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.

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1 SCOPE

This guide relates to the classification of general medical devices and the application of the classification rules and related guidance. This guide does not apply to active implantable medical devices or *in-vitro* diagnostic medical devices. This guide sets out, inter alia, the reasons for classification and the method by which classification can be determined.

2 INTRODUCTION

This document is a guide for classifying medical devices covered by the European Directive 93/42/EEC ('the Directive'), as amended and the related Irish regulation, S.I. No. 252 of 1994, ('the Regulation'). It outlines the process for classifying medical devices and explains how to seek clarification on classification of a medical device.

The Directive and corresponding Irish Regulation define a series of rules which can be used to classify a medical device. It is the responsibility of the manufacturer to classify a medical device that they intend to place on the market. The classification of a device determines the applicable route(s) for establishing conformity with the Directive. 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 HPRA is responsible for arbitration in relation to classification when a Notified Body in Ireland has not been able to agree the classification of a medical device with a manufacturer. Guidance may also be sought from the HPRA directly by a manufacturer on the correct classification of 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

The rules governing device classification are listed in Annex IX of Directive 93/42/EEC and Schedule 9 of the related Irish regulation and are further elaborated on in the MEDDEV guidance 'MEDDEV 2.4/1 Guidelines for the Classification of Medical Devices'.

A number of useful documents are available on the EU Commission website, for dealing with borderline products:

Guidance on borderline relating to-	Document name or reference
AIMDs and MDs	MEDDEV 2.1/3
MDs and PPE	MEDDEV 2.1/4
IVDs	MEDDEV 2.14/1
MDs, IVDs, medicines, biocides, cosmetics.	Manual on Borderline and Classifcation in the Community Regulatory Framework for Medical Devices
MDs, biocides.	Manual of Decisions for Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products.

Clarification on a classification may be submitted using the HPRA documents listed below, which are available on the HPRA website at www.hpra.ie.

ADV-F0006 'Request for Classification of a Medical Device'
FIN-G0002 'Guide to Fees'
FIN-F0018 'Fee Application Form'.

4 CLASSIFICATION OF MEDICAL DEVICES

The manufacturer, in preparing for CE marking, should first determine if their product falls within the scope of the Directive or national Regulation, either as a medical device or as an accessory to a medical device, as defined in Article 1 of Directive 93/42/EEC and Article 2 of the Regulation.

In order to be classified as a medical device, the product should have a medical purpose and its primary mode of action will typically be physical.

4.1 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. 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	Higher Risk
III	Highest Risk

4.2 Classification rules

There are eighteen rules outlined in Annex IX of the Directive and related Regulation that lay down the basic principles of classification. In MEDDEV 2.4/1 Rev. 8, these rules are further explained and descriptive examples are provided. The eighteen rules are subdivided into four groups as follows:

Rules	Device
Rules 1 – 4	Non-invasive Devices
Rules 5 – 8	Invasive Devices
Rules 9 – 12	Active Devices
Rules 13 – 18	Special rules e.g. devices containing tissue of animal origin, drug-device combinations

Annex IX and related guidance documents outlines a number of key characteristics, listed below, that must be considered to correctly classify a device using the eighteen classification rules.

4.2.1 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 and therefore this has to be taken into account when determining classification. Continuous use is defined in MEDDEV 2.4/1 as the uninterrupted actual use for the intended purpose. Where use of a device is discontinued in order that the device is immediately replaced with an identical device (e.g. replacement of a urethral catheter) this shall be considered as continuous use of the device.

Duration of contact can be difficult in some instances to determine. For example, if a device such as a cream or ointment is applied to the body its duration of effect may be considered as a factor when determining the duration of contact.

4.2.2 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.

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.

4.2.3 Whether or not the device is active

A medical device is considered to be active if the 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. 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.

The concept 'act 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.

4.2.4 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.

5 GENERAL PRINCIPLES

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

- Medical devices are defined as articles which are intended to be used for a medical purpose.
- It is the intended purpose that determines the class of device and not the particular technical characteristics of the device.
- The intended purpose of the device should be substantiated (if required) and be representative of the technical characteristics of the device.
- It is the intended and not the accidental use of the device that determines its class.
- 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 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 not themselves classed as medical devices unless the manufacturer places them on the market with the specific intended purpose as a medical device.

- 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. 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.

6 WHEN TO APPLY TO THE HPRA FOR CLASSIFICATION DETERMINATION

It is the manufacturer that determines the appropriate class for their product. Consequently, the primary responsibility for the classification of a medical device is placed on the manufacturer. The manufacturer confirms the classification with a Notified Body of their choice. If there is uncertainty or disagreement between the manufacturer and the Notified Body, the matter must be referred to the Competent Authority for decision.

The HPRA will also accept formal requests from a manufacturer 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 or prior to notification regarding the register of Class I devices.

The HPRA also accepts formal requests for classification from other individuals / interested parties.

The relevant form, *ADV-F0006 Request for classification of a medical device*, can be downloaded from the 'Publications and Forms' section of www.hpra.ie. Applications cannot be reviewed without appropriately completed documents and data.

7 HOW TO FILL IN THE APPLICATION FORM

The application form is divided into four sections:
- Administrative information
- Device information
- Documentation to be attached
- Signed statement.

The form must be completed in full with any sections which are not applicable marked accordingly. 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.

7.1 Administrative information

This relates to section (a) of the form.

01. This is the date the application is made to the HPRA.
02/03. The name, address and contact details of the organisation making the application.
04/05. The name, address and contact details of the manufacturer, where the manufacture of the device takes place.
06/07. If the manufacturer is not based in Europe the name, address telephone, fax and e-mail address of the authorised representative.
08. Enter details of any Notified Body approval of quality system, product or process at the site referred to in 04 above. Details of the Notified Body including their unique identification number should be filled in here.

7.2 Device information

This relates to section (b) of the form.

09. Name of the device, i.e. the trade name used for the device.
10. A general description of the device.
11. Details of the intended uses of the device.
12/13. State whether the device is novel or is an existing device with a new use. Details of new or previously untested feature of the device including where applicable, functions and principles of operation.
14. Detail the label claims for the device.
15. The proposed classification for the device for classification review should be indicated.
16. The proposed classification rule for the device for classification review should be detailed. Evidence from legislation and guidance documentation to support use of this classification rule should be supplied if applicable.
17. If the manufacturer's proposed classification has been reviewed by a Notified Body, the outcome of the review by the Notified Body should be detailed, where appropriate.
18. The outcome of any review of the manufacturer's classification by another regulatory agency should be detailed, where appropriate. An example would be a device with an ancillary medicinal substance, which has been reviewed by another competent authority.
19. If the device has been approved by another regulatory agency, the outcome of the classification review should be detailed, including the reference number.
20. State whether there are similar devices on the market in the EU or EEA or elsewhere and their classification (if known).
21/22. State 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.

7.3 Documentation to be attached

This relates to section (c) 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.

23. The scientific, technical or medical rationale supporting the classification.
24. Additional scientific data and literature to support the classification.
25. A copy of the product label and instructions for use.
26. Photograph or drawing of the device.

7.4 Signed statement and fees

All applications must contain a statement to certify that the information and documentation submitted with this 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'.

8 CLASSIFICATION REVIEW PROCESS AT THE HPRA

8.1 Application

On receipt of a classification request, the HPRA logs the request using a 5 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 Clinical Assessment Review Group. If the classification is clear, the applicant is informed of the outcome in writing, generally within 30 days, and the file is closed.
Depending on the nature and complexity of the classification request it may become necessary for the HPRA to seek the opinion and/or assistance of other EU Member States. This is done 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.

The HPRA may seek the assistance of 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.

If it is still unclear whether the product falls under the medical devices legislation, the classification request may be sent to the HPRA Advisory Committee for Medical Devices for discussion.

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 EU Medical Devices Expert Group (MDEG) 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 Classifcation in the Community Regulatory Framework for Medical Devices*. Occasionally, certain classification decisions may result in the classification rules being amended to incorporate the new decision.

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

8.2 Appeal

Should an applicant disagree with the classification decision, they may appeal. Appeals should be submitted within 14 days of the date of the classification decision letter. The appeal should be directed to the Human Products Authorisation and Registration Department together 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.

9 BORDERLINE CLASSIFICATIONS

In certain cases, it may not be clear if a product falls under the medical device legislation or whether to classify a device as a medicine, cosmetic, biocide, personal protective equipment (PPE) etc.

The decision will largely depend on the particular intended use of the product, as assigned by the manufacturer, and on the demonstrated mode of action. The manufacturer's claims must be substantiated by relevant data (scientific/technical/clinical).

If, after an initial review by the HPRA, it is determined that the product could potentially be a medicinal/other product, the product may be referred to the HPRA Classification Committee. This committee is responsible for assessing the classification of products where their classification is not obvious, including products which are borderline medical devices/medicinal product, or occupy a borderline with other product categories. Alternatively, classification requests for borderline products may be sent directly to the Classification Committee.

At a European level, decisions made on borderline classification issues relating to medical devices are discussed at the Medical Device Expert Group's Classification and Borderline Working Group. Consensus positions reached at this group are documented in the *Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices*.

10 WHO TO CONTACT AT THE HPRA

Once completed, classification request form ADV-F0006 may be forwarded to the HPRA electronically at devices@hpra.ie. Alternatively, communication can be made by telephone, fax, and e-mail or by post:

Human Products Authorisation and Registration Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devices@hpra.ie

The HPRA encourages communication with the medical device sector. Should you have specific queries, please address these to the Human Products Authorisation and Registration Department of the HPRA who will endeavour to be of assistance.