# Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

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The views expressed in this document represent the agreements reached by the competent authorities of the Member State members of the Borderline and Classification Working Group, a subgroup of the Medical Device Coordination Group. The views are not legally binding as only the Court of Justice of the European Union can give an authoritative interpretation of Union law.

This Manual only serves as one of the support tools for case-by-case application of the Union legislation by the Member States in their respective jurisdictions. It remains for the national competent authorities and the national courts to reach decisions at national level.

The Manual is not a European Commission document, and it cannot be regarded as reflecting the official position of the European Commission.

**Table of contents**

**Introduction and scope** ..... 5

**1. Regulation (EU) 2017/745 on medical devices** ..... 7

1.1. **Qualification of medical devices** ..... 7

1.1.1. Borderline between medical devices and IVDs ..... 7

1.1.2. Borderline between medical devices and medicinal products, including advanced therapy medicinal products (ATMPs) ..... 7

1.1.3. Borderline between medical devices and biocides ..... 13

1.1.4. Borderline between medical devices and substances of human origin ..... 13

1.1.5. Borderline between medical devices and cosmetic products ..... 13

1.1.6. Borderline between medical devices and food ..... 14

1.1.7. Borderline between medical devices and personal protective equipment ..... 14

1.1.8. Borderline between medical devices and general consumer products ..... 16

1.1.9. Other medical device borderlines ..... 16

**1.2. Classification of medical devices** ..... 21

1.2.1. Rule 1 ..... 21

1.2.2. Rule 2 ..... 22

1.2.3. Rule 3 ..... 22

1.2.4. Rule 4 ..... 23

1.2.5. Rule 5 ..... 23

1.2.6. Rule 6 ..... 23

1.2.7. Rule 7 ..... 23

1.2.8. Rule 8 ..... 24

1.2.9. Rule 9 ..... 26

1.2.10. Rule 10 ..... 26

1.2.11. Rule 11 ..... 26

1.2.12. Rule 12 ..... 26

1.2.13. Rule 13 ..... 27

1.2.14. Rule 14 ..... 27

1.2.15. Rule 15 ..... 27

1.2.16. Rule 16 ..... 27

1.2.17. Rule 17 ..... 27

1.2.18. Rule 18 ..... 27

1.2.19. Rule 19 ..... 27

1.2.20. Rule 20 ..... 27

1.2.21. Rule 21 ..... 28

1.2.22. Rule 22 ..... 28
**2. Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices** ..... 28
**2.1 Qualification of IVDs** ..... 28
2.1.1. Borderline between IVDs and medical devices ..... 28
2.1.2. Borderline between IVDs and general laboratory equipment ..... 29
2.1.3. Other IVD borderlines ..... 29
**2.2 Classification of IVDs** ..... 29
2.2.1. Rule 1 ..... 29
2.2.2. Rule 2 ..... 29
2.2.3. Rule 3 ..... 30
2.2.4. Rule 4 ..... 30
2.2.5. Rule 5 ..... 30
2.2.6. Rule 6 ..... 30
2.2.7. Rule 7 ..... 30
**Index** ..... 31

## Introduction and scope

Determining whether a given product falls under the definition of a medical device and the application of the classification rules fall within the competence of the authorities of the Member States where the product is on the market. However, when different interpretations of EU legislation occur, public health may be put at risk and the internal market distorted. As both are matters of concern to the Member States and the Commission, it essential to facilitate a dialogue among regulators. Appropriate participation of various stakeholders should also be ensured.

This document, hereafter called the Manual, records the agreements reached by the Member State members of the Borderline and Classification Working Group (BCWG)[1] following the exchanges under the Helsinki Procedure under Regulation (EU) 2017/745 on medical devices (the MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR). The purpose and operation of the Helsinki procedure is described in the dedicated document here. The BCWG is chaired by the European Commission and consists of representatives of competent authorities from all Member States with a number of stakeholder associations as observers.

The aspects concerning the borderline between medical devices and other types of products, also known as qualification of a product, are generally governed by Article 4 *Regulatory status of products* of the MDR and the corresponding Article 3 of the IVDR. Borderline cases are those for which it is not clear from the outset whether a given product is a medical device, or an *in vitro* diagnostic medical device (IVD), or not. Various paragraphs under Article 1 *Subject matter and scope* of both Regulations are also relevant. They exclude certain types of products from the scope of the Regulations. Where a given product does not fall within the definition of medical device or is excluded from their scope, other EU or national legislation may be applicable. This Manual will however not provide indications to that effect.

The Manual should be read in conjunction with other documents providing guidance on borderline, such as MDCG 2022-5 *Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices* and MDCG 2019-11 *Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746*.

Once a product is qualified as a medical device, a certain risk class will be assigned to it, namely I, IIa, IIb, III. For a product qualified as an IVD, the risk classes are A, B, C and D. The aspects concerning classification of medical devices are governed by MDR Article 51 *Classification of devices* and Annex VIII *Classification rules*. For IVDR the corresponding references are Article 47 and Annex VIII. In the context of this Manual, classification cases are those for which the competent authorities of the Member States identify a difficulty in the uniform application of the classification rules.

[1] The BCWG is a sub-group of the Medical Device Coordination Group set up according to Article 103 of Regulation (EU) 2017/745 and Article 98 of Regulation (EU) 2017/746

The Manual should be read in conjunction with other documents providing guidance on classification, such as MDCG 2021-24 *Guidance on classification of medical devices* and MDCG 2020-16 *Guidance on classification rules for in vitro diagnostic medical devices under Regulation (EU) 2017/746.*

Other relevant MDCG guidance documents may be published here.

This Manual does not relieve national competent authorities from their duty to issue decisions in the areas of qualification and classification for individual products taking into account all its characteristics on a case-by-case basis, while acting under the supervision of the courts.

# 1. Regulation (EU) 2017/745 on medical devices

## 1.1. Qualification of medical devices

The respective sections will be populated when cases are finalised under the Helsinki Procedure.

### 1.1.1. Borderline between medical devices and IVDs

This section covers the borderline between products that may fall under the MDR or under the IVDR, where the conclusion is that the product should be qualified as a medical device.

### 1.1.2. Borderline between medical devices and medicinal products, including advanced therapy medicinal products (ATMPs)

This section covers the borderline between products that may fall under the MDR, or possibly under Directive 2001/83/EC on the Community code relating to medicinal products for human use, or under Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or under Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

#### 1.1.2.1 Nasal spray with antibodies for COVID-19

**Background**

The spray contains antibodies that inactivate the SARS-CoV-2 virus and, as a result, the virus is no longer able to reproduce and enter mucosal cells. The antibodies, obtained from the colostrum of infected cows, are sprayed into the human nose where they can attach to the viruses and inactivate them.

**Outcome**

According to the information provided by the manufacturer, the principal intended action of the spray is achieved through antibodies binding to the virus. As a result, the virus is no longer able to reproduce and enter mucosal cells.

Considering the product's principal mode of action and that a medical device cannot achieve its principal intended action by pharmacological, immunological or metabolic means, the above mentioned spray should not be qualified as a medical device.

#### 1.1.2.2 Graphite crucible

**Background**

The product is a graphite crucible used in conjunction with the radionuclide Technetium-99m (Tc-99m) for imaging the airways (lung ventilation scintigraphy). The graphite crucible is made of pure carbon and is intended for the preparation of the aerosol.

The resulting aerosol is an ultra-fine dispersion of nanosized pure carbon particles encapsulating Tc-99m (average 30-60 nm). It is produced by heating Tc-99m in the carbon crucible in an oven for a few seconds at 2,750 °C in the presence of argon gas.

The aerosol is then inhaled by the patient via a mouthpiece and penetrates to the sub-segmental areas of the lung.

Once inhaled by a patient suspected of having a pulmonary embolism (PE) or other pulmonary obstructive pathology, a gamma camera is used to generate the image.

The question is about the qualification of the graphite crucible.

**Outcome**

According to Article 1 (6) of Directive 2001/83/EC, radiopharmaceutical is: "Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose."

According to Article 1 (8), a kit is: "Any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration."

The graphite crucible comes under the latter definition. The graphite crucible:

- is made of pure carbon and is intended for the preparation of an aerosol;
- is an inherent component of the aerosol (carbon particles carrying the radionuclide Tc-99m).

Consequently, graphite crucible does not fall under the definition of medical device or accessory and should not be qualified as such.

### 1.1.2.3 Product for professional removal of dental biofilm

**Background**

Qualification of a product for professional removal of dental biofilm/plaque, consisting of a syringe prefilled with $TiO_2$ + polymer (inert) and a vial of hydrogen peroxide ($H_2O_2$): The $H_2O_2$ shall be mixed with the content of the syringe before use, resulting in a gel that is applied by the syringe on to the teeth in the gingival area. The product is intended as a "stand alone" device or together with a motorized brush for professional debridement of teeth and implanted implants, by dissolving biofilm/killing bacteria and increasing the effectiveness of mechanical removal of biofilm/plaque, which causes inflammatory situations. Their removal therefore brings advantages with regard to the following aspects:

- attenuation of degradation of dental enamel;
- attenuation of inflammation/gingivitis;
- attenuation of the onset of periodontitis, bone damage and loss of teeth;
- attenuation of the onset of peri-implantitis, when used on implant surface.

During use, the syringe is intended to guarantee a final concentration ranging from 3% to 5% of $H_2O_2$. The gel destroys bacteria and viruses with reactive oxygen species (ROS).

**Outcome**

The product has a medical intended purpose based on claims regarding attenuation of inflammation - gingivitis, periodontitis and peri-implantitis. However, the antimicrobial action of ROS, which is considered as the principal intended action, should be considered pharmacological, immunological or metabolic mode of action. The decision of ECJ ruling 6 September 2012, case C-308/11, also supports that such antimicrobial actions on the human body should be considered pharmacological. Consequently, considering the principal mode of action, this product should not be qualified as a medical device.

In regard to the prefilled syringe, it has to be considered that a device which is placed on the market in such a way that the device and a medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to the Regulation (EU) 2017/745 on medical devices shall apply as far as safety and performance-related device features are concerned.

### 1.1.2.4 Root canal irrigation solution

**Background**

Two root canal irrigating solutions intended to be used in endodontic treatment are placed on the market as medical devices consisting of sodium hypochlorite (NaOCl) 3% aqueous solution for canal irrigation and another solution with chlorhexidine digluconate (CHX) 2% root canal solution for final irrigation and debridement of root canals.

According to the manufacturer, NaOCl 3% solution is intended to irrigate the root canal of the tooth as needed for debridement during instrumentation. The CHX 2% solution is intended to be used for the irrigation and debridement of root canals after instrumentation in endodontic treatment.

The manufacturer indicates that the aim of the irrigation is to dissolve the tissues and to have a cleaning effect. For both products, the manufacturer does not claim the disinfection of root canals but argues that NaOCl and CHX solutions act as “a liquid mechanical file” and considers that the infection is treated by a mechanical action.

**Outcome**

Sodium hypochlorite (NaOCl) and chlorhexidine (CHX) are substances which have antimicrobial properties. NaOCl has an antimicrobial action and has the ability to dissolve biofilm components. CHX is an active ingredient of many approved medicinal products.

Both substances are medicinal substances with known pharmacological effects documented in the literature. Furthermore, according to the state of art in endodontics, the root canal treatment is a procedure aiming to clean and disinfect the root canals of the tooth by using irrigating solutions containing sodium hypochlorite and chlorhexidine.

If the manufacturer can demonstrate that the principal mode of action is the rinsing and the irrigation so that the solutions remove debris and necrotic tissues (mechanical action), the irrigating solutions fulfil the definition of medical device.

Moreover, as they contain a substance (NaOCl or CHX) which, if used separately, is considered to be a medicinal product, and as they have a disinfecting action, these solutions should be considered as having an antimicrobial action ancillary to that of the device (disinfection of the root canal before obturation according to the state of art), unless the absence of these effects can be proven.

Not claiming a disinfectant action is not sufficient to demonstrate that a substance doesn't have an action ancillary to that of the device.

As stated in MDCG-2022-5 "The determination of the nature of the substance, i.e. whether it is "considered to be a medicinal product" is independent of the intention of the manufacturer, of the quantity of the substance in the device and of the method or route of administration. Also, the determination of whether the substance "has an action ancillary to that of the device" is scientifically objective and does not depend on the manufacturer's intention for the action of that substance in the device.

Therefore, scientific evidence, and not the claims, is the only aspect relevant for the determination of pharmacological action. Thus, unless the manufacturer can provide robust scientific evidence that NaOCl or CHX in the irrigating solution has no antibacterial or antiseptic action in or on the human body or its constituents, using suitably scientifically rigorous tests, root canal irrigating solutions containing NaOCl or CHX should be classified as class III per rule 14 of Annex VIII to the MDR.

#### 1.1.2.5 Classification of red blood cell additive solutions containing adenine

**Background**

Nowadays, there are several medical devices systems for red blood cells (RBCs) processing and storage. These systems may include different parts, combined or not, such as: filters, empty transfer bags, anti-coagulant solutions, and, used in a final storage step, a preservation/additive solution with adenine.

Adenine has been used for over 40 years in RBCs concentrates bags to increase the RBCs shelf life. Adenine helps maintain ATP production for RBCs metabolism and cell shape maintenance.

This survivability of RBCs is correlated with the level of ATP concentration which inexorably decreases over time. The RBCs' ATP concentration decrease is caused by depletion of the adenine nucleotide pool, mediated by deamination of adenosine monophosphate (AMP) to inosine monophosphate. Adenine reverses this nucleotide depletion by reacting with 5-phosphoribosyl-1-pyrophosphate in the presence of adenine phosphoribosyl transferase (APRTase) to yield additional AMP. During RBCs storage ex vivo, the adenine is also incorporated into AMP and the concentrations of free adenine decline to minimal levels towards the end of the storage period.

In view of the above, most whole blood collections are separated quickly after collection into RBCs, platelets, and plasma components. The RBCs are resuspended in an additive solution containing adenine to allow adequate storage.

The question has arisen as how medical devices that includes additive solutions with adenine used in RBC's processing are classified.

**Outcome**

Adenine is a substance, which yields additional AMP in the blood and is used to increase the shelf life of the red blood cells and thus their conservation. In view of the mechanism of action of adenine as described by the manufacturer and taking into consideration the note 4 of the section 1.2.2 in the MDCG 2022-5 rev.1, adenine is involved in a biochemical process inherent to the proper functioning of the red blood cells intended for infusion. In this context, the mode of action of adenine meets the definition of metabolic action defined in MDCG 2022-5.

Note also the existence of an CHMP opinion of September 15 2022 which, although mainly concerns citrate solutions, also mentions adenine and in particular its pharmacological action in two referenced publications.

Therefore, the mode of action of adenine can be either a metabolic mode of action or a pharmacological mode of action (or both) as defined in MDCG 2022-5.

According to Rule 14, Annex VIII to the Regulation (EU) 2017/745 on medical devices, all devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.

Consequently, adenine used in additive solutions for RBCs processing in such devices has an ancillary action to the device as medicinal substance. Therefore, the device should be classified as class III, according to rule 14.

### 1.1.2.6 Classification of dual action cream with menthol and capsaicin

**Background**

According to the manufacturer the product is a dual action cream with cooling and warming effect with menthol, capsaicinoids and some other additional substances. The intended purpose of the cream is relieving muscle and joint pain through dual action. Menthol cools, relieves pain, reduces swelling and reduces muscle tension. Capsicum extract warms the treated area.

The mechanism is mediated by the TRP family of ion channels, and the effect is lasting from half an hour to a few hours. The manufacturer claims that the principal intended action of menthol in the product is achieved by physiological (activity of ion channels) and by chemical means. The manufacturer claims that the secondary intended action is achieved by capsaicin giving a sense of warmth and having a relaxing effect. The manufacturer’s justification is that the amount of capsaicin in the product is not at the level of capsaicin in medicinal products. The manufacturer states that the intended action of the product is not achieved by pharmacological, immunological or metabolic means and asks for validation that such a medical device would be class IIa according to Rule 21 of the MDR.

**Outcome**

The intended purpose of the cream is to relieve muscle and joint pain. Both substances, menthol and capsaicin, have a recognized pharmacological action in pain management. Both menthol and capsaicin act upon receptors to achieve their effect, hence they act by pharmacological means. As the principal intended action is claimed to be achieved by menthol, the product is outside the definition of a medical device. Furthermore, in *MDCG 2022 – 5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices*, "Products containing peppermint oil or menthol with intended medical purposes such as the relief of discomfort and pain in muscles and joints, relief of back pain, etc. as their principal mode of action is pharmacological involving interaction with the cold-sensitive receptors in the skin.", are given as examples of medicinal products. The manufacturer bears the burden of proof for the non-pharmacological, non-immunological or non-metabolic effect of his product. In the absence of evidence that the main intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, a product should not be qualified as a medical device and consequently, the discussion on classification of the product is irrelevant.

**1.1.2.7 Lactose tablets for vaginal use**

**Background**

The product is a non-sterile vaginal tablet consisting of 99 % lactose monohydrate, Ph. Eur grade. The intended purpose, as declared by the manufacturer, is the reduction of unpleasant vaginal odour and discharge associated with bacterial vaginosis, and relief of vaginal irritation and soreness. Recommended use is one tablet daily, administered intravaginally.

The mode of action proposed by the manufacturer is that the lactose is a nutrient for the indigenous flora of lactic acid bacteria, while the organisms causing bacterial vaginosis (*Gardnerella vaginalis* and others) do not use lactose for growth. The lactic acid bacteria produce components with adverse effect on the growth of *Gardnerella* and similar flora, namely lactic acid which is the main product of the metabolization of lactose, along with similar natural growth inhibiting substances.

**Outcome**

The lactose tablet achieves its principal intended action by metabolic means in or on the human body, as the consumption of the lactose by the lactic acid bacteria is a metabolic process and the indigenous lactic bacteria is considered as part of the human body, ref. note 4 in MDCG 2022-5 *Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices*, section 1.2.2.

As the principal intended action of the product is achieved by metabolic means in the human body the product should not be qualified as a medical device.

### 1.1.3. Borderline between medical devices and biocides

This section covers the borderline between products that may fall under the MDR or possibly under Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

#### 1.1.3.1 Substance for textile treatment

**Background**

The product is a concentrate for water-based treatment of textile materials to impart antifungal, antimicrobial and antiviral properties in various applications.

The intended purpose is the prevention of human infectious diseases caused by microorganisms spread through contact with surfaces, especially textile ones. The infectious diseases intended to be prevented are influenza, COVID-19 and hospital-acquired infections.

**Outcome**

This product does not act on individual patients, rather, it imparts antifungal, antimicrobial and antiviral properties onto textiles. Based on the information provided by the manufacturer this product should not be qualified as a medical device.

### 1.1.4. Borderline between medical devices and substances of human origin

This section covers the borderline between products that may fall under MDR or possibly under Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells or Directive 2002/98/EC on blood and blood components.

### 1.1.5. Borderline between medical devices and cosmetic products

This section covers the borderline between products that may fall under the MDR or possibly under Regulation (EC) No 1223/2009 on cosmetic products.

#### 1.1.5.1 Qualification of microabrasion dental stain removers

**Background**

Dental stain removers which act by microabrasion, used as tooth whiteners, have been qualified by some manufacturers as medical devices and placed on the market as such.

In the case of dental stain removers, to justify the medical purpose, manufacturers state that the microabrasion technique is based on a combination of mechanical and chemical action, e.g. for the treatment of fluorosis stains, amelogenesis imperfecta, cleidocranial dysplasia and to remove

residual bonded resin and enamel stains following bracket debonding at the conclusion of orthodontic treatment.

**Outcome**

The removal of dental stains to improve the appearance of teeth, which is the intended purpose defined by the manufacturer, regardless of the method or technique utilized and regardless of the staining being the result of a disease or treatment, does not represent a medical purpose.

Also, stain removers will not treat amelogenesis imperfecta and cleidocranial dysplasia, the removal of the dental stain in such cases does not change an aesthetic purpose into a medical one.

If the manufacturer cannot provide robust and scientific evidence that the dental stain removers have a role in the prevention, treatment or alleviation of a disease, the products should not qualify as medical devices.

Thus, products used for improving the appearance of teeth do not comply with the legal definition of medical device established in the MDR and should not be qualified as medical devices.

### 1.1.6. Borderline between medical devices and food

This section covers the borderline between products that may fall under MDR on medical devices or possibly under Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

### 1.1.7. Borderline between medical devices and personal protective equipment

This section covers the borderline between products that may fall under the MDR or possibly under Regulation (EU) 2016/425 on personal protective equipment.

#### 1.1.7.1 Rescue bag for patient transport

**Background**

The rescue bag is designed for the transportation of patients during rescue operations. According to the manufacturer, the product is intended to protect the patient mechanically, as well as thermally, during the salvage. The mechanical protection of the head is ensured by additional padding in the head area. To stabilize the patient during the transport, as well as to attach safety equipment during different manoeuvres, side straps are sewed onto the rescue bag. Furthermore, the product aims to avoid repeated unpacking and packing of the patient during changes of the transportation device, e.g. from the emergency rescue sledge to the ambulance. The general intended purpose of the rescue bag is the patient´s support and protection.

**Outcome**

The product in question enables stable and protected transport of patients in order to avoid the worsening of their state of health. The intended purpose of the product corresponds to the medical purpose of alleviation of, or compensation for, an injury or disability, according to Art. 2(1) of the MDR. It should be therefore qualified as a medical device. The risk class should be MDR class I, according to rule 1.

Please note that this entry refers solely to the qualification of the product as a medical device and that the manufacturer may also have to take into account other existing legislation for products used in emergency rescue.

### 1.1.7.2 Plexiglas box for caregiver protection

**Background**

The product is a safety box intended to prevent caregivers from being exposed to infection (i.e. COVID-19) by containing droplets expelled by the patient during endotracheal intubation, tracheotomy or any airway related procedure.

The box is intended to be placed over the patient's head, covering the upper body from head to shoulders. It is fixed to the bed or the operating table by straps. There are 2 holes for the physician's arms to allow access to the patient, and rectangular holes on the sides for insertion of ventilation circuits, anaesthesia circuits, infusion tubes. The intubation equipment is placed in the box. The physician inserts arms into the holes to intubate the patient.

The manufacturer designed two models of boxes, one for tracheotomy and one for intubation. They are intended by the manufacturer to secure and protect users during medical procedures.

**Outcome**

A medical device has the aim to provide protection of health and safety of the patient. An intended medical use may not be defined when the product is primarily intended to protect the caregiver or health care professional.

A product solely intended to protect a caregiver or health care professional by preventing exposure during a medical or surgical procedure, should not be qualified as a medical device.

### 1.1.7.3 Qualification of medical examination table covers

**Background**

Medical examination table covers are placed on the market with the intended purpose of covering the tables in medical exam room, on which the patients lay, to ensure a good level of hygiene and prevent the transmission of infectious agents, which can be easily transferred from patient to patient through contact with a common surface.

**Outcome**

Medical examination table covers are intended to be used for a specific medical purpose, namely the prevention of disease, as such they comply with the definition of medical device, according to point 1 of article 2 of Regulation (EU) 2017/745. Note that this qualification is not dependent on the cover's composition/chosen materials.

### 1.1.8. Borderline between medical devices and general consumer products

This section covers the borderline between products that may fall under the MDR or possibly under Directive 2001/95/EC on general product safety.

### 1.1.9. Other medical device borderlines

#### 1.1.9.1 Smartphone application for STI prevention strategies

**Background**

This application is intended by the manufacturer to "prevent sexually transmitted infections (STIs), by allowing for the exchange of information between different sexual partners."

It permits the recording of biological analysis results, like STI results, in order to share this information with other potential sexual partners, within a network. During an encounter, these results are shared by scanning a potential sexual partner's QR-code; the user then becomes part of each other's networks.

Where the functionality has previously been set up by the user, in case of positive tests for an STI the application sends automatic anonymised notifications to all those in their sexual network (two degrees of contact).

In this case, the application lets the user know what to do and helps him/her find the right services. For example, it encourages users to avoid unprotected sex and advises them on recommended testing practices based on their most recent data, limiting the spread of an STI within a sexual network and fostering earlier testing and treatment.

According to the manufacturer, this application also allows the evaluation, through "the risk calculator" function, of the risk of infection with an STI based on sexual habits, the number of connections, and also levels of infection in the network of sexual partners.

**Outcome**

The application transmits and exchanges data and information between partners. On this basis alone, the software would not perform an action on data other than communication, as per in MDCG 2019-11. The application does not prevent sexually transmitted diseases, but rather facilitates the exchange of information and communication between different users.

The application also contains a particular functionality that assesses the user's risk of contracting a STI. The risk calculation is based on the behaviour of this person and their contacts tree. In this case, the prevention does not rely on specific characteristics of the individual user (physiological parameters, etc...) but mainly on their sexual habits and behaviour towards their partners, within a sexual network.

Therefore, the risk calculation is based on indirect criteria and not on physiological parameters. It appears to be an epidemiologic tool rather than a prevention tool within the meaning of the medical device definition. As such, the "risk calculation to prevent STI diseases" cannot be considered as a medical purpose according to the definition of medical device.

The product does not therefore fulfil the definition of medical device, according to Regulation (EU) 2017/745, and should not be qualified as such.

#### 1.1.9.2 Medical calculators

**Background**

The intended purpose of a medical calculator is to facilitate one or more (sometimes up to 400) routine medical calculations at the point of care for multiple clinical disciplines by means of an app or webpage.

Calculation methods incorporated in the medical calculator are taken from or based on formulas or tables documented in research publications and (national) guidelines. Often, these calculations are relatively simple and could be done with a basic electronic calculator or even on paper (simple search). The healthcare professional enters several patient-specific variables after which the app calculates outcomes like risk scores, severity indexes, threshold values and other prognostic outcomes, depending on the specific calculation. The healthcare professional that uses the medical calculator at the point of care is likely to use the outcome of the calculation in making decisions about diagnosis or treatment of a patient in a routine setting.

Two examples of such medical calculations offered by this medical calculator are:

- calculation of stroke risk for patients with atrial fibrillation using the $CHA_2DS_2$-VASc Score to determine if patients need antithrombotic therapy (e.g. by prescribing anticoagulant medicine).
- calculation of the creatinine clearance using the Cockcroft-Gault Equation to determine the status of the kidney function. The calculated score is used to identify kidney failure and to help decide if dialysis is required.

**Outcome**

Calculation of a score according to a specific formula or an complex algorithm as mentioned in both examples is an action on data beyond the use of simple search as referenced in qualification decision step 3 of MDCG 2019-11 ("Decision steps for qualification of software as MDSW").

Also, the calculation is for the benefit of individual patients, as it does not only provide generic diagnostic or treatment pathways per decision step 4 of guidance MDCG 2019-11.

The presented device meets the definition of a medical device as it is intended by the manufacturer to be used for medical purposes in accordance with Regulation (EU) 2017/745.

Classification rule 11 applies, since it relates to software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, and classifies this product as at least class IIa. A higher classification may apply depending on the significance of the information provided by the device to support the healthcare professional's decision in the context of the patient's condition, as per guidance MDCG 2019-11 and MDCG 2021-24.

### 1.1.9.3 Needle Counters

**Background**

There are on the market products generally called needle counters, intended to allow the counting and to reconcile the count of suture needles and scalpels, after the procedure and before suturing the operating cavity. These needle counters are designed to facilitate the control of such small instruments. Some of the models have a magnetic base with numbered spaces and in other cases a high-density foam to hold them securely in place. There are also models which combine these solutions and some include a feature which allows to remove the scalpel from the handle safety, preventing work accidents, as claimed by the manufacturers.

These types of products are placed on the European market with indications such as:

- to guarantee the safe elimination of scalpel blades and suture needles used in operating rooms;
- to permit counting of scalpel blades and needles used in the operating room.

Some manufacturers claim that their intended use is the prevention of the severe consequences to the patient's health if any of such items were to remain on the human body after suturing.

**Outcome**

Needle counters, intended to allow the counting and reconciling the count of suture needles and scalpels, as well as their elimination, after the procedure and before suturing the operating cavity, do not comply with the legal definition of a medical device, according to Article 2 (1) of the MDR, since they are not intended for any specific medical purpose, and should not be qualified as such.

### 1.1.9.4 Temperature sensors embedded in orthopaedic devices for compliance tracking

**Background**

The product in question is a temperature sensor that is intended to be embedded in orthopaedic devices, for example scoliosis braces. It then tracks the use of the orthopaedic device, which are typically not very comfortable but have to be worn daily for long periods of time to be effective. This is done by regularly measuring their temperature, which rises close to body temperature during wear. The sensor's purpose is to log when and especially for how long the orthopaedic devices have been worn. The patients are informed that compliance is being tracked.

The question arose whether the sensor is an accessory for the orthopaedic medical devices it is intended to be used with. The orthopaedic devices can be used and be performant without the sensor, but it is claimed that the sensor increases patient compliance and therefore therapeutic success of the orthopaedic devices, as well as enables the treating doctors to better assess the

effectiveness of prescribed orthopaedic devices by eliminating a possible lack of patient compliance as a confounding factor.

**Outcome**

According to Article 2 (2) of the MDR, 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

Neither increasing patient compliance nor providing information to better assess the performance of a medical device can be said to specifically and directly aid that device's medical functionality. The sensor therefore does not specifically and directly assist the medical functionality of the orthopaedic medical devices in terms of their intended purpose and should not be qualified as an accessory for a medical device. Furthermore, the product should not be qualified as a medical device on its own.

**1.1.9.5 System intended to produce sclerosing foam**

**Background**

The system is intended to produce sclerosing foam for varicose veins treatment. It consists of two products to be used in combination: a sterile single use mixing capsule filled with air or with a mixture of gases ($O_2$/$CO_2$ equal parts), which has a port for the introduction of the sclerosing agent (medicinal product) and for the extraction of the newly formed foam. Also, the system includes a reusable digitally programmable electronic stirrer with a lodging designed to accommodate the capsule.

In order to produce the foam, first, the capsule with the gas is connected to the stirrer, then, the sclerosing medicinal product is injected into the capsule with a syringe through the port. Due to the magnetic stirrer, the sclerosing drug and the air are mixed to form a homogenous foam. After the foam is formed, it is removed by aspiration from the capsule with a syringe that is not included in the system, in order to be administered to the patient. Therefore, the system itself is not intended to administer the foam directly to the human body.

**Outcome**

This system is intended by its manufacturer to just produce, in an on-the-spot manner, the sclerosing foam, which is considered a medicinal product, and that is going to be introduced afterwards in the body by a syringe which is not part of the system.

In this case, as neither the system itself nor the capsule or the stirrer administer the foam directly to the patient, being only intended for the preparation of the medicinal product, it can be concluded that it does not fulfil the definition of a medical device according to Article 2 Regulation (EU) 2017/745 (MDR) and should not be qualified as such.

If a manufacturer of such a system would include in it a CE marked syringe intended to administer the foam, which is considered a medicinal product, to the human body, as the syringe is considered a medical device, the system would meet the definition of a procedure pack according to Article 2 (10) and as referred to in Article 22 of the MDR as it will consist of a

medical device combined with other products, not considered medical devices, packaged together and placed on the market with a specific medical purpose.

### 1.1.9.6 Mobile sterile air system

**Background**

The mobile sterile air system is a product designed to create a defined sterile zone for performing minor procedures in an operating theatre or medical practice under sterile conditions. To achieve sterile conditions, the product removes pathogens from the air through filters and creates a laminar airflow. This laminar flow of purified air creates a protected zone by displacing non-sterile air. The protected zone is defined by laser lines generated by the product, e.g. at the surgical site. The purpose of the product is therefore to remove dangerous pathogens from a defined area to reduce the risk of infection to the patient.

**Outcome**

The product in question enables an appropriate environment to perform medical interventions without having a specific medical purpose itself. The product therefore controls the environment and does not act directly in or on the human body. This leads to the conclusion, that the mobile sterile air system does not comply with the legal definition of a medical device according to Art. 2 (1) MDR and should not be qualified as such.

### 1.1.9.7 Device used intended to administer a medicinal product 


**Background**

The package for a medicinal product, used as laxative, is made to be used for rectal insertion and administration of the medicine. The package is a single dose mini tube, with a long nozzle.
This kind of packages are normally not put on the market on their own but are made available only as part of combined medicinal products.

A device which is invasive to a body orifice, for the purpose of administrating a medicinal product, falls under the definition of a medical device. Second sub-paragraph Article 1 (9) MDR states: “However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned.”

As a result, the medical device part, in this case also the packaging, must comply with the requirements of the MDR in accordance with article 117 MDR. Proof of conformity of Annex I MDR must be provided in the marketing authorisation dossier of the overall medicinal product.

**Outcome**

In this case, the packaging for a medicinal product, used as laxative, is designed for rectal insertion and administration of the medicinal product into the body, thereby falling under the definition of a medical device. Thus, it cannot be considered to being purely a "simple" packaging solution. Because the product forms a single integral medicinal product, which is intended exclusively for use in the given combination and which is not reusable, the medical device part (the packaging) must comply with the requirements of the MDR in accordance with article 117 MDR. Proof of conformity with annex I MDR must be provided in the marketing authorisation dossier of the integral medicinal product. Article 117 is implemented in the Annex I to Directive 2001/83/EC, point 12 of section 3.2.

## 1.2. Classification of medical devices

The respective sections will be populated when cases are finalised under the Helsinki Procedure.

### 1.2.1. Rule 1

#### 1.2.1.1 Rescue bag for patient transport

See entry 1.1.7.1.

#### 1.2.1.2 Penis holster 


**Background**

Penis holster is a medical device designed for men who are incontinent or unable to go to the toilet, for hospital and home use. It transports urine from the urinary meatus of the penis to a urine collection bag.

The penis holster is placed at the tip of the glans and is partially covered by the foreskin. The penile sleeve must be removed at least once every 24 hours for cleaning. The device can be reused for up to 30 days. Therefore, the device is intended to remain in place for several hours a day and up to maximum 24 hours.

The question regarding the classification of such device has arisen and, in particular, whether or not the device, given its anatomical position (under the mucous membrane and on the glans), falls within the definition of an invasive medical device and more precisely invasive by a body orifice.

**Outcome**

According to the MDCG 2021-24, an invasive device is defined as *"Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the*

*body…* " and a body orifice is "*Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma*." Additional to natural and artificial openings in the body only the external surface of the eyeball is considered as body orifice.

Taking into account its instructions of use, the penis holster is placed under the inner mucosa of the prepuce. The anatomical areas in contact with the device for its use (the inner mucosa of the prepuce) do not as such constitute an orifice of the human body according to the current legal definition and guidance.

Therefore, the penis holster shouldn't be considered as invasive device through a body orifice and should be classified as Class I according to rule 1 of Annex VII to the Regulation (EU) 2017/745 on medical devices.

### 1.2.2. Rule 2

### 1.2.3. Rule 3

#### 1.2.3.1 Syringe containing glass beads

**Background**

The intended purpose of the syringe containing glass beads is the aseptic collection via a wing needle (venous collection), transportation, incubation for prolonged coagulation and separation of small amounts of blood for obtaining autologous conditioned serum (ACS) with an increased concentration of growth factors and IL-1Ra. Following a centrifugation step, the ACS (without glass beads) is transferred to another syringe and stored at appropriate temperature until local injection into the same patient. The local injection site is not specified in the instructions for use. The manufacturer mentions though in his documentation that ACS is indicated for the treatment of knee osteoarthritis, for example.

According to the manufacturer, the containing glass beads increase the surface area to support the effectiveness of the product. The glass beads are made of DURAN® Borosilicatglas 3.3. They are polished and have a diameter of 3 mm. There is no further treatment or coating. The manufacturer describes that the function of these uncoated glass beads is based on the contact stimulation by polar surfaces such as glass to accelerate coagulation of the collected blood. It is stated that following contact with negatively charged surfaces, factor XII is converted into XIIa and initiates the coagulation.

**Outcome**

The syringe, a non-invasive device, is intended to modify the composition of blood intended for implantation or administration into the body. The biological and chemical composition of the blood is altered by the cumulative application of incubation and centrifugation.

Blood collection tubes containing glass beads for blood collection, incubation and centrifugation fall under the definition of medical device as defined in article 2 (1) MDR.

According to Rule 3, first paragraph, the device is to be classified in class IIb. The exception according to which the device would have to be classified as class lla medical device, does not apply here. It is not a simple filtration, centrifugation or exchange of gas or heat.

### 1.2.4. Rule 4

### 1.2.5. Rule 5

### 1.2.6. Rule 6

#### 1.2.6.1 Needles for root canal irrigation New

**Background**

The single-use flexible needles for root canal irrigation are intended to be used during an endodontic procedure.

The endodontic procedure consists in treating an infected tooth by making an opening in the crown of the tooth, removing organic and mineral debris and by cleaning and disinfecting the pulp chamber and the root canals with an antiseptic solution before reconstruction of the tooth crown.

The endodontic irrigation is an essential step in endodontic treatment. It allows to prepare the root canal to ensure its endodontic antisepsis. The single-use flexible needle is intended to be connected to a syringe which contains the irrigation solution usually composed of chlorhexidine or sodium hypochlorite to rinse and disinfect the root canal before the use of dental filling material.

Some manufacturers place these endodontic irrigation needles in class I per rule 5 of Annex VIII to the Regulation (EU) 2017/745 on medical devices (MDR), as they consider that the irrigation of the root canal does not comprise any surgical aspect since no incision is made in the gum or soft tissues by the dentist in the context of the treatment. For them, the irrigation aiming to clean and disinfect the root canal is not a surgical procedure.

**Outcome**

As an opening in the tooth is needed to reach the root canal and the damaged pulp, the endodontic treatment is considered as a surgically invasive procedure.

In the case of root canal irrigation needles, access to the root canal is not naturally available and requires a surgical opening in the tooth to be created. Since the use of this device is dependent on a prior surgical intervention, it meets the definition of a surgically invasive device under Rule 6 of Annex VIII of MDR.

Rule 5 applies to invasive devices introduced into a body orifice without surgical intervention. While the MDR defines a body orifice as including both natural openings and permanent artificial openings, such as a stoma, the drilled access to the root canal does not fall within this definition. It is a temporary surgical opening that is closed at the end of the procedure. Since the guidance MDCG 2021-24 specifies that surgical invasiveness applies when a device enters through an artificially created opening, Rule 5 is not the appropriate classification rule for this device.

Therefore, the root canal opening in which the needles are used is not a natural or permanent artificial body orifice. As the contact duration is transient, less than 60 min, the single-use flexible needles intended for root canal irrigation during an endodontic procedure falls under class IIa per Rule 6 of Annex VIII of MDR.

### 1.2.7. Rule 7

#### 1.2.7.1 Dermal filler implantable

**Background**

Dermal fillers are usually devices intended to be used for aesthetic purposes included in the annex XVI to the MDR. These devices are injected into the skin with a syringe, at different depths, to help fill in facial wrinkles and provide facial volume. Most of these wrinkle fillers are temporary (not permanent) because they are eventually absorbed by the body. Most dermal fillers today are constituted of hyaluronic acid.

There are also dermal fillers which are qualified as medical devices, as they are intended to compensate for fat loss, e.g. in HIV infected patients with severe facial lipoatrophy, caused by the highly active antitretroviral therapy. The result of this injection of dermal fillers is the modification of the anatomy.

According to Article 2(5) of the MDR:
'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.

**Outcome**

Dermal fillers which are wholly or mainly absorbed, are covered by rules 7 and 8 of Annex VIII to the MDR, depending on the intended duration of use.

As they are administered by injection, and this is considered a clinical intervention, they fulfil the definition of an implantable device, according to Article 2(5) of the MDR.

### 1.2.8. Rule 8

#### 1.2.8.1 Dermal filler implantable

See entry 1.2.7.1.

### 1.2.8.2 n-butyl-2-cyanoacrylate based adhesives

**Background**

The products are n-butyl-2-cyanoacrylate (nBCA) based adhesives that close the treated vessel via an adhesive seal. The products are intended for the permanent and complete endovascular adhesive closure of the great saphenous vein (GSV) and associated varicosities when treating venous reflux disease.

Different manufacturers have placed on the market these devices as Class IIb and Class III medical devices per Rule 8 under MDD. The rationale of manufacturers for different classifications was based on the time of degradation of nBCA.

Therefore, questions have arisen about whether the time of degradation of the embolizing agent changes the classification approach to Rule 8 of Annex VIII to the MDR.

**Outcome**

Third indent of rule 8 of Annex VIII to the MDR states that: "All implantable devices and long-term surgically invasive devices are classified as class IIb unless they […] – have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III."

According to MDCG 2021-24 guidance: "The term 'absorption' in the context of implantable devices refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. It does not apply to those substances that are excreted without modification from the body, e.g. insufflation gases for the abdominal cavity or laparoscopic and endoscopic procedures".

Considering that in the third indent of rule 8 8 of Annex VIII to the MDR there is no reference to the time of absorption, these devices should be classified as class III devices.

### 1.2.8.3 Custom-made cranial implant

**Background**

The product is a custom-made cranial implant that functions as a replacement for parts of the skull. It will be specifically made for a patient to replace parts of the skull in order to protect the brain from the environment.

The intended use of a custom-made skull implant requires that it is placed on the dura mater. The dura mater is part of the central nervous system since it is the outer layer of the meninges.

**Outcome**

In a normal situation when the cranium is anatomically intact, the outer layer of the meninges, the dura mater, touches the skull. A medical device that acts as a replacement of the skull will therefore come into contact with the dura mater as well. According to point 2.7 of Annex VIII to the MDR, the brain, meninges and spinal cord are part of the central nervous system.

It is not required that the cranial implant has an effect on or an interaction with the underlying tissue in order to be classified as a class III medical device. Medical devices that are intended specifically for use in direct contact with the central nervous system are classified as class III.

A custom-made cranial implant is specifically intended to be used in direct contact with the central nervous system. Therefore, it should be classified as class III, according to the second indent of rule 8 of annex VIII to the MDR.

### 1.2.9. Rule 9

#### 1.2.9.1 Argon coagulation units

**Background**

These units are used in argon plasma coagulation, a monopolar electrosurgical technique where the argon plasma takes the role of the application electrode, which makes the intervention using this technique contactless.

The argon coagulation unit ensures the delivery and controlled flow of argon to the argon electrode. The unit is intended to be connected to two argon cylinders and an electrosurgical generator. The unit enables adjustment of the argon flow, checks the argon volume in the connected cylinders and ensures the selection between the connected cylinders.

**Outcome**

Due to their intended use, i.e. to enable the argon plasma coagulation and the dependence on an electrical energy source, argon coagulation units are active therapeutic devices. Argon coagulation units directly influence the argon plasma coagulation where the electrical energy is administered to the body tissues by the argon plasma stream, which takes the role of the application electrode. Taking into account the site of application as well as the nature and the density of the applied energy, argon coagulation units are considered to be delivering energy in a potentially hazardous way. Therefore, argon coagulation units should be classified as class IIb devices according to Rule 9.

### 1.2.10. Rule 10

### 1.2.11. Rule 11

#### 1.2.11.1 Medical calculators

See entry 1.1.9.2

### 1.2.12. Rule 12

### 1.2.13. Rule 13

### 1.2.14. Rule 14

#### 1.2.14.1 Root canal irrigation solution

See entry 1.1.2.4

### 1.2.15. Rule 15

### 1.2.16. Rule 16

#### 1.2.16.1 Ethylene oxide gas cartridges

**Background**

Ethylene oxide (EtO) gas is a sterilant. The product in question is a single-use cartridge containing 100% EtO. The intended use for these cartridges is to sterilise and disinfect medical devices.

An EtO gas sterilisation cycle consists of five steps preconditioning and humidification, gas introduction, exposure, evacuation and air washes. The EtO gas cartridges are used as the source of EtO. EtO gas cartridges cannot perform the sterilization process by themselves; however, the sterilization cycle cannot occur, without these cartridges.

Therefore, the question has arisen, as whether EtO gas cartridges should be considered at least as Class IIa medical devices, since they enable and participate to the sterilization cycle.

**Outcome**

Rule 16 of the Regulation (EU) 2017/745 states that "[…] All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, 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 IIb. […]"

In this case, these products specifically intended to be used for sterilization of medical devices in healthcare institution are covered by Rule 16 of Annex VIII to the MDR and should be classified at least as class IIa medical devices.

### 1.2.17. Rule 17

### 1.2.18. Rule 18

### 1.2.19. Rule 19

### 1.2.20. Rule 20

### 1.2.21. Rule 21

### 1.2.21. Saline solutions for nasal irrigation

**Background**

The saline solutions for nasal irrigation are intended to relieve nasal congestion in infants, children and adults, by dissolving mucus in the nose. These solutions are commonly used to treat acute and chronic rhinosinusitis and to alleviate cold-like symptoms. Saline solution consists of 0.9% (w/w) of sodium chloride (NaCl) dissolved in purified water. They may be placed on the market in single-dose, multi-dose or bulk packaging, in sterile or non-sterile condition.

Some manufacturers have classified their saline solutions for nasal irrigation as class I medical devices under the MDR according to Rule 5, which applies to invasive devices with respect to body orifices.

**Outcome**

The saline solution for nasal irrigation, which is a mixture of water and sodium chloride, is considered to be a combination of substances. Moreover, sodium chloride solution is locally dispersed to dissolve mucus in the nasal cavity where it is achieving its intended purpose.

The guidance MDCG 2021-24 on classification of medical devices mentions that devices similar to saline solutions, such as salt water used as nose or throat sprays, are examples of devices falling within class IIa according to rule 21. In addition, this guidance also indicates that products acting in the nasal or oral cavities may, to some extent, be ingested or inhaled. These products will be class IIa devices if they achieve their purpose only in these cavities.

Furthermore, the guidance MDCG 2022-5 on borderline between medical devices and medicinal products also quotes salt water used as nose or throat sprays as examples of substances-based devices intended to be introduced into the human body or applied to the skin.

Therefore, since the saline solution is a device composed of substances intended to be applied in the nasal cavity, and it achieves its intended purpose in this cavity, this device should be in class IIa according to the third indent of Rule 21.

### 1.2.22. Rule 22

## 2. Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

### 2.1 Qualification of IVDs

The respective sections will be populated when cases are finalised under the Helsinki Procedure.

### 2.1.1. Borderline between IVDs and medical devices

This section covers the demarcation between products that may fall under the IVDR or under the MDR, where the conclusion is that the product should be qualified as an IVD.

#### 2.1.1.1 FeNO measuring device

**Background**

The product is intended by its manufacturer to be used for the measuring of fractional exhaled Nitric Oxide (FeNO). NO is a gas produced by cells involved in the inflammation associated with allergic or eosinophilic asthma. The NO is exhaled, meaning that the NO level, which is related to the occurrence of some diseases, may be measured in the breath. The patient is instructed by the healthcare professional to inhale through the filter of the breathing handle and then to exhale slowly back through the filter.

The product is composed of different parts, where the instruments and breathing handle are regarded as *in vitro* diagnostic medical devices, but the disposable filter (viral and bacterial) that has to be changed for each new measurement session and for each patient is CE marked according to the Regulation (EU) 2017/745 in class I.

**Outcome**

The exhaled air is no longer part of the human body and therefore the exhaled air is considered to be a gaseous specimen derived from the human body, which is subsequently analysed by a device outside of the body. The device provides information for a medical purpose concerning a physiological or pathological state, which would qualify this product as an *in vitro* diagnostic medical device according to the Regulation (EU) 2017/746.

Since the principal intended purpose of the product is to be used for the examination of specimens derived from the human body for the purposes of providing information, according to the definition in Article 2(2) of the Regulation (EU) 2017/746, it is qualified as an *in vitro* diagnostic medical device.

### 2.1.2. Borderline between IVDs and general laboratory equipment

### 2.1.3. Other IVD borderlines

## 2.2 Classification of IVDs

The respective sections will be populated when cases are finalised under the Helsinki Procedure.

### 2.2.1. Rule 1

### 2.2.2. Rule 2

#### 2.2.3. Rule 3

#### 2.2.4. Rule 4

#### 2.2.5. Rule 5

#### 2.2.6. Rule 6

#### 2.2.7. Rule 7

# Index


## A

Argon coagulation units ..... 25

## C

Classification of dual action cream with menthol and capsaicin ..... 10
Classification of red blood cell additive solutions containing adenine ..... 9
Custom-made cranial implant ..... 24

## D

Dermal filler implantable ..... 23
Device used intended to administer a medicinal product ..... 19

## E

Ethylene oxide gas cartridges ..... 26

## F

FeNO measuring device ..... 28

## G

Graphite crucible ..... 7

## L

Lactose tablets for vaginal use ..... 11

## M

Medical calculators ..... 16
Mobile sterile air system ..... 19

## N

Nasal spray with antibodies for COVID-19 ..... 6
n-butyl-2-cyanoacrylate based adhesives ..... 24
Needle Counters ..... 17
Needles for root canal irrigation ..... 22

## P

Penis holster ..... 20
Plexiglas box for caregiver protection ..... 14
Product for professional removal of dental biofilm ..... 7

## Q

Qualification of microabrasion dental stain removers ..... 12

## R

Rescue bag for patient transport ..... 13
Root canal irrigation solution ..... 8

## S

Saline solutions for nasal irrigation ..... 27
Smartphone application for STI prevention strategies ..... 15
Substance for textile treatment ..... 12
Syringe containing glass beads ..... 21
System intended to produce sclerosing foam ..... 18

## T

Temperature sensors embedded in orthopaedic devices for compliance tracking ..... 17