



## Medical Devices

### IRELAND Arthur Cox

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#### 1. Definition of medical devices

What is the definition of a medical device in your jurisdiction?

The regulation of medical devices in Ireland is largely driven by EU Legislation, of which the applicable law is set out in the Medical Device Directive 93/42/EEC, the Active Implantable Medical Device Directive 90/385/EEC, and the In-Vitro Diagnostic Medical Device Directive 98/79/EC (as amended) (the “**Directives**”).

National legislation transposing those Directives (as amended) include the European Communities (Medical Devices) Regulations 1994 (S.I. 252/1994) (as amended in 2001, 2002 and 2009), the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. 253/1994) (as amended in 2009), the European Communities (*In-Vitro* Diagnostic Medical Devices) Regulations 2001 (S.I. 304/2001), the European Communities (Medical Devices) (Reclassification of Breast Implants) Regulations (S.I. 358/2003) 2003, the European Communities (Medical Devices) (Tissues of Animal Origin) Regulations 2003 (S.I. 554/2003) and the European Communities (Medical Devices) (Reclassification of Hip, Knee and Shoulder Joint Replacements) (Amendment) Regulations 2007 (S.I. 92/2007) (collectively referred to hereunder as the “**Medical Devices Legislation**”).

The Irish Medicines Board (the “**IMB**”) is the competent authority for the regulation of medical devices on the Irish market, being the competent authority appointed under the Medical Devices Legislation. The IMB serves to ensure that all such devices which are placed on the market in Ireland meet the essential requirements of the Medical Devices Legislation.

There are three types of medical devices outlined in the Medical Devices Legislation. They are as follows:

- (a) General Medical Devices;
- (b) Active Implantable Medical Devices; and
- (c) In-Vitro Diagnostic Medical Device.

General medical devices are defined under S.I. 252/1994 (as amended by Regulation 5 of S.I. 110/2009 Regulations) as:

*“Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of –*

- (a) *Diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- (b) *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- (c) *Investigation, replacement or modification of the anatomy or of a physiological process; or*
- (d) *Control of conception*

*and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means”.*

An active implantable medical device is defined under S.I. 253/1994 (as amended by Regulation 4 of S.I. 109/2009) as:

*“Any medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure”.*

An in-vitro diagnostic medical device is defined under S.I. 304/2001 as:

*“A medical device being a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens,*

*including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*

- (a) *Concerning a physiological or pathological state;*
- (b) *Concerning a congenital abnormality;*
- (c) *For the purpose of determining the safety and compatibility with potential recipients; or*
- (d) *For the purpose of monitoring a therapeutic measure*

*and includes a specimen receptacle but does not include a product for general laboratory use unless such product, in view of its characteristics, is specifically intended by the manufacturer to be used for in vitro diagnostic examination.*

## **2. Combination products**

- i. Which legal regime (on medicinal product or on medical devices) applies to combination products incorporating both medicinal products (drugs/biologics) and medical devices?

General medical devices incorporating a medicinal product continue to be regulated under Medical Devices Legislation, but are subject to high levels of conformity assessment. Under S.I. 252/1994, the special rules of classification under Schedule 9 state that all devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in the relevant legislation (Medicinal Products (Licensing and Sale) Regulations (S.I. 142/1998) and the European Council Directive 65/65/EEC) and which is liable to act on the human body with action ancillary to that of the devices, are to be classified under Class III (Highest Risk).

Medicinal products are defined in Irish legislation according to the definition under Article 1(2) of the EC Directive 65/65/EEC as:

*“Any substance or combination or substances presented for treating or preventing disease in human beings or animals.*

*Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product”.*

As for conformity with Medical Devices Legislation, a number of requirements are set out in Schedule 1 of S.I. 252/1994. Section 7.3 provides that where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined above, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex 1 to Directive 2001/83/EC. The notified body will then seek a scientific opinion from one of the

competent authorities designated by the EU Member States or the European Medicines Agency on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device.

Furthermore, if the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.

The IMB is the licensing authority for medicinal products for human use in Ireland pursuant to the provisions of the Irish Medicines Board Act 1995. Medicinal products may not be marketed without a current product authorization, in accordance with S.I. 142/1998.

- ii. Are combination products (combining drugs and medical devices) subject to separate regulation in your jurisdiction?

No, combination products combining medical devices and drugs are regulated under the general Medical Devices Legislation. Under Rule 13, they are classified under Class III.

- iii. If the answer to (i) is negative, what is the scope of application of the legal regimes: evaluating both the drug and device components of the combination product?

The regulation of combination products presents a challenge for the Irish Medicines Board. Combination Products typically consist of medicinal products and medical devices, but increasingly can involve elements of advanced therapies (e.g. gene therapy/tissue-engineered products), information technology, cosmetics, herbal medicines etc. The first step when dealing with a combination product involving medicinal products and medical devices is to qualify or classify the overall combination product, as either a device combination or a drug combination. The Irish Medicines Board is available to assist with this process. The classification depends on the intended purpose and presentation of the product, and how the mechanism of action is achieved (i.e. pharmacological, physical, metabolic or immunological as a primary effect). Depending on the category into which the product falls, there are two alternative paths to regulation.

If the product is a "Device Combination", the notified body assess the product to ensure compliance with the Medical Devices Legislation, and seeks a scientific opinion from the Irish Medicines Board (or European Medicines Agency as the case may be) on the medicinal aspects of the product, specifically the quality, safety and efficacy of the medicinal product. The opinion is delivered within 210 days, and if all is in order, the Notified Body certifies the product, which once CE marked the product can be placed on the market in any EU state.

If the product is a "Drug Combination", the regulatory pathway is determined by medicinal product legislation and in particular Directive 2001/83/EC as implemented into Irish law, and marketing authorisations must be sought from the Irish Medicines Board (or European Medicines Agency as the case may be) in the usual way. The difficulty is that there is currently no mechanism for separately approving the medical device component of the product, and the ultimate product is not CE marked. The challenge is

for competent authorities (including the Irish Medicines Board) to harmonise their approaches, and for there to be a formal system of assessing the device aspect of the combination product.

- iv. What are the general conditions for review, approval and marketing the combination product?

If classified as a medicinal product, the general conditions for review, approval and marketing are as per Directive 83/2001/EC as implemented by the Medicinal Products (Control of Placing on the Market) Regulations (S.I. 540/2007) (as amended). Otherwise, if classified as a medical device, the general conditions for review, approval and marketing are as per the Medical Devices Legislation.

### 3. Borderline products

Are there any official and binding criteria for determination whether the product is a medicinal product or medical device, or whether a product is a device requiring pre-review or a non-medical device?

The decision as to whether a product will be deemed a medicinal product or a medical device 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 and will be subject to review by the IMB. In the event that the IMB determine that the product could potentially be a medicinal or other product, the product may be referred to the IMB Classification Committee, which is responsible for assessing the classification of products where their classification is not obvious, including those which are borderline medical devices/medicinal products. Alternatively, classification requests for borderline products may be sent directly to the Classification Committee as opposed to being referred by the IMB. 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.

There are certain products which were formerly regulated as medicinal products and which are now regulated as Medical Devices under Directive 93/42/EC (as amended). These include contact lens care products (not intended for administration into the eye), certain medicated dressings, concentrates for haemodialysis, certain irrigation fluids, bone cements containing antibiotics which are ancillary to the primary purpose of the cement, blood collection bags containing anti-coagulant solutions, intrauterine contraceptive devices containing copper and absorbable sutures.

- i. Are there any legal and binding criteria for determination whether the product is a medical device or medicinal product?

There are no legal and binding criteria as such, other than as set out above.

- ii. If the answer to (i) is positive, what are the main principles for differentiation?

Not applicable.

- iii. Are there any significant court or administrative judgments demonstrating the rules of product differentiation?

None that we are aware of in Ireland.

- iv. How is software that may have some related-medical applications regulated in your jurisdiction?

Under Schedule 1 of the Medical Devices Regulations, general medical devices incorporating software or which are medical software in themselves must be validated according to the state of the art, taking into account the principles of development lifecycle, risk management, validation and verification. Furthermore, devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply. Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.

#### 4. Cellular or tissue based products

Are there any official or binding criteria for determination whether a product is a animal or human based tissue or a medical device?

No. See above response at question 3 and 3(i).

- i. How are products composed of cells or animal/human tissue regulated in your jurisdiction?

##### Animal Tissue

Under the European Communities (Medical Devices) (Tissues of Animal Origin) Regulations 2003 (the “**Tissue Regulations**”), detailed specifications are provided in relation to the risks of transmitting transmissible spongiform encephalopathies (TSE) under normal conditions of use to patients or others, via medical devices manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue. The Tissue Regulations only apply to medical devices which are intended to come into contact with the human body but do not apply if contact is with intact skin only. The animal tissues covered include those originating from bovine, ovine and caprine species, as well as deer, elk, mink and cats.

Before medical devices containing tissues of animal origin can be placed on the market, they must comply with the provisions relating to general medical devices as well as the additional provisions under the Tissue Regulations. The Tissue Regulations require a manufacturer, before lodging an application for conformity to attain a CE marking, to carry out a risk analysis and a risk management scheme in accordance with the Annex to EC Directive 2003/32/EC in conjunction with a notified body. As part of this evaluation, the relevant notified body will take account of the TSE certificate of suitability issued by the European Directorate for the Quality of Medicines. The IMB shall further seek the opinion of the Competent Authorities of other Member States and give due consideration to any comments received.

### **Human Tissue**

With certain exceptions, requirements relating to quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells for human application are regulated under the Quality and Safety of Human Tissues and Cells Regulations, (S.I. 158/2006). These Regulations apply to ‘prescribed activities’, which are defined as any activity consisting of the donation, procurement, testing, processing, preservation, storage or distribution of tissues or cells for human applications. Any individual or site which carries out any prescribed activity is required to be authorised by the IMB.

In order to obtain authorisation, an application must be made to the IMB for a Tissue Establishment Authorisation. Compliance with the requirements of relevant Regulations must be demonstrated by applicants. To ensure that compliance with these requirements are maintained, Blood and Tissue inspectors monitor compliance through regular on-site inspections. In order to make a variation to an authorisation, an application to make a variation to a tissue establishment authorisation must be completed and sent to the IMB. In accordance with this legislation, the IMB has established a reporting system for the notification of suspected Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) associated with human tissues and cells.

- ii. Are there any legal and binding criteria for determination whether the product is a medical device or cellular/tissue based product?

No. See above response at question 3 and 3(i).

- iii. If the answer to (ii) is positive, what are the main principles for differentiation?

Not applicable.

- iv. Are there any significant court or administrative judgments demonstrating the rules of product differentiation?

None that we are aware of in Ireland.

### **5. Admission to trade of medical devices**

What are the requirements for admission (import) of medical devices into trade?

#### **General Medical Devices**

Under Regulation 14(1) of the Medical Devices Regulations, all Irish and EU based manufacturers who place a device onto the Irish market in their own name are obliged to inform the IMB of their registered address, and supply the IMB with a description of the device which is sufficient to identify it. In respect of manufacturers who do not have a registered place of business in the EU, Regulation 14(3) requires the authorized representatives, who have been designated by manufacturers to be their legal representatives in the EU and who have a place of business in Ireland, to inform the IMB of their registered place of business, the type of device and such evidence that the authorised representative has been appointed by the manufacturer to act on his behalf.

Devices carrying the CE mark may be freely marketed anywhere in the European Union<sup>1</sup>, and do not require any further assessment before entering the Irish market.

However, in relation to non-CE marked medical devices, clinical investigations are usually required to gather clinical data that is sufficient to demonstrate conformity to the requirements of the Medical Devices Regulations.

Clinical investigations that are likely to require notification and review by the IMB prior to commencement include:

- (a) New devices – when a novel device is being used in human subjects for the first time where the device components, features and the methods of action are previously unknown;
- (b) Modification of an existing device: if a device is modified significantly such that the safety and/or clinical performance may be affected;
- (c) Device containing untested materials: if a proposed device contains materials which have not previously been tested in contact with human subjects;
- (d) Device materials used in a different location or for a different duration: when existing materials are used and come in contact with new body locations or are used for a significantly longer duration; or
- (e) Device proposed for a new function: where a device is being used for a new function outside of the manufacturer's indications for use/intended purpose.

### **In-Vitro Diagnostic Medical Devices**

Manufacturers of In-Vitro Diagnostic Medical Devices also have registration obligations. Under Regulation 10(1) of the In-Vitro Regulations, all Irish based manufacturers who place a device onto the Irish market in their own name are obliged to inform the IMB of their registered address, and supply the IMB with:

- (i) In the case of devices being reagents, reagent products and calibration control materials, with information relating to the common technological characteristics or analytes thereof, or both, any of any significant change thereto; and
- (ii) In the case of devices to which Annex II of Directive 98/79/EC applies and devices for self-testing, with a description of the device which is sufficient to identify it, including the analytical and where appropriate, diagnostic parameters as referred to in Annex I, Part A of the above Directive, the outcome of

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<sup>1</sup> Where the medical device is to be exported outside of the European Economic Area, it will be necessary to apply to the IMB for a Certificate of Free Sale.



performance evaluation pursuant to Annex VIII, certificates and any significant change thereto.

In respect of manufacturers who do not have a registered place of business in the EU, Regulation 10(4) requires the authorised representative, who has been designated by manufacturers to be their legal representatives in the EU and who have a place of business in Ireland, to inform the IMB of their registered place of business, the matters specified in (a) and (b) above, and such evidence that the authorised representative has been appointed by the manufacturer to act on his behalf.

### **Active Implantable Medical Devices**

Under the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. 253/1994), there are similar registration requirements to those set out under the general medical devices legislation.

- i. Is clinical assessment required for admitting (importing) medical devices into trade?

### **General Medical Devices**

Devices carrying the CE mark may be freely marketed anywhere in the European Union<sup>2</sup>. and do not require any further assessment before entering the Irish market. Clinical assessments are usually required before non-CE marked medical devices may enter the Irish market. When such clinical investigations are to be carried out in Ireland, an application to the IMB is required. Typically applications are submitted by commercial sponsors e.g. medical device manufacturers. By this application, the manufacturer is proposing to conduct an investigation to gather the necessary clinical data to demonstrate the basic safety and performance of their device. The IMB encourages pre-submission meetings with potential sponsors of clinical investigations.

Applications to conduct clinical investigations are reviewed by Human Products Authorisation & Registration Department of the IMB prior to the investigation starting. The IMB reviews the regulatory, technical and clinical aspects of the application. Documentation typically reviewed by the IMB includes: the device risk analysis; design documentation; materials documentation; cytotoxicity/biocompatibility data; sterilization; pre-clinical data; existing clinical data and the clinical investigations protocol; patient information sheets/consent forms and the investigator's brochure etc.

The IMB aims to provide an initial response on the application by day 30 of the 60 days allowed. By day 60 of the review process the final opinion of the review panel is referred to the Management Committee of the IMB for decision.

Clinical investigation applications will receive a unique identification number, CIV ID, (if not previously assigned) for the purposes of notification to the EUDAMED database.

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<sup>2</sup> Where the medical device is to be exported outside of the European Economic Area, it will be necessary to apply to the IMB for a Certificate of Free Sale.

The IMB reviews applications to conduct clinical investigations in Ireland in parallel with the appropriate Ethics Committee review.

If the IMB review has a satisfactory outcome, the sponsor will be issued with a “Letter of no objection”. In order for any clinical investigation to commence in Ireland, both the IMB and the Ethics Committee must have issued a final positive opinion. The final opinion of the Ethics Committee must be submitted to the IMB prior to commencement of the investigation.

Some clinical investigations, such as those using CE marked devices within their intended purpose, may not require review. The IMB is happy to discuss what type of device investigations require notification and review by the IMB with individuals intending to conduct clinical investigations involving devices.

- ii. If the answer to (i) is positive, are clinical trials required or is there an alternative basis for clinical assessment?

See above.

- iii. Is certification by an external certifying body required for compliance assessment of medical devices, or is a manufacturer’s declaration of conformity sufficient?

This depends on the level of risk of the medical device in question and is dealt with in detail below at question 9.

- iv. Is administrative pre-clearance or pre-approval of medical devices required for admission of medical devices into trade, or is post-launch notification sufficient?

Certain pre-launch requirements must be satisfied. All medical devices must be CE-marked, with the exception of those being used as part of a clinical investigation. There is also a requirement to notify the IMB of a manufacturer’s registered address as set out at question 5 above, and this notification usually occurs pre-launch.

## **6. Processing of personal data (privacy)**

What are the rules of processing of personal data in a number of activities performed by manufacturer/s distributors/ healthcare units with the use of medical devices.

There are no specific provisions under Medical Devices Legislation relating to the processing of personal data by manufacturers/distributors/healthcare units. Accordingly, the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003, which implement Data Protection Directive 95/46/EC, apply. Such data would be classified as sensitive personal data under the Data Protection legislation, in that it relates to the medical history of a patient, and so requires additional precautions in that any transfer of this data would require the explicit informed consent or the anonymisation of patient records.

Guidelines have been issued by the Data Commissioner in Ireland which provide a comprehensive overview of the data protection considerations which need to be taken account of in advance of undertaking medical research which involves the use of personal data. Anonymisation of patient records and/or freely given and informed patient consent are

the basis for how the Data Commissioner wishes to see medical research undertaken from a privacy perspective. The guidelines unfortunately make no reference to the separate ethical obligations regarding confidentiality which need to also be considered when undertaking research in this area.

Furthermore, the Freedom of Information Acts 1997 and 2003 apply to information held by the IMB. This legislation provides that any person is entitled to apply to certain bodies for access to information not otherwise publicly available. Each person has a right to: (i) access records held by the IMB; (ii) correct personal information relating to oneself held by the IMB where it is inaccurate, incomplete or misleading; and (iii) access reasons for decisions made by the IMB directly affecting oneself. There are a number of exemptions under the Acts to protect sensitive information where its disclosure may damage key interests of the State or third parties. Where the IMB invokes these provisions, the decision may be appealed. Under the Medical Devices Department of the IMB, the records held include:

- (a) files relating to adverse incident reports and investigations;
  - (b) records of applications for determination of medical devices status;
  - (c) CEN standards relating to medical devices and diagnostics;
  - (d) National and EU legislation and guidelines;
  - (e) Reports from internal meetings;
  - (f) Documentation from external meetings; and
  - (g) Policies, guidelines, standard operating procedures, work instructions and forms.
- i. Are there any specific rules protecting the privacy of personal data of consumers purchasing medical devices, by manufacturer/distributors?
- No, other than the usual sensitive personal data protection rules set out above.
- ii. Are there any specific rules of processing of personal data sourced by means of medical devices containing software, by healthcare units?
- No, other than the usual sensitive personal data protection rules set out above.
- iii. Are there any specific rules of processing of personal data by manufacturers/distributors in case of collecting reports on medical incidents from customers?
- No, other than the usual sensitive personal data protection rules set out above.
- iv. What is the standard for reporting adverse events, and is reporting of events in foreign countries required, and using what standards?

Ireland follows the reporting criteria of the Medical Devices Directive that are further substantiated in MEDDEV 2.12/1 rev. 5.

## 7. Reimbursement

What is the optimal model of reimbursement of medical devices?

- i. What are the rules of granting reimbursement of medical devices in your jurisdiction?

Reimbursement of medical devices is conducted through the "Aids and Applicances" Scheme operated by the Health Services Executive. Increasingly health technology assessments are playing a role, with the Health Information Quality Authority (the body with responsibility for conducting HTAs in Ireland) producing two sets of guidelines in 2010, the "Guidelines for Budget Impact Analysis of Health Technologies in Ireland" and "Guidelines for the Economic Evaluation of Health Technology in Ireland".

## 8. Distribution

Is distribution and promotion of medical devices subject to legal regulation?

Not currently.

- i. Are there any specific regulations determining mode of business activity of medical devices distributors?

No.

- ii. Is administrative permit for medical devices distribution required?

No.

- iii. Are there any specific limitations in distributing medical devices in your jurisdiction?

No.

- iv. Are obligations of distributors of medical devices specifically legally regulated?

No.

- v. What specific rules exist for advertising and promoting medical devices?

The Medical Devices Legislation does not specifically regulate the advertising of medical devices.

On the 27 June 2011, a new Irish Code of Ethics will be launched by the Minister for Health and Children in Ireland, which will be binding on all Irish Medical Devices Association ("IMDA") and Irish Medical and Surgical Trade Association ("IMSTA") members. This code is not underpinned by legislation.

The Code has been developed by the IMDA and the IMSTA and is largely based on that of Eucomed, the European medical technology industry association. It is hoped that this Code will play an important role in governing interactions between medical technology companies and healthcare professionals, and embed ethical behaviour into routine

professional collaborations. Following registration, letters of commitment will be sent to IMDA and IMSTA members. Signed commitments to the Code of Ethics will be on a voluntary basis for the first 18 months.

## 9. Manufacturing

How are manufacturing practices regulated?

### General Medical Devices

The manufacturing of general medical devices is regulated by S.I. 252/1994, transposing European Directive 93/42/EEC, which sets out 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. It is the classification of a device which determines the applicable route for establishing conformity with Medical Devices Legislation, for the required CE mark to be affixed to the device.

The manufacturer confirms the classification with a notified body of their choice, which in turn is responsible for ensuring that the conformity assessment procedures are followed by the manufacturer. The only notified body in Ireland is the National Standards Association of Ireland (“NSAI”). Their role is to ensure that the device conforms with the essential requirements and to established standards in design and production. Should the manufacturer and the notified body be unable to come to an agreement, the matter must be referred to the IMB.

First of all, the manufacturer should determine if their product falls within the scope of Medical Devices Legislation – for this it should have a medical purpose and its primary mode of action will typically be physical.

General medical devices and related accessories must then be classified into one or four classes, which are based on the perceived risk of the device to the patient or user. The level of regulatory control applied to medical devices is proportionate to the degree of risk associated with the device.

The rules governing device classification are listed in Schedule 9 of S.I. 252/1994. For general medical devices, the categories are as follows:

Class	Type	Conformity Assessment <sup>3</sup>
I	Low risk	Manufacturer
IIa	Medium risk	The Notified Body at Production
IIb	Higher risk	The Notified Body at Design and Production
III	Highest risk	The Notified Body at Design, Production and Verification of Design dossier

<sup>3</sup> The Conformity Assessment relates to conformity with the requirements of the Regulations (and in particular the Essential Requirements) and the affixing of the CE Mark.

There are a further 18 rules outlined in Schedule 9 of S.I. 252/1994 which lay down the basic principles of classification. These rules are subdivided into four categories: (i) Rules 1-4 (non-invasive devices); (ii) Rules 5-8 (invasive devices); (iii) Rules 9-12 (active devices); and (iv) Rules 13-18 (special rules – devices containing tissue of animal origin, drug-device combinations).

IMB guidelines also set out a number of key characteristics that must be considered to correctly classify a device using the 4 classification categories, which are: (i) Duration of contact with the patient – transient, short term or long term; (ii) Degree of invasiveness; (iii) Whether or not the device is active; and (iv) Part of the body affected.

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. If several rules are applicable then the rule which results in the highest class applies.

### **In-Vitro Diagnostic Medical Devices**

The manufacturing of in-vitro diagnostic medical devices is regulated under S.I. 304/2001. Additional requirements must be satisfied however, over and above the essential requirements that all general medical devices must conform to, before in-vitro medical devices can obtain a CE marking. These requirements are set out below and depend on whether the device is classified under List A or List B in Annex II of the Directive 98/79/EC.

### **Active Implantable Medical Devices**

The manufacturing of active implantable medical devices is regulated under S.I. 253/1994 (as amended by S.I. 109/2009). There is no classification as such and the required conformity assessment procedure is set out below.

- i. Are there any specific standards or regulations determining the quality of manufacturing practices?

### **General Medical Devices**

A conformity assessment procedure must be carried out to confirm that the design and/or production ensures compliance with Medical Devices Legislation. Depending on the classification of the device, this assessment will be carried out by the manufacturer (Class I) or the relevant notified body (e.g. NSAI). It is only after such conformity is confirmed that approval to affix the CE marking will be issued. As noted above, every device placed on the market in Ireland must bear the CE mark in a visible and legible form, subject to certain exceptions.

A device falling within Class I may bear the CE marking only if its manufacturer follows the EU Declaration of Conformity procedure set out in Schedule 7 of the Regulations. As for affixing CE marking to devices falling within Class IIa, IIb or III, the manufacturer additionally has to comply with the procedure set out under Schedules 2, 4, 5 or 6 of the Regulations. Class I devices placed on the market in a sterile condition and/or with a measuring function must be accompanied by the identification number of the relevant

notified body having regard to the additional requirements under Schedules 2,4,5, or 6 of the Regulations.

The following is an overview of the essential requirements as per the Regulation 5 and Schedule 1 of the Regulations:

- (a) The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety;
- (b) The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety;
- (c) The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. ;
- (d) The devices must achieve the performances intended by the manufacturer;
- (e) The characteristics and performances referred to above must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
- (f) The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.
- (g) Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

Further requirements as to design and construction are set out under Schedule 1, with particular attention to be paid to: (i) the choice of materials used; (ii) the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device; and (iii) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of potential users as set out in detail in Schedule 1 S.I. 252/1994 (as amended). The Regulations also list the particulars which must be contained in the instructions for use, which are also set out in Schedule 1 S.I. 252/1994 (as amended).

### **In-Vitro Diagnostic Medical Devices**

All devices in this category must comply with the same essential requirements set out above, with account being taken of the device's intended purpose. However, for devices specified in List A or B of Annex II of the Directive 98/79/EC, a device shall be treated as complying with the relevant essential requirements if it is designed and manufactured in conformity with the common technical specifications drawn up for the device, unless there are reasonable indications that the device does not comply with those requirements. Furthermore, a device to which the above relates shall be treated as having been manufactured in accordance with the common technical specifications if, for justifiable reasons, it is not so manufactured but manufactured in accordance with technical specifications that are at least equivalent to such common technical specifications, unless there are reasonable indications otherwise.

The conformity procedures are as set out in Annex III of Directive 98/79/EC. However, for devices involving self-testing, CE marking shall only be granted by the notified body if additional conformity procedures are followed, which depend on whether the device is specified in List A or B of Annex II of the Directive 98/79/EC. Devices for performance evaluation shall follow the procedures specified in Annex VIII.

### **Active Implantable Medical Devices**

All medical devices falling under this category must also comply with the essential requirements for general medical devices, set out above. Additional requirements relating to the design and construction of these devices are set out in Schedule I of S.I. 253/1994, and correspond to Annex I of Directive 90/385/EEC. These provide that implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure that they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted. Devices must also bear a code by which they and their manufacturer can be unequivocally identified and it must be possible to read the code without the need for a surgical operation. Each device must bear, legibly, a number of particulars on the sterile pack and on the sales packaging, as detailed in Schedule I of S.I. 253/1994.

In determining whether a device complies with the requirements under the Directive, a decision shall be based in particular on clinical data. A device shall be treated as complying with an essential requirement if it conforms with a relevant national standard,





unless there are reasonable indications that the device does not comply with such requirements.

The CE marking granted after such an assessment must be affixed in a visible and legible form on the sterile pack, any sales packaging and on the instruction sheet, and the mark shall in each case be accompanied by the relevant notified body identification number for that device.

- ii. If the answer to (i) is positive, how are these good manufacturing practices or quality system regulations reviewed and enforced?

### **General Medical Devices**

The conformity assessment procedure set out above is conducted by the relevant notified body (e.g. NSAI), whose role it is to ensure that the device conforms with the essential requirements and to established standards in design and production. Should the manufacturer and the Notified Body be unable to come to an agreement, the matter must be referred to the IMB, in its role as the Competent Authority for medical devices under the relevant legislation.

A CE marking will only be issued by the notified body, and the device will subsequently only be placed on the market, if the device conforms with requirements set out under the Medical Devices Legislation. Regulation 6 of the Regulation states that the CE marking must be in a visible, legible and indelible form on the device or its sterile pack, the instructions for use as well as any sales packaging.

Furthermore, manufacturers are obliged to ensure that they keep good records of the manufacturing of the medical device and Schedule 7 of the Regulations oblige the manufacturer to activate a vigilance system to notify the competent authorities should one of the following incidents occur:

- (a) Any malfunction or deterioration in the circumstances and/or performance of a device which might lead to or might have led to the death of a patient or to a serious deterioration in his health; or
- (b) Any technical or medical reason connected with the characteristics on the performance of a device for the reasons referred to in subparagraph (a) leading to systematic recall of devices of the same type by the manufacturer.

It is prohibited under the Regulations to place on the market or put into service a device which does not comply with the relevant essential requirements or which does not bear the CE marking. If an authorised officer appointed by the IMB has reasonable grounds for suspecting that an offence under these Regulations has been committed on any premises, he may seek a search warrant from the District Court to search said premises. Any person or body corporate found guilty of an offence under these Regulations shall be liable on summary conviction to imprisonment for up to 6 months and/or a fine up to £1,000 (now €1269.74). When an offence is committed by a body corporate with the consent, connivance or by the negligence of any person who is a director, manager,

secretary or other officer of that body corporate, such person may also be personally liable.

### **In-Vitro Diagnostic Medical Devices**

Such devices may not be placed on the market without a CE marking in a visible, legible and indelible form. CE markings for In-Vitro Diagnostic medical devices must also be accompanied by the identification number of the notified body responsible for implementation of the conformity assessment procedures relating to the device as set out in Annex III, IV, VI and VII of Directive 98/79/EC.

Penalties and liability under these Regulations are on the same terms as those set out above in relation to general medical devices.

### **Active Implantable Medical Devices**

Similarly, such devices may not be placed on the market without a CE marking in a visible, legible and indelible form and such mark shall, in each case, be accompanied by the relevant notified body identification number responsible for the conformity assessment procedure. The CE marking will only be affixed if the manufacturer follows the EC declaration of conformity procedure applicable to general medical devices, or alternatively follows the EC type-examination procedure together with (i) the EC verification procedure or (ii) the EC declaration of conformity to type procedure. Both of these procedures are set out in Regulation 6 of S.I. 253/1994.

Manufacturers are obliged to keep available for inspection any documentation required under the relevant conformity assessment procedures. Penalties and liability are on the same terms as those set out above in relation to general medical devices.

- iii. Are establishments manufacturing medical devices, or components of medical devices, required to be registered with a government regulator?

### **General Medical Devices**

Under Regulation 14(1) of S.I. 252/1994, Irish based manufacturers who place a device onto the Irish market in their own name are obliged to inform the IMB of their registered address, and supply the IMB with a description of the device which is sufficient to identify it. In respect of manufacturers who do not have a registered place of business in the EU, Regulation 14(3) requires the authorized representatives, who have been designated by manufacturers to be their legal representatives in the EU and who have a place of business in Ireland, to inform the IMB of their registered place of business, the type of device and such evidence that the authorised representative has been appointed by the manufacturer to act on his behalf.

### **In-Vitro Diagnostic Medical Devices**

Manufacturers of In-Vitro Diagnostic Medical Devices also have registration obligations. Under Regulation 10(1) of S.I. 304/2001, all Irish based manufacturers who place a

device onto the Irish market in their own name are obliged to inform the IMB of their registered address, and supply the IMB with:

- (a) In the case of devices being reagents, reagent products and calibration control materials, with information relating to the common technological characteristics or analytes thereof, or both, any of any significant change thereto; or
- (b) In the case of devices to which Annex II of Directive 98/79/EC applies and devices for self-testing, with a description of the device which is sufficient to identify it, including the analytical and where appropriate, diagnostic parameters as referred to in Annex I, Part A of the above Directive, the outcome of performance evaluation pursuant to Annex VIII, certificates and any significant change thereto.

In respect of manufacturers who do not have a registered place of business in the EU, Regulation 10(4) requires the authorised representative, who has been designated by manufacturers to be their legal representatives in the EU and who have a place of business in Ireland, to inform the IMB of their registered place of business, the matters specified in (a) and (b) above, and such evidence that the authorised representative has been appointed by the manufacturer to act on his behalf.

#### **Active Implantable Medical Devices**

Under S.I. 253/1994 there are similar registration requirements to those set out under the general medical devices legislation

- iv. Are these establishments inspected regularly by government regulators or authorized bodies, and what is the mode of such inspections?

As the Competent Authority for medical devices in Ireland, the IMB may conduct post-marketing surveillance in relation to medical devices manufactured by Irish based manufacturers and those placed on the Irish market. This post-market surveillance forms part of the review by the IMB of manufacturers' compliance with the Directive and the Regulations.

The Compliance Department of the IMB carries out audits of medical device manufacturers on a regular basis. The type of audits that are conducted are as follows:

- (a) Proactive post-market surveillance audits;
- (b) 'For cause' post-market surveillance audits;
- (c) Custom-made medical device audits; and
- (d) Other audits pertaining to the register of medical devices.

The aim of these audits is to ensure that medical device manufacturers are operating in compliance with the Medical Device Legislation. The notice period given will depend on whether the audit is proactive (where notice period is usually about four weeks) or



reactive (for example where the audit arises from a public health issue, a request to go onsite immediately may be made by the IMB). Another key area in which the audit team is involved in is the surveillance of the medical device market to identify issues and trends in order to highlight priority areas for the medical devices market.

The IMB also monitors notified body activity in Ireland.

## 10. Regulatory Guidance

How are the requirements communicated to medical device manufacturers?

The requirements are communicated to medical device manufacturers largely by way of IMB guidelines and relevant guidance from industry organisations, including the IMDA and the IMSTA.

- i. In what form do the laws and regulations appear that are applicable to medical device manufacturers?

The laws and regulations that are applicable to medical device manufacturers appear in the form of national statutory instruments and regulations, which transpose the relevant EU legislation.

- ii. Are informal guidance or the opinions of regulators available to device makers, and in what form?

The Irish Medicines Board regularly produce guidance, which is influenced by MEDDEV guidance at an EU level. These guidelines are available at [www.imb.ie](http://www.imb.ie).