HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Classification of a Medical Device

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

This guide relates to the qualification of medical devices and the application of the classification rules and related guidance. This guide does not apply to *in-vitro* diagnostic medical devices. It outlines the process for classifying medical devices and explains how to seek clarification on classification of a medical device. This guide sets out, inter alia, the reasons for classification and the routes to correctly qualify or classify a product under the Medical Device Regulation 2017/745 (MDR).

2 INTRODUCTION

The Regulation provides the legal definition of a medical device and defines a series of rules, which can be used to classify a medical device. **It is the responsibility of the manufacturer to correctly qualify and classify their products before placing them on the EU market.** The classification of a device determines the applicable route(s) for establishing conformity with the Regulation. The classification should, as applicable, be reviewed by and agreed with the notified body chosen by the manufacturer to conduct the conformity assessment.

In its role as the competent authority for medical devices, the Health Products Regulatory Authority (HPRA) is responsible for arbitrations in relation to MDR classifications when a notified body and a manufacturer based in Ireland are unable to agree on the classification of a medical device. A manufacturer may also seek guidance directly from the HPRA on the classification of a device prior to submission of an application for CE marking to a notified body or prior to notification regarding the register of Class I devices.

3 LEGISLATION AND GUIDANCE

Whether or not a product qualifies as a medical device depends on whether it meets the definition of a medical device as outlined in Article 2(1) of the MDR.

The rules governing device classification are listed in Annex VIII of the MDR. These rules are further detailed in MDCG 2021-24 Guidance on Classification of Medical Devices. A number of other useful documents, which can assist with borderline and classification issues, are available on the EU Commission website.

4 QUALIFICATION AND CLASSIFICATION OF MEDICAL DEVICES

The manufacturer, in preparing for CE marking, should first determine, based on its intended purpose, if the product qualifies either as a medical device or as an accessory to a medical device, as defined in Article 2 of the MDR, outlined below:

''medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:
- *devices for the control or support of conception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.'*

''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);'

4.1 Qualification

In order to qualify as a medical device, the product should have an intended medical purpose in accordance with the legal definition of a medical device and its primary mode of action will typically be physical. Article 1(6) excludes several product types from the scope of the MDR. These include, but are not limited to cosmetic products, medicinal products, advanced therapy medicinal products, viable transplants/tissues/cells or products containing viable biological material.

Drug-device combinations (DDC) may be regulated as devices under the MDR provided the medicinal product's action is ancillary to that of the device. In accordance with Article 1(9), devices for the administration of medicinal products are regulated as devices, provided they do not form a single integral DDC with a medicinal product when placed on the market exclusively in that combination. See Article 1(9) for further detail.

Factors such as the degree of invasiveness, the part of the body affected, duration of use, and whether or not the device is active determine the classification. As outlined in Annex XVI of the Regulation, certain devices without an intended medical purpose fall within the scope of the

MDR. The list provided in Annex XVI is not exhaustive and can be amended by the European Commission to bring additional products within the scope of this Annex. Products contained in Annex XVI must be classified in accordance with the implementing regulations on Annex XVI devices.

4.2 General principles of classification

The following is a list of general principles that should be kept in mind when qualifying and classifying a device:

- Medical devices are products intended to be used for a specific medical purpose.
- It is usually the intended purpose that determines the class of device; however, technical characteristics may have a direct bearing on the intended purpose or may be explicitly called out by the classification rules (e.g. Rule 19 on nanotechnology).
- The intended purpose of the device should be substantiated (if required) and be representative of the technical characteristics of the device.
- Promotional and advertising material used and provided by the manufacturer is considered to be closely interlinked with the device's intended purpose.
- It is the intended and not the accidental use of the device that determines its class. However, if the normal clinical use of the device changes in time with evolving clinical practice such that the intended purpose and classification of the device changes, this should be addressed by the manufacturer and the conformity of the device assessed for the new intended purpose.
- It is the intended purpose assigned by the manufacturer to the device that determines the class of device and not the class assigned to other similar products.
- Accessories are generally classified separately from their parent device.
- The mode of action of a medical device should be clear and evidenced with appropriate data to confirm this mode of action.
- If the device can be classified according to several rules, then the highest possible class applies.
- Multipurpose equipment, which may be used in combination with medical devices, are generally not themselves classed as medical devices unless the manufacturer places them on the market with a specific medical purpose.
- If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.
- Standalone software is regarded as driving or influencing the use of a device and so falls automatically into the same class. The Regulation includes a specific rule aimed at software (Rule 11). Software is classified on a case-by-case basis. If the output of the software is general patient information, the software is generally not a device. If the output of the software is based on analysing/manipulating clinical data to facilitate diagnosis or determine treatment schedules, the software is more likely to be a medical device. MDCG 2019-11 provides specific guidance on the qualification and classification of standalone software and applications.

4.3 Level of risk

General medical devices and related accessories must be classified into one of four classes, which are based on the perceived risk of the device to the patient or user. Factors such as the degree of invasiveness, the part of the body affected, duration of use, and whether or not the device is active determine the classification. The classification of a device determines the conformity assessment options that are applicable to the device, with higher risk devices undergoing higher levels of assessment.

Class	Type
I	Low risk
IIa	Medium risk
IIb	High risk
III	Highest risk

4.4 Classification rules

There are 22 rules outlined in Annex VIII of the Regulation that lay down the basic principles of classification. In addition, there are several implementing rules, which serve to guide manufacturers in applying the appropriate classification rule. This section serves as a gentle introduction to classification rules; however, these rules are further explained in MDCG 2021-24 and descriptive examples are provided. The 22 rules are subdivided into four groups as follows:

Rules	Device
Rules 1 – 4	Non-invasive devices
Rules 5 – 8	Invasive devices
Rules 9 – 13	Active devices
Rules 14 – 22	Special rules, e.g. devices containing tissue of animal origin, drug-device combinations, nanomaterial, etc.

Annex VIII and related guidance documents outline a number of key factors, listed below, that must be considered to appropriately classify a device using the 22 classification rules. In the event several rules, or if, within the same rule, several sub-rules apply to the same device, the strictest rule and sub-rule will apply resulting in a higher classification.

4.4.1 Duration of contact

In determining the correct classification of a device the duration that the device is in continuous contact with the patient is defined as transient, short term or long term. The longer the device is in contact with the patient or user, the greater the risk. This is taken into account when determining classification. Continuous use is defined in MDCG 2021-24 as:

'(a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed;
and (b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.'

4.4.2 Degree of invasiveness

A device, which in whole or in part, penetrates inside the body either through a body orifice or through the skin surface, is invasive. Invasiveness is generally categorised as invasive of a body orifice (including the surface of the eye), surgically invasive devices and implantable devices.

'Surgically invasive' means any device which pentrates inside the body through the surface of the body and a device which produces penetration other than through a body orifice.

An implantable device is one which is intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye by surgical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. This factor is further elaborated in MDCG 2021-24.

4.4.3 Whether or not the device is active

A medical device is considered to be active if its operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. As per MDCG 2021-24, medical devices intended solely to transmit energy between an active medical device and the patient where there is no significant change in the energy (e.g. nature, density, level) are not considered to be active medical devices. Software is considered an active device.

Any device which is used, alone or in combination wih other devices, to support, modify, replace or restore biological functions or structures for the treatment or alleviation of an illness, injury or disability is considered an 'active therapeutic device'. Simarily, any device which is used, alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities is considered an 'active device intended for diagnosis and monitoring'.

The concept of 'acting by converting energy' includes conversion of energy in the device and/or conversion at the interface between the device and the tissues or in the tissues.

4.4.4 Part of the body affected

The anatomy affected by the use of the device must be considered. Devices in contact with the central nervous system or the central circulatory system are automatically placed in a higher risk category.

4.4.5 Special rules

In some cases, it may be necessary to take account of aspects of a medical device not covered by factors discussed above. Rules 14-22 of Annex VIII provide a list of 'special rules' which give consideration for aspects of a device's characteristics which cannot be categorised into the factors outlined in sections 4.4.1-4.4.4. These rules provide scope for, but are not limited to, devices incorporating medcinal substances, contraception, disinfection, nanometerials and drug-device combinations. These rules are further elaborated in the guidance document MDCG 2021-24.

5 WHEN TO APPLY TO THE HPRA FOR CLASSIFICATION DETERMINATION

It is ultimately the responsibility of the manufacturer to correctly/appropriately qualify and classify their products. The manufacturer confirms the classification with a notified body of their choice. If there is disagreement between the manufacturer and the notified body, the matter can be referred to the competent authority of the manufacturer for decision, as per Article 51 (2) of the MDR.

The HPRA will also accept requests for the classification of a medical device, drug-device combination and borderline product prior to submission of an application for CE marking to a notified body. The HPRA also accepts requests for classification from other individuals / interested parties.

The form *Request for classification of a Human Health Product (ADV-F0001)* can be downloaded from the 'Publications and Forms' section of www.hpra.ie. Applications cannot be reviewed without appropriately completed documents and data.

6 HOW TO FILL IN THE APPLICATION FORM

The application form is divided into six sections:
- Administrative information
- Product/device information
- Additional information
- Documentation to be attached
- Fees
- Signed statement

The form must be completed in full in order for the HPRA to provide an informed opinion; however, some specific sections may be marked as 'not applicable' if necessary. Appropriate data supporting the intended use, claims or mode of action should be made available (if applicable). All applications, including the supporting data, must be in English.

6.1 Administrative and device information

This relates to sections (a) and (b) of the form.

The form must include information on the name, address and contact details of the organisation making the application, the manufacturer and where the manufacture of the device takes place.

Details of the intended use, label claims, mechanism of action and novelty of the device should be provided. The outcome of any review of the manufacturer's classification by another regulatory agency should be detailed, where appropriate. Additionally, the applicant should state whether there are similar devices on the market in the EU or EEA or elsewhere and their classification (if known).

6.2 Additional information

This relates to section (c) of the form.

The proposed classification, including detailed rationale (evidence from legislation and guidance documents) to support the use of the proposed classification rule should be supplied. If the manufacturer's proposed classification has been reviewed by a notified body, the outcome of the review should be provided, where possible. An outline should be given of what degree of patient intervention is required in the use of the device or whether it is to be used by professional healthcare providers or the general public.

6.3 Documentation to be attached

This relates to section (d) of the form.

The supporting data must be paginated for ease of review at the HPRA. The page reference must be clearly indicated in the boxes provided. Scientific, technical or medical rationale should be submitted along with any additional scientific data and literature to support the classification. A copy of the product labelling, instructions for use, promotional material and photographs of the device should also be provided.

6.4 Fees and signed statement

This relates to section (e) and (f) of the form.

All applications must contain a statement to certify that the information and documentation submitted with the application is correct in detail and all information requested has been supplied. The application should be signed by a senior technical or regulatory representative of the manufacturer. A fee is payable for this process. For details, see the HPRA Guide to fees and Fee application form.

7 CLASSIFICATION REVIEW PROCESS AT THE HPRA

7.1 Application

Upon receipt of a classification request, the HPRA logs the request using a five-digit classification number. This reference number, which has the format CL-XXX, should be used in all future correspondence with the HPRA. Once logged, the classification request is reviewed by the department's technical and policy teams. If the classification is clear, the applicant is informed of the outcome in writing, generally within 50 working days, and the file is closed once the window for appeals (30 calendar days) elapses. Depending on the nature and complexity of the classification request, it may be referred to the HPRA's Borderline Products Committee, which meets once a month, or externally to our wider European network for further discussion. The Borderline Products Committee is responsible for assessing the status of a particular product and determining whether the product meets the definition of a medicinal product, medical device or cosmetic.

An enquiry to our wider European colleagues is carried out by circulating a query using an agreed European format and procedure. The query provides basic information on the device but does not specify the name of the product or manufacturer. The applicant for classification will be informed that the issue has been referred to external parties for review. If a consensus is reached on the classification, the applicant is informed of the outcome.

In certain cases, there may be no majority EU consensus. In this instance, the HPRA may formally request to have the classification issue listed at the next available meeting of the Borderline and Classification Working Group (BCWG) of the Medical Device Coordination Group (MDCG) or related working group on classification, to make the final decision on classification. Once scheduled at this meeting, the HPRA presents the case and if a common position is agreed, the manufacturer and, where appropriate, the notified body is informed. The final consensus position will be published, with background information, in the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices.

The HPRA may seek the assistance of external clinical or technical external experts. In this case, a confidentiality agreement is signed and the expert must declare if they have a conflict of interest. If the classification is clear at this point, the applicant is informed of the outcome.

In any of the above cases, if it is felt that a meeting with the applicant would be worthwhile, a meeting may be convened.

7.2 Appeals

Should an applicant disagree with the classification decision, they may appeal. Appeals should be submitted in writing within 30 calendar days of the date of the classification decision letter. The appeal should be directed to devices@hpra.ie with all supporting information for consideration of the appeal. The decision of the HPRA following appeal shall be final. A fee is payable for an appeal to the HPRA.

8 WHO TO CONTACT AT THE HPRA

Once completed, classification request form ADV-F0001 may be forwarded to the HPRA at devices@hpra.ie. Alternatively, communication can be made by telephone or by post:

Medical Devices Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77
Telephone: +353-1-6764971

The HPRA encourages communication with the medical device sector. Should you have specific queries, please address these to the Medical Devices department of the HPRA who will endeavour to be of assistance.