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COMMON SUBMISSION DOSSIER TEMPLATE

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Contents Page

Preface iii

1 Introduction 1

2 Purpose 1

3 Scope 1

4 Terms and definitions 2

5 Preparation of CSDT 2

6 Elements of CSDT 3

6.1 Executive summary 3
6.2 Relevant essential principles and rule used to demonstrate conformity 5
6.3 Description of medical device 5
6.4 Summary of design verification and validation documents 9
6.4.1 Pre-clinical studies 9
6.4.2 Software validation studies 10
6.4.3 Medical devices containing biological material 11
6.5 Clinical evidence 13
6.7 Medical device labelling 14
6.8 Risk analysis 15
6.9 Manufacturer information 16

APPENDIX A – Example of an Essential Principles Conformity Checklist 18
APPENDIX B – List of configurations of medical device to be registered 20

Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- "shall" indicates a requirement;

- "should" indicates a recommendation;

- "may" indicates a permission; and

- "can" indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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COMMON SUBMISSION DOSSIER TEMPLATE

1 Introduction

The Common Submission Dossier Template (CSDT) is a format to be used for submitting the required information as evidence of conformity of medical device to Essential Principle of Safety and Performance (hereafter referred to as Essential Principles). It is considered as summary of technical documentation of medical device. Essentially, the CSDT contains similar elements that are addressed in the GHTF guidance document titled “Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)”. The format of CSDT is based upon the goal to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Manufacturers of all classes of medical device are expected to demonstrate conformity of the device to the EPSP through collection and examination of evidence of conformity in technical documentation that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer’s determination with respect to such conformity. This technical documentation must be updated as necessary to reflect the current status, specification and configuration of the device.

The evidence of conformity of medical device to the EPSP must be compiled in the format of CSDT for the purpose of conformity assessment and submission of application for medical device registration to provide evidence to the Authority or Conformity Assessment Body (CAB) that the subject medical device is in conformity with the Essential Principles. The CSDT need to be kept in the premise for audit or inspection purposes.

2 Purpose

This document is intended to provide guidance on the preparation of CSDT to be submitted to the CAB or Authority for conformity assessment and/or application for medical device registration. In particular, this document provides further explanation on information to be included for each element of CSDT and format that the in formation to be submitted in.

3 Scope

This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0006: Definition of Medical Device, excluding

those used for in vitro diagnostic examination of specimens derived from the human body.

4 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

4.1 Authority

The Medical Device Authority, Ministry of Health Malaysia.

4.2 Conformity Assessment Body (CAB)

The conformity assessment body registered under section 12 of Act 737.

4.3 Essential Principles

Essential Principles of Safety and Performance as describe in APPENDIX 1 of Third Schedule of Medical Device Regulation 2012.

4.4 Manufacturer

As defined in section 2 of Act 737.

4.5 Medical Device

As defined in section 2 of Act 737 and described in MDA/GD/0006: Definition of Medical Device.

4.6 Recognized Standard

A standard that is deemed by the Authority to offer the presumption of conformity to specific essential principles of safety and performance.

4.7 Technical Documentation

The documented evidence, normally an output of the quality management system that demonstrates conformity of a device to the Essential Principles of Safety and Performance of Medical Devices.

5 Preparation of CSDT

The preparation of CSDT must be made in accordance with the requirements specified in Appendix 2 of Third Schedule of Medical Device Regulation 2012.

A CSDT should be prepared by a manufacturer as a summary of the technical documentation of the medical device.

The CSDT must contain all elements of CSDT as specified in Appendix 2 of Third Schedule of Medical Device Regulation 2012. Where there are elements not applicable to the medical device dealt with, the justification for the non-applicability should be provided.

The CSDT should be in English or Bahasa Malaysia.

The depth and detail of the information contained in the CSDT will depend on:

(a) the classification of the subject device;

(b) the complexity of the subject device;

(c) novel technology that is incorporated with the medical device;

(d) it is an already marketed medical device type that is now being offered for an intended use different from the original one;

(e) it is new to the manufacturer;

(f) the device type has been associated with a significant number of adverse events, including use errors;

(g) it incorporates novel or potentially hazardous materials;

(h) the device type raises specific public health concerns.

The information contained in the CSDT should be supported by relevant supporting documents for example copies of labels, certificates and reports. Where such supporting documents that are referenced within CSDT, every document must be submitted in full, i.e. all the pages of a document must be submitted. Those documents must be legible and within its validity period. All certificates or reports submitted must be and should be signed-off and dated by the person issuing the report. This person should be authorized to issue such documents. All supporting documents that are referenced within the CSDT submission shall be submitted as annexes to the CSDT.

6 Elements of CSDT

6.1 Executive summary

An executive summary shall be provided with the CSDT, which shall include the following information:

(a) an overview which covers an introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features (e.g. nanotechnology) and a synopsis of the content of the CSDT;

(b) commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries;

(c) intended uses and indications in its label;

(d) list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in all reference agencies; copies of certificates or approval letters from each reference agency and declaration on labelling, packaging and instructions for use (IFU);

NOTE 1:

(i) For CE marked devices, the declaration of conformity by the manufacturer must be submitted, in addition to the EC certificate issued by the notified bodies.

*(ii) If the labelling, packaging and IFU of the medical device for sale in Malaysia is **identical** to that approved by each reference agency, a declaration that the labelling, packaging and IFU of the medical device for sale in Malaysia is **identical** to that approved by each reference agency is to be provided.*

*(iii) If the labelling, packaging and IFU of the medical device for sale in Malaysia is **not identical** to that approved by each reference agency, the differences between Malaysia's labelling, packaging and IFU and each reference agency's approved labelling, packaging and IFU is to be described. The reason for the differences must also be provided.*

(e) status of any pending request for market clearance; and

(f) important safety and performance related information which include-

i- summary of reportable adverse events and field corrective actions (FCAs); and

ii- a description of the medical device if the medical device contains animal or human cells, tissues and/or derivatives thereof, rendered non-viable (e.g. porcine heart valves, catgut sutures, etc.); cells, tissues and/or derivatives of microbial or recombinant origin (e.g. dermal fillers based on hyaluronic acid derived from the bacterial fermentation processes); and/or irradiating components, ionizing (e.g. x-ray) or non-ionising (e.g. lasers, ultrasound, etc.), a description must be provided.

6.2 Relevant essential principles and rule used to demonstrate conformity

The CSDT should identify the Essential Principles that are applicable to the device and the general rule or method used to demonstrate conformity to each applicable Essential Principle. The rules or methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc. The specific documents related to the rule or method used to demonstrate conformity to the Essential Principles should be referenced in this element.

The evidence of conformity should be provided in tabular form called Essential Principles Conformity Checklist. It should be provided in CSDT together with supporting documentation available for review as required. A sample of the essential principles conformity checklist is included in Appendix A.

For example, a completed Essential Principles conformity checklist can be used to demonstrate that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. As such, CSDT would then include a declaration of conformity to the standard or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements. When the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the CSDT should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the manufacturer uses other means, such as internal standards, the CSDT should describe the means.

Not all the essential principles will apply to all devices and it is for the manufacturer of the device to assess which are appropriate for his particular device product. In determining this, account must be taken of the intended purpose of the device.

6.3 Description of medical device

Besides a general description of the device, a more detailed description of the medical device attributes is necessary to explain how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. A complete description of each functional component, material or

ingredient of the device should be provided, with labelled pictorial representation of the device in the form of diagrams, photographs or drawings, as appropriate.

To fulfil the requirements under this section, the following information shall be submitted:

(a) A complete description of the medical device;

(b) Principles of operation or mode of action;

(c) Risk class and applicable classification rule for the medical device according to the Rules of Classification for General Medical Devices as specified in Appendix 1 of First Schedule of Medical Device Regulation 2012;

(d) A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device. For example, patients implanted with a stent or heart valve need to be managed with appropriate medication such as warfarin, as recommended by the manufacturer;

(e) A description or complete list of the various configurations of the medical device to be registered. This is to be provided using the format as in Appendix B;

(f) A complete description of the key functional elements (e.g. its parts or components, including software if appropriate), its formulation (e.g. if it is combined with drug component, the formulation need to be described as well), its composition and its functionality;

(g) An explanation of any novel features;

(h) Where appropriate, this will include labelled pictorial representation (e.g. diagrams, photographs and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(i) Intended use of the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device;

(j) Indications which is a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the device is intended;

(k) Instructions of use including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging by other formats/forms;

(l) Contraindications which is a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit;

(m) Warnings to inform on specific hazard alert that a user needs to know before using the device.

(n) Precautions to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.

(o) Potential adverse effects or side effects from the use of the medical device, under normal conditions. These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user if the device is used under normal condition.

(p) Alternative therapy for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended. This is a description of any alternative practices or procedures to support its intended use. For example, for a drug eluting stent, alternative therapies will include exercise, diet, drug therapy, percutaneous coronary interventions (e.g. balloon angioplasty, atherectomy and bare metal stenting) and coronary artery bypass graft surgery. This does not include any treatment practices or procedures that are considered investigational.

(q) Materials to describe their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include:

i- List of materials of the medical device making either direct (e.g. with the mucous membrane) or indirect contact (e.g., during extracorporeal circulation of body fluids) with a human body;

ii- Complete chemical, biological and physical characterization of the materials of the medical device making either direct (e.g. mucous membrane) or indirect contact (e.g., during extracorporeal circulation of body fluids) with a human body;

iii- For medical devices intended to emit ionising radiation, information on radiation source (e.g. radioisotopes) and the material used for shielding of unintended, stray or scattered radiation from patients, users and other persons shall be provided.

(r) Other relevant specifications and descriptive information which include the functional characteristics and technical performance specifications and other important descriptive characteristics which have not been detailed out above but it is necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device).

NOTE 2:

*(i) Information requested for under item **(i)** to **(o)** would be typically found in the instructions for use (IFU). Therefore, the IFU can be submitted in lieu of these sections. Any of the sections **(i)** to **(o)** that are not addressed in the IFU must be addressed separately in the submission dossier. The IFU is also known as the products insert user or operating manual.*

*(ii) The functional characteristics and technical performance specifications for the device requested in **(r)** including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles. A list of the features, dimensions and performance attributes of the medical device, its variants and accessories that would typically appear in the product specification made available to the end user, e.g. in brochures and catalogues, will satisfy the requirements of this section.*

*(iii) This section **(r)** allows for the inclusion of other descriptive information about the medical device that is not addressed in the preceding sections. For example, when demonstrating compliance with the Essential Principles for an ingested camera pill used to image the gastrointestinal tracts of outpatients, manufacturers may wish to describe in detail in this section the use of a patient card (drafted in the local language) to be carried by the patient during the period of imaging. In the event of non-excretion of the camera pill or acute stomach pain, the patient card can be produced to attending physicians, thereby reducing the risk of miscommunication between patient and physician.*

6.4 Summary of design verification and validation documents

This section should summarize or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device. Such documentation should typically include:

(a) declarations/certificates of conformity to the “recognized” standards listed as applied by the manufacturer; and/or

(b) summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.

EXAMPLE: The completed Table of Conformity to the Essential Principles that a recognized test standard was used as part of the rule or method to demonstrate conformity to one Essential Principle. Section 4 of the CSDT would then include a declaration of conformity to the standard or other certification permitted by the relevant Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements.

The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the device:

(a) a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the device with reference to the Essential Principles;

(b) engineering tests;

(c) laboratory tests (e.g: sterility tests, metrology tests, etc);

(d) biocompatibility tests;

(e) animal tests;

(f) simulated use;

(g) software validation.

6.4.1 Pre-clinical studies

This section should summarize or reference or contain report and/or certification and/or declaration of;

(a) Biocompatibility test conducted on materials used in a medical device;

(b) Pre-clinical physical tests conducted on the medical device;

(c) Pre-clinical animal studies to support the probability of effectiveness in humans.

Biocompatibility Test

Biocompatibility test is conducted to predict how biomaterials interact with the human body and determine the clinical success of a medical device. At a minimum, biocompatibility tests must be conducted on samples from the finished, sterilized device. All materials that are significantly different must be characterized. Information describing the tests, the results and the analyses of data must be presented.

Pre-clinical physical tests

Pre-clinical physical test (e.g. mechanical tests, electrical safety tests, accelerated aging tests, etc) is be conducted to predict the adequacy of device response to physiological stresses, undesirable conditions and forces, long-term use and all known and possible failure modes. Complete pre-clinical physical test data must be provided, as appropriate.

Pre-clinical animal studies

Pre-clinical animal studies used to support the probability of effectiveness in humans must be reported. These studies must be undertaken using good laboratory practices. The data collected for the study includes any pre-clinical laboratory or animal studies, as appropriate for the medical device. The conclusion of the study should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

The report of all tests mentioned above must include the objectives, methodology, results, analysis and manufacturer's conclusions. All data must be presented in the report.

6.4.2 Software validation studies

This section should summarize or reference or contain report and/or certification and/or declaration of software validation studies. Software validation studies

need to be conducted to ensure the correctness of a software product which cannot be fully verified in a finished product. The manufacturer and/or device sponsor must provide evidence that validates the software design and development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments.

6.4.3 Medical devices containing biological material

This section requires results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents to be provided in the CSDT. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

To fulfil the requirements under this section, the following information shall be submitted:

(a) a list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives, rendered non-viable and cells, tissues and/or derivatives of microbial or recombinant origin;

(b) detailed information concerning the selection of sources/donors;

(c) detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;

(d) process validation results to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents;

(e) full description of the system for record keeping allowing traceability from sources to the finished medical device.

NOTE 3:

1. *For all aspects of verification and validation described in section 5.4 and in sub-sections 5.4.1, 5.4.2 and 5.4.3, where no testing was undertaken for the medical device, a rationale for that decision must be provided. Evidence to support the rationale shall be provided.*

2. *For medical devices provided sterile, the following information is to be provided in this section:*

   (i) detailed information of the initial sterilisation validation including bio burden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. If initial sterilisation validation is not performed, adequate justification must be provided. For example, if reference to the sterilisation validation conducted for another medical device is made for the medical device in the application, the justification for the applicability of the previously conducted validation to the current medical device must be provided. In addition, the initial sterilisation validation report for the reference medical device must be provided;

   (ii) evidence of the on-going revalidation of the process. Typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilisation processes;

   (iii) detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed in accordance with those standards, and a summary of results;

   (iv) post-sterilisation functional test on the medical device;

   (v) if the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.

3. *For medical devices with a shelf life, data demonstrating that the relevant performances and characteristics of the medical device are maintained throughout the claimed shelf life which the "expiry" date reflects is to be provided in this section. This may include:*

   (i) prospective studies using accelerated ageing, validated with real time degradation correlation; or

   (ii) retrospective studies using real time experience, involving e.g. testing of stored samples, review of the complaints history or published literature etc.; or

   (iii) a combination of (i) and (ii).

If real time shelf life data is not available, shelf life data collected from accelerated studies can be used to support the initial shelf life claim. The rationale for the parameters selected for the accelerated studies must be provided. Shelf life data collected from accelerated studies must be supported by real time testing to confirm the initial shelf life claim. The final real time study report must be submitted when completed.

4. *As the absence of an "expiry" date constitutes an implicit claim of an infinite shelf life, evidence demonstrating the following shall be provided:*

   (i) that there are no safety-related performances or characteristics which are likely to deteriorate over time, or

   (ii) that the extent of any likely deterioration does not represent an unacceptable risk, or

   (iii) that the period over which unacceptable deterioration occurs is far beyond the likely time of the first use of the medical device e.g. 30 years.

5. *For devices that do not have expiry dates (e.g. infusion pump, digital thermometer), the projected useful life of the medical device must be provided. Manufacturers may refer to TS/ISO 14969 (Medical devices – Quality management systems – Guidance on the application of ISO 13485:2003) for information on how to determine the projected useful life.*

6. *For medical devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, studies demonstrating conformity with metrological requirements shall be provided.*

6.5 Clinical evidence

This section should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of

(a) a systematic review of existing bibliography,
(b) clinical experience with the same or similar devices, or
(c) clinical investigation.

NOTE 4:

Clinical investigation is most likely to be needed for higher risk class devices or for devices where there is little or no clinical experience.

Information required in this section is to be provided in the form of a clinical evaluation report. This clinical evaluation report documents the assessment and

analysis of clinical data to verify the clinical safety and performance of the medical device when used as intended by the manufacturer.

Clinical evidence of effectiveness may comprise device-related investigations conducted domestically or other countries. It may be derived from relevant publications in a peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

6.6 Use of existing bibliography

If clinical evaluation is done by conducting a systematic review of existing bibliography, the copies of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness are required. These will be a subset of the bibliography of references. General bibliographic references should be device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application.

6.7 Medical device labelling

This section should summarize or reference or contain information on medical device labelling to the extent appropriate to the complexity and risk class of the device. Medical device labelling is a descriptive and informational product literature that accompanies the device any time while it is held for sale or shipped. It may include the following document;

(a) Sample of labels on the device and its packaging

(b) Instructions for use

(c) Other literature or training materials (such as physician’s manual)

(d) Instructions for installation and maintenance (if applicable).

(e) Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).

Apart from device labelling, the promotional material and product brochures shall be provided in this section to aid in the evaluation of the medical device.

Sample of labels on the device and its packaging

This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling, which is not provided on the outer packaging must be easily legible through this outer packaging.

If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

The sample of labels on the medical device and its packaging are to be provided for the primary and secondary levels of packaging and shall be provided in the original colour. It can be provided in the form of artwork. The sample of labels should be in accordance with the labelling requirement as specified in the Sixth Schedule of Medical Device Regulation 2012. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated.

Instructions for use, training materials & instructions for installation and maintenance

The instructions for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the device. Where applicable, this section should include instructions for training of the end-users for competent use of the device for its intended purpose, as well as installation and maintenance of the device.

6.8 Risk analysis

This section should summarize or reference or contain information on risk analysis conducted for the medical device. The risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity, novelty and risk class of the device.

Risk management report

A risk management report should contain;

i- a list of possible hazards for these devices. This should include indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards, such as ionizing radiation from an X-ray machine,
ii- the technique used to analyse risk to ensure that it is appropriate for the device and the risk involved,
iii- the evaluation of these risks against the claimed benefits of the device,
iv- the description on the method(s) used to control or reduce risk to acceptable levels,
v- the identification of individual or organization that carries out the risk analysis.

Information required in this section is to be provided in the form of a risk management report. It is recommended that the risk management activities be conducted according to ISO 14971. The accompanying documents referenced in the risk management report, including the risk management plan and results of risk assessment and risk control is to be provided. The risks and benefits associated with the use of the medical device should be described.

6.9 Manufacturer information

This section should summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.

Manufacturing process

Manufacturing process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output.

EXAMPLE: The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labelling, storage of the device. Sufficient detail must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization method and processing should be included, if any. Detailed proprietary information on the manufacturing process is not required. The information may

be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device.

If multiple facilities are involved in the manufacture of device, the manufacturing activities carried out at each site should be clearly identified and the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. If the manufacturing process of a product consists of a number of sub-assembly processes, the manufacturing sites where each of these sub-assembly processes are carried out must be identified, and the relationship between these processes must be shown; or if multiple sites manufacture the same product, each of these sites must be identified.

The sites (including contract manufacturers) where design and manufacturing activities are performed shall be identified. Quality Management System certificates are to be provided for the design and manufacturing sites (including contract manufacturers) as an annex to the CSDT submission. Firms that manufacture or process the device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The manufacturer should inform these contractors of the need to supply detailed information on the device. However, it is not the intent of this section to capture information relating to the supply of sub-components (e.g. printed circuit boards, motors, compressors, batteries) that contributes towards the manufacture of the finished device itself except in cases where the components are part of a medical device system (e.g. femoral stem and acetabular cups of a hip implant system, tubes and connectors for IV set).

APPENDIX A – Example of an Essential Principles Conformity Checklist

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will 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.			
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: (a) identify hazards and the associated risks arising from the intended use and foreseeable misuse, (b) eliminate or reduce risks as far as possible (inherently safe design and construction),			

(c) where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, (d) inform users of the residual risks due to any shortcomings of the protection measures adopted.			

NOTE 5:

The Essential Principles conformity checklist is to be prepared based on the list of Essential Principles found in the Guidance Document MDA/GD/0007: Essential Principles of Safety and Performance of Medical Devices. The medical device to which the Essential Principles conformity checklist is applicable should be identified on the checklist itself. Where applicable, the various configurations/variants of the medical device covered by the checklist are to be identified in the checklist. The columns in the recommended format for the checklist should be completed as follows:

(a) Applicable to the medical device?

Either a 'Yes' or 'No' answer is required. If the answer is 'No' this should be briefly explained. For example: For a medical device that does not incorporate biological substances, the answer to Essential Principle 9.2 would be 'No – The medical device does not incorporate biological substances.'

(b) Method of conformity

State the title and reference of the standard(s), industry or in-house test methods(s), comparison study(ies) or other method used to demonstrate compliance. For standards, this should include the date of the standard and where appropriate, the clause(s) that demonstrates conformity with the relevant Essential Principle. Where a standard is referred to more than once in the checklist, the reference number and date can be repeated. Conformity with the Essential Principles can be demonstrated by another means if the recognized standards are not available.

(c) Identity of specific documents

This column should contain the reference to the actual technical documentation that demonstrates compliance to the Essential Principle, i.e. the certificates, test reports, study reports or other documents that resulted from the method used to demonstrate compliance, and its location within the technical documentation.

APPENDIX B – List of configurations of medical device to be registered

Guidelines on completing the table below:

1. For the "Name as per Device Label" column:
   (a) For a medical device family, list the names of the constituent members in this column. Enter the identifier associated with each constituent member in the "Identifier" column.
   (b) For a medical device group, list the names of the constituent medical devices in this column. Enter the identifier associated with each constituent medical device in the "Identifier" column.
   (c) For a medical device system, list the names of every constituent component in this column. Enter the identifier associated with each constituent component in the "Identifier" column.
2. For the "Identifier" column, identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the product owner and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number.
3. For the "Brief Description of Item" column, give a brief description of the key distinguishing attributes or specifications of each item. Examples of a brief description of a constituent member of a family include the following: For percutaneous transluminal coronary angioplasty (PTCA) catheters: 10 mm balloon length and 2 mm balloon diameter.
4. A list of configurations is to be provided with each FAMILY/GROUP/SYSTEM medical device application.

Name of Medical Device FAMILY/GROUP/SYSTEM:	-	
Proposed Grouping for Medical Device (FAMILY/GROUP/SYSTEM):		
Name as per Device Label	**Identifier**	**Brief Description of Item**

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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