surveillance Plan

The post market surveillance plan section describes within the technical documentation what systems are in place to ensure appropriate post market surveillance data is collected. This section shall include:

a) Sources of potential post market surveillance data:

i) Information concerning serious incidents (such as death, life threatening injury), including information from periodic safety update report (PSURs), and field safety corrective actions

ii) Records referring to non-serious incidents and data on any undesirable side-effects, this should include post-market data on:
(1) near miss incidents
(2) usability
(3) Misuse incidents
(4) Reported side effects and especially unexpected or new side effects

iii) Information from trend reporting (i.e. trending complaints to determine if there is a spike that would indicate a potential issue). The data collected from point (ii) above should show evidence on statistical analysis when relevant and frequencies of occurrence should be presented in a readable manner

iv) Relevant specialist or technical literature, databases and/or registers

v) Information, including feedbacks and complaints, provided by users, distributors and importers

vi) Information solicited from users via forums, trade shows social media or other means

b) a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market

c) Effective and appropriate methods and processes to assess the collected data, consideration should also be given to statistical methods

d) Ensure suitable indicators and threshold values been chosen that will be used in the continuous reassessment of the benefit-risk analysis and of the risk management.

e) Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field

f) Methods and protocols to manage the events subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period.

g) Methods and protocols to communicate effectively with SFDA, economic operators and users regarding medical device issues.

h) Procedures:
   i) Reference to procedures to fulfil the manufacturer's obligations
   ii) Systematic procedures to identify and initiate appropriate measures including corrective actions

i) A PMCF plan as referred to in Part B of Annex (6), or a justification as to why a PMCF is not applicable

j) Effective tools to trace and identify devices for which corrective actions might be necessary

8) Periodic Safety Update Report and Post Market Surveillance Report

a) Post-market surveillance report

Manufacturers of class A devices shall prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the SFDA upon request.

b) Periodic safety update report
Manufacturers of class B, class C and class D devices shall prepare a periodic safety update report (PSUR) for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:
   i) The conclusions of the benefit-risk determination
   ii) The main findings of the Post-market clinical follow-up (PMCF)

iii) The volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device

Manufacturers of class C and D devices shall update the PSUR at least annually.

Manufacturers of class B devices shall update the PSUR when necessary and at least every two years.

Annex (4) IVD Technical Documentation

The technical documentation shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the below elements:

1) Device Description and Specification, Including Variants and Accessories:

This section defines the device and any accessories. The following points shall be documented and shall include information relating to the variants and accessories covered by the technical documentation:

a) Product or trade name and a general description of the device including its intended purpose and intended users (list all products or variants that are covered by the technical file, including any accessories).

b) Clear identification of device by product code, model number, catalogue number or other unambiguous means.

c) The intended purpose of the device which may include information on:
iii) What is to be detected and/or measured;
iv) Its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;
v) The specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
vi) Whether it is automated or not;
vii) Whether it is qualitative, semi-quantitative or quantitative;
viii) The type of specimen(s) required;
ix) Where applicable, the testing population;
x) The intended user;
xi) In addition, for companion diagnostics, the relevant target population and the associated medicinal product(s).

d) The description of the principle of the assay method or the principles of operation of the instrument.

e) The rationale for the qualification of the product as a device;

f) The risk class of the device and the justification for the classification rule(s) applied in accordance with Annex (5).

g) The description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers;

and where applicable

h) The description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;

i) For instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;

j) For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;

k) A description of any software to be used with the device;

l) A description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

m) A description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.

n) Reference to previous and similar generations of the device
   i) An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;
   ii) An overview of identified similar devices available markets, where such devices exist.

2) Information to be Supplied by The Manufacturer:

Information provided by the manufacturer conveys information to the user or clinician and is a key part of the technical documentation. The Technical Documentation shall include a full set of labels for the device and packaging which includes the instructions for use (IFU) and any promotional material as applicable. Information provided by the manufacturer shall fulfill the essential principles of safety and performance requirements set out in Annex (2).

Specific considerations shall be considered for:

a) When instructions for use are provided to the user in non-paper format (e.g. electronic) "except when the device is intended for near-patient testing and for self-testing", the risks associated with doing so should be considered, e.g. security against modification.

b) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to SFDA.MD/ ISO 15223-1 that provides examples of appropriate symbols, and any symbols not defined in internationally recognized standards shall be explained in the instructions for use (IFU).

c) Promotional material must not contain claims that exceed those in the instructions for use, clinical evaluation or technical documentation. For devices intended for self-testing, the advertising and marketing material shall be provided in both languages (Arabic and English).

d) Manufacturer's instructions for handling, storage, transportation, installation, maintenance (including service manuals), and disposal of the medical devices shall be made available to the SFDA or any relevant party in English and, when requested, in Arabic.

3) Design and Manufacturing Information

This section provides details on the device design and how it is manufactured. This section shall include:

a) Full device description
   i) Technical drawings (clearly labelled and explained)
   ii) Bill of materials
   iii) Information to describe the function and assembly of the device
   iv) A description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device
   v) For instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software
   vi) For instruments and software, an overview of the entire system

vii) For software, a description of the data interpretation methodology, namely the algorithm
viii) For devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self-testing or near-patient testing

b) Technical specifications (as applicable)
   i) Device features
   ii) Dimensions
   iii) Performance attributes
   iv) Voltages
   v) Output
   vi) Temperatures
   vii) Flows
   viii) Weight
   ix) Speed
   x) Other specifications

c) Requirements documentation
   i) User requirements
   ii) Product requirements
   iii) Software requirements
   iv) Hardware requirements
   v) Other requirements

d) Design Traceability
   i) Traceability matrix to show how user requirements have been validated and product/design requirements have been verified.

e) Design Stages
   i) Reference to design procedure
   ii) Description of design stages
   iii) Confirmation of the verification and validation conducted on the device

f) Manufacturing processes
   i) Manufacturing information to include:
      (1) Manufacturing process flow
      (2) Manufacturing specifications including in process testing
      (3) Final inspection and acceptance criteria
      (4) Manufacturing validation

g) Manufacturing structure

   i) Name and address of place where design was carried out (all sites and subcontractors)
   ii) Name and address of place where manufacturing is carried out (all sites and subcontractors)
   iii) Detail of suppliers including identification of critical suppliers
   iv) Confirmation of subcontractor contracts (if applicable)

4) Essential Principles of Safety and Performance

This section within the technical documentation is intended to demonstrate how the manufacturer has met the essential principles of safety and performance set out in Annex (2), taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The Essential Principles

checklists shall be used to demonstrate this and should form this section of the technical documentation. The demonstration of conformity shall also include:

a) The essential principles requirements that apply to the device and an explanation as to why others do not apply;

b) The method or methods used to demonstrate conformity with each applicable essential principles requirement;

c) Any standards, or other solutions applied;

d) The precise identity of the controlled documents offering evidence of conformity with each standard, or other method applied to demonstrate conformity with the essential principles requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5) Benfit-Risk Analysis and Risk Management

This section of the technical documentation documents the benefit to risk assessment and demonstrates that the device is considered safe. This section may directly refer to the device risk assessment or the clinical evaluation (or both). A risk/benefit statement should appear in these documents and this may be repeated here, or reference made to it.

a) Risk management should be documented and should contain as a minimum:
   i) Procedure
   ii) Risk Management Plan
   iii) Risk Analysis
   iv) Risk Management Report

   Evidence of these documents shall appear within the technical documentation. The Risk Management Plan, Analysis and Report could be combined into one document or separate documents, as long as each part meets the requirements for planning, analysis and reporting.

   Risks should be controlled to ensure they are ‘as low as possible’ and the risk analysis criteria should be either referenced or explained.

b) The risk management procedure should ensure required elements are addressed:
   i) Risk Analysis
   ii) Risk Evaluation
   iii) Risk Control
   iv) Production & Post-production information

   Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. SFDA.MD/ ISO 14971 provides direction and further information for conducting Risk Management activities.

c) Risk management plan shall include:
   i) Assignment of responsibilities and authorities
   ii) Requirements for review of risk management activities
   iii) Criteria for risk acceptability, based on the manufacturer’s policy for determining acceptable risk
   iv) Verification activities

v) Activities related to collection and review of relevant production and post-production information

d) Risk management analysis shall include:
   i) A description and identification of the medical device that was analyzed
   ii) A picture or diagram if appropriate
   iii) A description of the intended purpose from a functional point of view
   iv) Identification of the persons who conducted the risk analysis] – (Risk analysis should be conducted using a multi-disciplinary team (high risk devices should have more focussed experts involved))
   v) Scope and date of the analysis
   vi) Analysis of findings:
      (1) Ensure the risk scale make sense, are the severities and occurrences in the analysis similar to what is expected for the device?
      (2) Ensure the risks re-calculated after risk reductions have been put in place
      (3) Ensure that instructions for use are not being employed as risk mitigation
      (4) Ensure that risk mitigations that do not design out a hazard do not reduce severities (electrocution does not reduce in severity when the probability of occurrence is reduced)
      (5) Consider the risk mitigations that are listed and their effects on the risk are similar to what is expected for the device
      (6) Ensure the overall acceptability of each risk has been stated
      (7) Possible relevant hazards to consider:
         (a) Usability, including foreseeable misuse (not reading instructions for use (IFU), home use, reuse, local language)
         (b) Mechanical hazards (pinch, traps, trips)
         (c) Electrical hazards (leakage, fire, burn, ingress, power limitation, accidental disconnect/shutdown)
         (d) Biological hazards (cleaning, sterility, leaching, toxic materials, includes user and patient)
         (e) Software hazards (safety, security, confidentiality, utility over lifetime)

e) Risk Management report shall include:
   i) Confirmation that the risk management activities have been carried out as planned
   ii) Overall Residual Risks are discussed and is acceptable
   iii) Post-market information (evidence that mechanisms are in place to ensure this information can be collected)

6) Product Verification and Validation

This section of the technical documentation lists the methods and standards used to verify and validate the product. The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of Medical Devices Law and in particular the applicable Essential Principles of Safety and Performance.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service. This includes:

a) Information on analytical performance of the device

i) Specimen type

This Section shall describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such as duration, temperature limits and freeze/thaw cycles.

ii) Analytical performance characteristics

(1) Accuracy of measurement

(a) Trueness of measurement

This Section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow an assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a certified reference material or certified reference method is available.

(b) Precision of measurement

This Section shall describe repeatability and reproducibility studies.

(2) Analytical sensitivity

This Section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.

(3) Analytical specificity

This Section shall describe interference and cross reactivity studies performed to determine the analytical specificity in the presence of other substances/agents in the specimen.

Information shall be provided on the evaluation of potentially interfering and cross-reacting substances or agents on the assay, on the tested substance or agent type and its concentration, specimen type, analyte test concentration, and results.

Interferents and cross-reacting substances or agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

(a) Substances used for patient treatment such as medicinal products;
(b) Substances ingested by the patient such as alcohol, foods;
(c) Substances added during specimen preparation such as preservatives, stabilizers;
(d) Substances encountered in specific specimen types such as hemoglobin, lipids, bilirubin, proteins;
(e) analytes of similar structure such as precursors, metabolites or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that can mimic the test condition.

(4) Metrological traceability of calibrator and control material values

(5) Measuring range of the assay

This Section shall include information on the measuring range regardless of whether the measuring systems are linear or non-linear, including the limit of detection and describe information on how the range and detection limit were established.

This information shall include a description of specimen type, number of specimens, number of replicates, and specimen preparation including information on the matrix, analyte levels and how levels were established. If applicable, a description of any high dose hook effect and the data supporting the mitigation such as dilution steps shall be added.

(6) Definition of assay cut-off
This Section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, such as:
(a) The population(s) studied: demographics, selection, inclusion and exclusion criteria, number of individuals included;
(b) Method or mode of characterization of specimens;
(c) Statistical methods such as Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

iii) The analytical performance report.

b) Information on clinical performance and clinical evidence. Performance Evaluation Report, according to Annex (7).

The documentation shall contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, together with an assessment of those reports.

The clinical performance study documents shall be included and/or fully referenced in the technical documentation.

c) Stability (excluding specimen stability)

This Section shall describe claimed shelf life, in use stability and shipping stability studies.

i) Claimed shelf-life
This Section shall provide information on stability testing studies to support the shelf life that is claimed for the device. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions. The three lots do not need to be consecutive. Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claims but shall be followed up with real time stability studies.
Such detailed information shall include:
(1) The study report including the protocol, number of lots, acceptance criteria and testing intervals;
(2) Where accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described;
(3) The conclusions and claimed shelf life.

ii) In-use stability
This Section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device, regardless of whether real or simulated. This may include open vial stability and/or, for automated instruments, on board stability.

In the case of automated instrumentation, if calibration stability is claimed, supporting data shall be included.

Such detailed information shall include:

(1) The study report (including the protocol, acceptance criteria and testing intervals);
(2) The conclusions and claimed in-use stability.

iii) Shipping stability
This Section shall provide information on shipping stability studies for one lot of devices to evaluate the tolerance of devices to the anticipated shipping conditions.

Shipping studies may be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold.

Such information shall describe:
(1) The study report (including the protocol, acceptance criteria);
(2) The method used for simulated conditions;
(3) The conclusion and recommended shipping conditions.

d) Software verification and validation
The documentation shall contain evidence of the validation of the software, as it is used in the finished device. Such information shall typically include the summary results of all verification, validation and testing performed in-house and applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

e) Additional information required in specific cases

i) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with regard to packaging, sterilization and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

ii) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected.

iii) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications

iv) If the device is to be connected to other equipment in order to operate as intended, a description of the resulting combination including proof that it conforms to essential principles when connected to any such equipment having regard to the characteristics specified by the manufacturer.

7) Post-market surveillance plan

The post market surveillance plan section describes within the technical documentation what systems are in place to ensure appropriate post market surveillance data is collected. This section shall include:

a) Sources of potential post market surveillance data:

i) Information concerning serious incidents (such as death, life threatening injury), including information from periodic safety update report (PSURs), and field safety corrective actions

ii) Records referring to non-serious incidents and data on any undesirable side-effects, this should include post-market data on:
(1) near miss incidents
(2) usability
(3) Misuse incidents
(4) Reported side effects and especially unexpected or new side effects

iii) Information from trend reporting (i.e. trending complaints to determine if there is a spike that would indicate a potential issue). The data collected from point (ii) above should show evidence on statistical analysis when relevant and frequencies of occurrence should be presented in a readable manner

iv) Relevant specialist or technical literature, databases and/or registers

v) Information, including feedbacks and complaints, provided by users, distributors and importers

vi) Information solicited from users via forums, trade shows social media or other means

b) A proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market

c) Effective and appropriate methods and processes to assess the collected data, consideration should also be given to statistical methods

d) Ensure suitable indicators and threshold values been chosen that will be used in the continuous reassessment of the benefit-risk analysis and of the risk management.

e) Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field

f) Methods and protocols to manage the events subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period.

g) Methods and protocols to communicate effectively with SFDA, economic operators and users regarding medical device issues.

h) Procedures:

i) Reference to procedures to fulfil the manufacturer's obligations
ii) Systematic procedures to identify and initiate appropriate measures including corrective actions

i) A PMPF plan as referred to in Part 3 of Annex (7), or a justification as to why a PMPF is not applicable

j) Effective tools to trace and identify devices for which corrective actions might be necessary

8) Periodic Safety Update Report and Post Market Surveillance Report

a) Post-market surveillance report

Manufacturers of class A and B devices shall prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the SFDA upon request.

b) Periodic safety update report

Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

i) The conclusions of the benefit-risk determination;
ii) The main findings of the PMPF;
iii) The volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class C and D devices shall update the PSUR at least annually. That PSUR shall be part of the technical documentation as specified.

Annex (5) Risk Classification Rules for Medical Devices

1. Medical Devices & Devices without a Medical Purpose

1.1 Definitions Specific to the Classification Rules

1.1.1 Duration of Use

- Transient: means normally intended for continuous use for less than 60 minutes.
- Short Term: means normally intended for continuous use for between 60 minutes and 30 days.
- Long Term: means normally intended for continuous use for more than 30 days.

1.1.2 Invasive and Active Devices

- Body Orifice: means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.
- Invasive Device: means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- Surgically Invasive Device: means an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and a device which produces penetration other than through a body orifice.
- Implantable Device: means any device, including those that are partially or wholly absorbed, which is intended:
    - to be totally introduced into the human body, or
    - to replace an epithelial surface or the surface of the eye,

  by clinical intervention and which is intended to remain in place after the procedure.

  Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.
- Reusable Surgical Instrument: means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.
- Active Device: means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.
- Active Therapeutic Device: means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

- Active Device Intended for Diagnosis and Monitoring: means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- Central Circulatory System: means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior, iliac arteries, femoral arteries and renal arteries.
- Central Nervous System: means the brain, meninges, spinal cord and cerebrospinal fluid.
- Injured Skin or Mucous Membrane: means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

1.1.2 Others

- Non-Viable: means having no potential for metabolism or multiplication.
- Derivative: means a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.
- Nanomaterial: means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials.
- Particle: for the purposes of the definition of nanomaterial, means a minute piece of matter with defined physical boundaries.
- Agglomerate: for the purposes of the definition of nanomaterial, means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.
- Aggregate: for the purposes of the definition of nanomaterial, means a particle comprising of strongly bound or fused particles.
- Serious Deterioration in State of Health: means any of the following:
    - life-threatening illness or injury,
    - permanent impairment of a body structure or a body function,
    - hospitalization or prolongation of patient hospitalization,
    - medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
    - chronic disease

1.2 Implementing Rules

- Application of the classification rules shall be governed by the intended purpose of the devices.

- If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Table 1 of this document shall be classified in their own right separately from the device with which they are used.
- Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.
- If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.
- If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.
- In calculating the duration referred to in Section 1.1.1, continuous use shall mean:
- The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and
- The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.
- A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

Table 1 - Groups of products without an intended medical purpose

#	Product description
1	Contact lenses or other items intended to be introduced into or onto the eye.
2	Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3	Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4	Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5	High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6	Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

2.3 Classification Rules

2.3.1 Non-Invasive Devices

Rule 1

All non-invasive devices are classified as class A, unless one of the rules set out hereinafter applies.

Rule 2

All non-invasive devices intended for channeling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class B:

- if they may be connected to a class B, class C or class D active device; or
- if they are intended for use for channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class C.

In all other cases, such devices are classified as class A.

Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class C, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class B.

All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class D.

Rule 4

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

- class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
- class C if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;
- class B if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and
- class B in all other cases.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.

2.3.2 Invasive devices

Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class A active device are classified as:

- class A if they are intended for transient use;
- class B if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class A; and
- class C if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class B.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class B, class C or class D active device, are classified as class B.

Rule 6

All surgically invasive devices intended for transient use are classified as class B unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class D;
- are reusable surgical instruments, in which case they are classified as class A;
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class D;
- are intended to supply energy in the form of ionising radiation in which case they are classified as class C;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class C; or
- are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class C.

Rule 7

All surgically invasive devices intended for short-term use are classified as class B unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class D;
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class D;
- are intended to supply energy in the form of ionizing radiation in which case they are classified as class C;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class D;
- are intended to undergo chemical change in the body in which case they are classified as class C, except if the devices are placed in the teeth; or
- are intended to administer medicines, in which case they are classified as class C.

Rule 8

All implantable devices and long-term surgically invasive devices are classified as class C unless they:

- are intended to be placed in the teeth, or on prepared tooth structure, in which case they are classified as class B;
- are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class D;
- have a biological effect or are wholly or mainly absorbed, in which case they are classified as class D;
- are intended to undergo chemical change in the body in which case they are classified as class D, except if the devices are placed in the teeth;
- are intended to administer medicinal products, in which case they are classified as class D;
- are active implantable devices or their accessories, in which cases they are classified as class D;
- are breast implants or surgical meshes, in which cases they are classified as class D;
- are total or partial joint replacements, in which case they are classified as class D, with the exception of ancillary components such as screws, wedges, plates and instruments; or
- are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class D with the exception of components such as screws, wedges, plates and instruments.

2.3.3 Active Devices

Rule 9

All active therapeutic devices intended to administer or exchange energy are classified as class B unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class C.

All active devices intended to control or monitor the performance of active therapeutic class C devices, or intended directly to influence the performance of such devices are classified as class C.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class C.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class D.

Rule 10

Active devices intended for diagnosis and monitoring are classified as class B:

- if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, or in the near infra-red spectrum, in which case they are classified as class A;

- if they are intended to image in vivo distribution of radiopharmaceuticals; or
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class C.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class C.

Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class B, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class D; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class C.

Software intended to monitor physiological processes is classified as class B, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class C.

All other software is classified as class A.

Rule 12

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class B, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class C.

Rule 13

All other active devices are classified as class A.

2.3.4 Special Rules

Rule 14

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product including a medicinal product derived from human blood or human plasma and that has an action ancillary to that of the devices, are classified as class D.

Rule 15

All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class C, unless they are implantable or long term invasive devices, in which case they are classified as class D.

Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class C.

All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class B, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class C.

This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

Rule 17

Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class B.

Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are nonviable or rendered non-viable, are classified as class D, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only. In which case they are in Class A.

Rule 19

All devices incorporating or consisting of nanomaterial are classified as:

- class D if they present a high or medium potential for internal exposure;
- class C if they present a low potential for internal exposure; and
- class B if they present a negligible potential for internal exposure.

Rule 20

All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class B, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as class C.

Rule 21

Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

- class D if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- class D if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;
- class B if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
- class C in all other cases.

Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class D.

2. In Vitro Diagnostic Medical Devices

2.1 Definitions Specific to the Classification Rules

- Kit: means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination
- Specimen Receptacle: means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.
- Device for Self-Testing: means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services.
- Device for Near-Patient Testing: means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional.
- Companion Diagnostic: means a device which is essential for the safe and effective use of a corresponding medicinal product to:
    - identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
    - identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.
- Calibrator: means a measurement reference material used in the calibration of a device.
- Control Material: means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device.
- Transmissible agent: an agent capable of being transmitted to a person, as a communicable, infectious or contagious disease.

2.2 Implementing Rules

- Application of the classification rules shall be governed by the intended purpose of the devices.
- If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
- Accessories for an in vitro diagnostic medical device shall be classified in their own right separately from the device with which they are used.
- Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.
- Calibrators intended to be used with a device shall be classified in the same class as the device.
- Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.
- The manufacturer shall take into consideration all classification and implementation rules in order to establish the proper classification for the device.
- Where a manufacturer states multiple intended purposes for a device, and as a result the device falls into more than one class, it shall be classified in the higher class.
- If several classification rules apply to the same device, the rule resulting in the higher classification shall apply.
- Each of the classification rules shall apply to first line assays, confirmatory assays and supplemental assays.
- the technical/scientific/medical expertise of the intended user (lay person or healthcare professional).
- the importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician.
- the impact of the result (true or false) to the individual and/or to public health.

2.3 Classification Rules

Rule 1

Devices intended to be used for the following purposes are classified as class D:

a) detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;

b) detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;

c) determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

Rule 2

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C, except when intended to determine any of the following markers:

a) ABO system [A (ABO1), B (ABO2), AB (ABO3)];

b) Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];

c) Kell system [Kel1 (K)];

d) Kidd system [JK1 (Jka), JK2 (Jkb)];

e) Duffy system [FY1 (Fya), FY2 (Fyb)];

in which case they are classified as class D.

Rule 3

Devices are classified as class C if they are intended:

a) for detecting the presence of, or exposure to, a sexually transmitted agent;

b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;

c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;

d) for pre-natal screening of women in order to determine their immune status towards transmissible agents;

e) for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

f) to be used as companion diagnostics;

g) to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

h) to be used in screening, diagnosis, or staging of cancer;

i) for human genetic testing;

j) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

k) for management of patients suffering from a life-threatening disease or condition;

l) for screening for congenital disorders in the embryo or foetus;

m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

Rule 4

a) Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B.

b) Devices intended for near-patient testing are classified in their own right.

Rule 5

The following devices are classified as class A:

a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination;

b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;

c) specimen receptacles.

Rule 6

Devices not covered by the above-mentioned classification rules are classified as class B.

Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as class B.

Annex (6) Clinical Evaluation and Post-Market Clinical Follow-Up

Part (A): Clinical Evaluation

1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:
   a) establish and update a clinical evaluation plan, which shall include at least:
      - an identification of the essential principals of safety and performance that require support from relevant clinical data;
      - a specification of the intended purpose of the device;
      - a clear specification of intended target groups with clear indications and contra-indications;
      - a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;
      - a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
      - an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
      - an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non- viable animal or human tissues, are to be addressed; and
      - a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part (B) of this Annex with an indication of milestones and a description of potential acceptance criteria;
   b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;
   c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;
   d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and
   e) analyze all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

2. The clinical evaluation shall be thorough and objective, and take into account both favorable and unfavorable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's claims in respect of the device.

3. A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

   - technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;
   - biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachable;
   - clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

   The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

4. The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device.

   The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the essential principals of safety and performance and shall be part of the technical documentation for the device in question. Both favorable and unfavorable data considered in the clinical evaluation shall be included in the technical documentation.

Part (B): Post-Market Clinical Follow-Up

5. PMCF shall be understood to be a continuous process that updates the clinical evaluation referred Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which is SFDA approved and is placed on the market or put into service within its intended purpose, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence

6. PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.

6.1. The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating Clinical data with the aim of:

a) confirming the safety and performance of the device throughout its expected lifetime,

b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,

c) identifying and analyzing emergent risks on the basis of factual evidence,

d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex (1), and

e) identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

6.2. The PMCF plan shall include at least:

a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

d) a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex (1);

e) the specific objectives to be addressed by the PMCF;

f) an evaluation of the clinical data relating to equivalent or similar devices;

g) reference to any relevant common specification (CS), recognized standards when used by the manufacturer, and relevant guidance on PMCF; and

h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.

7. The manufacturer shall analyze the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.

8. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation Part A of this Annex and in the risk management referred to in Section 3 of Annex (1). If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

Annex (7): Performance Evaluation, Performance Studies and Post-Market Performance Follow-Up

1. Performance Evaluation

Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer. To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan.

The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence. The performance evaluation shall be thorough and objective, considering both favourable and unfavourable data.

Its depth and extent shall be proportionate and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.

1.1. Performance evaluation plan

As a general rule, the performance evaluation plan shall include at least:

- a specification of the intended purpose of the device;
- a specification of the characteristics of the device .
- a specification of the analyte or marker to be determined by the device;
- a specification of the intended use of the device;
- identification of certified reference materials or reference measurement procedures to allow for metrological traceability;
- a clear identification of specified target patient groups with clear indications, limitations and contra- indications;
- an identification of the essential principles requirements that require support from relevant scientific validity and analytical and clinical performance data;
- a specification of methods, including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it;
- a description of the state of the art, including an identification of existing relevant recognized standards, guidance or best practices documents;
- an indication and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the intended purpose or purposes and for the analytical and clinical performance of the device;
- for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making;
- an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria;

- the PMPF planning . Where any of the above mentioned elements are not deemed appropriate in the Performance Evaluation Plan due to the specific device characteristics a justification shall be provided in the plan.

1.2. Demonstration of the scientific validity and the analytical and clinical performance:
As a general methodological principle the manufacturer shall:

- identify through a systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;
- appraise all relevant data by evaluating their suitability for establishing the safety and performance of the device;
- generate any new or additional data necessary to address outstanding issues.

1.2.1. Demonstration of the scientific validity
The manufacturer shall demonstrate the scientific validity based on one or a combination of the following sources:

- relevant information on the scientific validity of devices measuring the same analyte or marker; — scientific (peer-reviewed) literature;
- consensus expert opinions/positions from relevant professional associations;
- results from proof of concept studies;
- results from clinical performance studies.

The scientific validity of the analyte or marker shall be demonstrated and documented in the scientific validity report.

1.2.2. Demonstration of the analytical performance
As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

For novel markers or other markers without available certified reference materials or reference measurement procedures, it may not be possible to demonstrate trueness. If there are no comparative methods, different approaches may be used if demonstrated to be appropriate, such as comparison to some other well-documented methods or the composite reference standard. In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

Analytical performance shall be demonstrated and documented in the analytical performance report.

1.2.3. Demonstration of the Clinical Performance
Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

- clinical performance studies;
- scientific peer-reviewed literature;
- published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in the clinical performance report.

1.3. Clinical evidence and performance evaluation report

1.3.1. The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of its device with the essential principles requirements. The amount and quality of that data shall allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit or benefits and safety, when used as intended by the manufacturer. The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit or benefits and safety will be achieved according to the state of the art in medicine.

1.3.2. Performance evaluation report

The clinical evidence shall be documented in a performance evaluation report. This report shall include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of those reports allowing demonstration of the clinical evidence.

The performance evaluation report shall in particular include:

- the justification for the approach taken to gather the clinical evidence;
- the literature search methodology and the literature search protocol and literature search report of a literature review;
- the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety;
- the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated;
- the clinical evidence as the acceptable performances against the state of the art in medicine;
- any new conclusions derived from PMPF reports.

1.3.3. The clinical evidence and its assessment in the performance evaluation report shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's PMPF, as part of the performance evaluation and the post-market surveillance system. The performance evaluation report shall be part of the technical documentation. Both favourable and unfavourable data considered in the performance evaluation shall be included in the technical documentation.

2. Clinical Performance Studies

2.1. Purpose of clinical performance studies

The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic testing. This information is used to

demonstrate compliance with the relevant essential principles requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device.

2.2. Ethical considerations for clinical performance studies

Each step in the clinical performance study, from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

2.3. Methods for clinical performance studies

2.3.1. Clinical performance study design type

Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential bias.

2.3.2. Clinical performance study plan

Clinical performance studies shall be performed on the basis of a clinical performance study plan (CPSP).

The CPSP shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study. It shall contain in particular the following information:

a) the single identification number of the clinical performance study

b) identification of the sponsor, including the name, address of the registered place of business and contact details of the sponsor and, if applicable, the name, address of the registered place of business and contact details of its contact person or legal representative.

c) information on the investigator or investigators, namely principal, coordinating or other investigator; qualifications; contact details, and investigation site or sites, such as number, qualification, contact details and, in the case of devices for self-testing, the location and number of lay persons involved;

d) the starting date and scheduled duration for the clinical performance study;

e) identification and description of the device, its intended purpose, the analyte or analytes or marker or markers, the metrological traceability, and the manufacturer;

f) information about the type of specimens under investigation;

g) overall synopsis of the clinical performance study, its design type, such as observational, interventional, together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis and/or medicine;

h) a description of the expected risks and benefits of the device and of the clinical performance study in the context of the state of the art in clinical practice, and with the exception of studies using left-over samples, the medical procedures involved and patient management;

i) the instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other

articles to be included or excluded and the specifications on any comparator or comparative method used as reference;

j) description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors;

k) the analytical performance with justification for any omission;

l) parameters of clinical performance to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions;

m) information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity of target population and, if applicable, information on vulnerable subjects involved, such as children, pregnant women, immuno-compromised or elderly subjects;

n) information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens;

o) monitoring plan;

p) data management;

q) decision algorithms;

r) accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices;

s) statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements;

t) description of the informed consent process, including a copy of the patient information sheet and consent forms;

u) procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting;

v) criteria and procedures for suspension or early termination of the clinical performance study;

w) criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up;

x) procedures for communication of test results outside the study, including communication of test results to the performance study subjects;

y) policy as regards the establishment of the clinical performance study report and publication of results;

z) list of the technical and functional features of the device indicating those that are covered by the performance study;

aa) bibliography.

2.3.3. Clinical performance study report

A clinical performance study report, signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

3. Post-market Performance Follow-Up

3.1. PMPF shall be understood to be a continuous process that updates the performance evaluation and shall be specifically addressed in the manufacturer's post-market surveillance plan. When conducting PMPF, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device , with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, of ensuring the continued acceptability of the benefit-risk ratio and of detecting emerging risks on the basis of factual evidence.

3.2. PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.

3.2.1. The PMPF plan shall specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of:

a) confirming the safety and performance of the device throughout its expected lifetime,

b) identifying previously unknown risks or limits to performance and contra-indications,

c) identifying and analysing emergent risks on the basis of factual evidence,

d) ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio,

e) identifying possible systematic misuse.

3.3. The PMPF plan shall include at least:

f) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;

g) the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies;

h) the specific objectives to be addressed by the PMPF;

i) an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art;

j) reference to any relevant recognized standards when used by the manufacturer, and relevant guidance on PMPF;

k) a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer.

3.4. The manufacturer shall analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the performance evaluation report and be part of the technical documentation.

3.5. The conclusions of the PMPF evaluation report shall be taken into account for the performance evaluation and in the risk management. If, through the PMPF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

3.6. If PMPF is not deemed appropriate for a specific device then a justification shall be provided and documented within the performance evaluation report.

Annex (8) Implant Card and Information to be Supplied to the Patient with an Implanted Device

1. The manufacturer of an implantable device shall provide together with the device the following:

   a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

   b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

   c) any information about the expected lifetime of the device and any necessary follow-up;

   d) any other information to ensure safe use of the device by the patient, including the information in point (u) of Essential Principle (23.4) of Annex (1).

   The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in Arabic and English language. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

   In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device.

2. Health institutions shall make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identity.

3. The following implants shall be exempted from the obligations laid down in this Annex: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Saudi Food and Drug Authority, when necessary, will amend this list by adding other types of implants to it or by removing implants therefrom.

Annex (9) Summary of Safety and Clinical Performance

Summary of safety and clinical performance

1. For implantable devices and for class D devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

   The summary of safety and clinical performance shall be written in a way that is clear to the intended user.

   The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the SFDA. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and clinical performance shall include at least the following aspects:

   a) the identification of the device and the manufacturer, including the Primary UDI-DI;

   b) the intended purpose of the device and any indications, contraindications and target populations;

   c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

   d) possible diagnostic or therapeutic alternatives;

   e) reference to any standards applied;

   f) the summary of clinical evaluation as referred to in Annex (6), and relevant information on post-market clinical follow-up;

   g) suggested profile and training for users;

   h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The SFDA may set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance.

Annex (10): Electronic Instructions for Use (e-IFU)

1. The physical information provided with the device shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form; and where relevant, the URL (Uniform Resource Locator) indicating the web address with clear navigation to where the e-IFU is located on the internet should be provided to users.
2. For medical devices fitted with a built-in system visually displaying the instructions for use, the display of the instructions for use shall not impede the safe use of the device, in particular life-monitoring or life-supporting functions.
3. Manufacturers of devices that want to provide instructions for use in electronic form instead of in paper form shall undertake a documented risk assessment which shall cover at least the following elements:
    a) knowledge and experience of the intended users in particular regarding the use of the device and user needs;
    b) characteristics of the environment in which the device will be used;
    c) knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form;
    d) access of the user to the reasonably foreseeable electronic resources needed at the time of use;
    e) performance of safeguards to ensure that the electronic data and content are protected from tampering;
    f) safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device;
    g) foreseeable medical emergency situations requiring the provision of information in paper form;
    h) impact caused by the temporary unavailability of the specific website or of the Internet in general, or of their access in the healthcare facility as well as the safety measures available to cope with such a situation;
    i) evaluation of the time period within which the instructions for use shall be provided in paper form at the users' request.
4. The risk assessment shall also be updated in view of the experience gained in the post-marketing phase.
5. The e-IFU shall clearly state the date of release, and target regulatory jurisdiction and should be version controlled. For online IFU, obsolete versions of the IFU shall remain accessible to the public where appropriate.
6. Information in the e-IFU shall include all requirements specified in Annex (1) and Annex (2).
7. For devices with a defined expiry date, except implantable devices, they shall keep the instructions for use available for the users in electronic form for at least 2 years after the end of the expiry date of the last produced device.

8. For devices without a defined expiry date and for implantable devices, they shall keep the instructions for use available for the users in electronic form for a period of 15 years after the last device has been manufactured.
9. Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements:
    a) the instructions for use shall be provided in a commonly used format that can be read with freely available software;
    b) it shall be protected against hardware and software intrusion;
    c) it shall be provided in such a way that the server downtime and display errors are reduced as far as possible;
    d) all previous versions of the instructions for use issued in electronic form and their date of publication shall be available on the website;
    e) The IFU should be readily accessible and should not require the creation of an online account or password;
    f) The IFU approved for the Saudi market should be readily identified as such.

Annex (11): Innovative Medical Device Summary Form

Click here for printable and editable version

1	Applicant Name	
2	Organization Information (name, address and contact information for company/university/manufacturer)	
3	Device Name	
4	Type of Medical Device (Medical Device (MD) or In-Vitro Medical Device (IVD)	
5	Device History (If the device has been previously authorized, address previous history interaction with regulatory; such as, FDA, EU, TGA etc.)	
6	Risk Class (A, B, C or D) and Rationale (Refer to Annex 5)	
7	Choose the applicable Innovative Medical Device Designation Criteria	□ The medical device is designed with innovative features in the technology, indications for use, or performance attributes that have no equivalence in the local/global market. □ The medical device provides a considerable clinical/medical advantage over existing alternative treatments. □ Other (explain in the below section)
8	Provide detailed rationale for considering the device as an Innovative Medical Device.	
9	Intended Use *Which may include:* – Indication of the device (treat/prevent/diagnose/monitor) – Patient population (age/gender/disease) – Body parts affected Intended user	
10	Device Description *Which may include:*	

	– Brief description (written/ diagram/picture) Mechanism of action (how the device achieves its intended purpose)	
11	Device Characteristics (address all that apply) – Software – Biologic – Single use – Sterile (sterilization method) – Material used (Animal origin/human/tissue/medicinal substance) – Duration of body contact Other characteristics (reagents/components/accessories)	
12	Level of Evidence (identify and discuss) Pre-clinical data: – Animal studies – Usability study – Software validation – Sterilization validation – Risk-benefit analysis – Any other lab test Clinical Investigation documentation and Investigator's Brochure: – Pilot Study (if applicable) – Pivotal Study (if applicable) – Primary safety endpoint identified: (if yes, describe) – Primary effectiveness endpoint identified: (if yes, describe) Clinical Evaluation/Literature Review	
13	Attestations:	□ I confirm that the information given in this form is true, complete and accurate.
14	Signature:	

Annex (12) Fees, Application Review Time and Validity

See Circulars (Announcements) page on the SFDA website at https://www.sfda.gov.sa/en/circulars?keys=&date%5Bmin%5D=&date%5Bmax%5D=&tags=3

Annex (13): MDMA Certificate Content

SFDA will issue MDMA certificate in both Arabic and English containing the following:

- the manufacturer information
- sufficient information to identify the medical device or the medical devices group
- Medical Device National Listing Numbers for the medical devices included in the MDMA
- the period of its validity
- certificate number

Annex (14) Declaration of Conformity (DOC)
to “Medical Devices Law” and its Executive Regulation

To be printed on Manufacture Letterhead
Click here for printable and editable version

(يطبع على الورق الرسمي الخاص بالمصنّع)

We ..... <mmanufacture name>, <manufacture address> and <Establishment Medical Device National Registry (MDNR) number> hereby declare that the below mentioned medical device(s) conform to the “Medical Device Law” issued by the Royal Decree No. (M/54) dated 6/7/1442 H, and its Executive Regulation issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H. And willing to make the evidence of the fulfillment of these requirements available to the SFDA, upon request.

نقر نحن ..... <اسم المصنع> و<عنوان المصنع> و<رقم السجل الوطني للمنشأة> (عندما ينطبق ذلك) ..... أن الأجهزة والمستلزمات الطبية المذكورة أدناه تتوافق مع "نظام الأجهزة والمستلزمات الطبية" الصادر بالمرسوم الملكي رقم (م/٥٤) وتاريخ ١٤٤٢/٧/٦هـ، ولائحته التنفيذية الصادرة بقرار مجلس إدارة الهيئة العامة للغذاء والدواء رقم (٣-٢٩-١٤٤٣) وتاريخ ١٤٤٣/٢/١٩هـ، وعلى استعداد لتقديم ما يثبت ذلك للهيئة عند الطلب.

Information of Medical Device(s)	معلومات الأجهزة والمستلزمات الطبية
Generic Name:	الاسم العام/الجنيس:
Trade/Brand Name:	الاسم التجاري/العلامة التجارية:
Model Name/Number:	رقم/اسم الطراز:
Intended Purpose:	الغرض من الاستخدام:
Risk Class:	درجة الخطورة:
Classification Rule Number:	رقم قاعدة تصنيف الخطورة:
Manufacturing Site:	موقع التصنيع:
Applied Standards:	المواصفات المطبقة:
Authorized Signatory	المخول بالتوقيع
Name:	الاسم:
Position:	المنصب:
Date:	التاريخ:
Signature:	التوقيع:

Annex (15): Bundling Criteria

Medical devices may be bundled/grouped within one application based on the criteria of each category below:

1. Medical Devices:
    1.1. Medical Devices Family
    1.2. Medical Devices System
    1.3. Medical Devices Procedure Pack

2. IVD Medical Devices

Note: If the device has **accessories**, they may be included with the device within the same MDMA application, unless they are marketed separately.

1. Medical Devices

1.1 Medical Device Family

Criteria	Examples
A maximum of 5 TFs of Medical devices may be bundled/grouped within one application only if they have: ▪ same legal manufacturer, ▪ same intended use/purpose, ▪ same risk class, ▪ same GMDN code (optional), and ▪ has a common physical design, construction material and manufacturing process. Note: TOTAL NUMBER of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	▪ A catheter with multi lengths. ▪ Condoms that differ in size and color but are manufactured from the same material and sharing comment intended use ▪ Steerable guide wires that are available in various lengths and possess various tip shapes and tip flexibilities. ▪ Devices that do not share common intended purpose including key indications, medical conditions, and patient populations can not be bundled together. ▪ Devices covered by one technical documentation that covers full set of configurations and marketed with different brand names and different subset configurations. ▪ Contact lenses are available as toric lens and spherical lens. These products have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall not be considered as family.

1.2 Medical Devices System

Criteria	Examples
Medical devices compromising a system may be bundled/grouped within a maximum of 5 TFs only if they: ▪ have same legal manufacturer; ▪ are intended to be used in combination to complete a common intended use/purpose. ▪ are sold under a medical devices system name; or the labeling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use/purpose with the system. Note that only one system per application. If the items of the system have different risk-classes, the highest risk-class will be considered. Note: only one system per application. Note: TOTAL NUMBER of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	– A hip replacement medical devices system comprising of femoral and acetabular components. The components must be used in combination to achieve a common intended use/purpose of total hip replacement. The size of the components may vary. – An electrosurgical unit with forceps, electrodes, electrode holders, leads, plug adaptor, when used together for a common intended use/purpose. – An endoscopy tower, which consists of endoscopy camera, registered as a main part then the items like screen, scopes and surgical tools attached to the scope registered as accessories.

1.3 Medical Devices Procedure Pack

Criteria	Examples
Medical devices compromising a procedure pack may be bundled/grouped within a maximum of 5 TF only if they: ▪ same legal manufacturer ▪ same intended use/purpose and under the same specialty. ▪ same risk class. Submission requirements: - For the pack: applicant shall submit TF documents. - For each component: Manufacture shall submit TF for the component. ▪ Note: Any submitted approval should be in combination with letter of agreement from each manufacturer of procedure pack components to supply technical documentation to the SFDA upon request. ▪ Where the manufacturer wishes to market any component of the procedure pack separately, applicant shall apply for another application. ▪ If the procedure pack includes a drug, applicant shall provide the "Registration Certificate of a Pharmaceutical Product", for the included drug, issued by SFDA/Drug Sector. Note: TOTAL NUMBER of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	– Examples on procedure packs: - ENT procedure pack - ophthalmic procedure pack - urology surgical procedure pack - orthodontic procedure packs – Examples on specialty: - anesthesiology - cardiovascular - chemistry dental - ear, nose, and throat - gastroenterology and urology - general and plastic surgery - general hospital - neurology - obstetrical and gynecological - ophthalmic - orthopedic - physical medicine - radiology

2. IVD Medical Devices

Criteria	Examples
▪ Maximum of 5 TFs can be submit in one application, must follow these criteria: ▪ Same Risk Classification. ▪ Same legal manufacture. ▪ Same intended use/Same principle of operation ▪ Closely similar design and manufacturing process ▪ Note: TOTAL NUMBER of IVD medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	Examples on IVD products with same intended use/purpose: - culture media (blood agar and MacConkey agar) - susceptibility tests - blood collection tubes (e.g. EDTA, heparin) Examples on IVD products with different intended use/purpose: - blood agar and enzyme tests - HIV and ABO grouping - pregnancy kit and Hepatitis virus Examples of lab specialty: - biochemistry - hematology - microbiology - histology - serology

Annex (16): Definitions & Abbreviations

Active Device	means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.
Adverse Event	means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a performance study, whether or not related to the device for performance study.
Analytical Performance	means the ability of a device to correctly detect or measure a particular analyte.
Benefit-Risk Determination	means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer.
Clinical Benefit	means the positive impact of a device related to its function, such as that of screening, monitoring, diagnosis or aid to diagnosis of patients, or a positive impact on patient management or public health.
Clinical Data	means information concerning safety or performance that is generated from the use of a device and is sourced from the following: – clinical investigation(s) of the device concerned, – clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated, – reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated, – clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.
Clinical Evaluation	means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.
Clinical Evidence	means clinical data and performance evaluation results, pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.
Clinical Investigation	means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.

Clinical Performance	means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.
CMR Substances	are substances that are carcinogenic, mutagenic or toxic for reproduction.
Companion Diagnostic	means a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.
Compatibility	is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to: (a) perform without losing or compromising the ability to perform as intended, and/or (b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or (c) be used together without conflict/interference or causing adverse events
Corrective Action	means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation.
Derivative	means a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.
Device for Performance Study	means a device intended by the manufacturer to be used in a performance study. A device intended to be used for research purposes, without any medical objective, shall not be deemed to be a device for performance study.
Device for Self-Testing	means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services.
Diagnostic Sensitivity	means the ability of a device to identify the presence of a target marker associated with a particular disease or condition.
Diagnostic Specificity	means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition.
Field Safety Corrective Action	means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

Recognized Standard	SFDA recognize number of standards developed by standards developing body (national and international) to help manufacturers to demonstrate conformity with SFDA requirements.
Incident	means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device.
Instructions For Use	means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.
Intended Purpose	means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation.
Interoperability	is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to: (a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or (b) communicate with each other, and/or (c) work together as intended.
KSA	Kingdom of Saudi Arabia
Lay Person	means an individual who does not have formal education in a relevant field of healthcare or medical discipline.
Likelihood Ratio	means the likelihood of a given result arising in an individual with the target clinical condition or physiological state compared to the likelihood of the same result arising in an individual without that clinical condition or physiological state.
MDS	Medical Devices Sector
Negative Predictive Value	means the ability of a device to separate true negative results from false negative results for a given attribute in a given population.
Non-Viable	means having no potential for metabolism or multiplication.
Performance	means the ability of a device to achieve its intended purpose as stated by the manufacturer.
Performance Evaluation	means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device.
Performance Study	means a study undertaken to establish or confirm the analytical or clinical performance of a device.

Positive Predictive Value	means the ability of a device to separate true positive results from false positive results for a given attribute in a given population.
Post-Market Surveillance	means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.
Predictive Value	means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition.
Reprocessing	means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.
Risk	means the combination of the probability of occurrence of harm and the severity of that harm.
Serious Adverse Event	means any adverse event that led to any of the following: (a) a patient management decision resulting in death or an imminent life-threatening situation for the individual being tested, or in the death of the individual's offspring, (b) death, (c) serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following: i. life-threatening illness or injury, ii. permanent impairment of a body structure or a body function, iii. hospitalization or prolongation of patient hospitalization, iv. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, v. chronic disease, (d) fetal distress, fetal death or a congenital physical or mental impairment or birth defect.
Serious Incident	means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.
SFDA	Saudi Food and Drug Authority
Specimen Receptacle	means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of

	specimens derived from the human body for the purpose of in vitro diagnostic examination.
Subject	means an individual who participates in a performance study and whose specimen(s) undergo in vitro examination by a device for performance study and/or by a device used for control purposes.
System	means a combination of products, either packaged together or not, which are intended to be inter- connected or combined to achieve a specific medical purpose.
UDI Carrier	means to convey the UDI by using Automatic identification and data capture (AIDC) and, if applicable, its human readable interpretation (HRI).
Unique Device Identifier (UDI)	means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

Annex (17): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
5.0 22/6/2020	– General Changing for complying with Medical Devices Law and its regulation – Changing in requirements of low-class medical devices – Changing from "Guidance on Requirements for Medical Device Listing and Marketing Authorization (MDS-G5)" to "Requirements for Medical Device Marketing Authorization (MDS-REQ1)" – Adding the "National Provisions and Requirements for Medical Devices" as the following in: • Annex (1) in points (7), (15.2), (16.5), (18.9),(18.10), (22.1), (23.1-a),(23.1-f), (23.1-i), (23.2-a),(23.4-a), (23.4-s-4) and (23.4-cc) • Annex (2) in points (7), (14.2) , (17.6), (17.7),(19.1), (20.1-a),(20.1-f), (20.2-a), (20.4.1-a),(20.4-2-h), (23.4-s-4) and (23.4-cc) • Annex (3) in points (d) and (e) • Annex (4) in points (c) and (d) – Adding Annexes form (7) to (11)