

Guide to Placing System and Procedure Packs on the Market



CONTENTS

1	SCOPE	3
2	INTRODUCTION	3
3	BACKGROUND	3
4	DEFINITIONS	4
4.1	Medical device	4
4.2	Manufacturer	5
4.3	Placing on the market of a medical device	5
4.4	Putting into service of a medical device	5
5	CE MARKING OF SYSTEM AND PROCEDURE PACKS AND OBLIGATIONS OF MANUFACTURERS AND ASSEMBLERS	5
5.1	System and procedure packs containing medical devices that all individually bear a CE mark	6
5.2	System and procedure packs containing medical devices that do not all individually bear a valid CE mark and treated as a device in its own right	9
6	TRACEABILITY	10
7	SYSTEM AND PROCEDURE PACKS THAT REQUIRE STERILISATION	10
8	WHO TO CONTACT AT THE HPRA	11

1 SCOPE

This document applies to system and procedure packs containing products that fall within the definition of a medical device under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and related amendments hereafter referred to as MDD that was transposed into Irish law by:

S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994 that became mandatory on 14 June 1998 (amended by S.I. No. 444 of 2001, S.I. No. 576 of 2002 and S.I. No. 110 of 2009) which will hereafter be called the 'Regulations'.

Active implantable, *in-vitro* diagnostic medical devices, and medicinal products are outside the scope of this document. Further information on how to deal with these products in this context may be obtained on the Health Products Regulatory Authority (HPRA) website at www.hpra.ie.

2 INTRODUCTION

The practice of assembling system and procedure packs brings the assembler within the remit of the Regulations. There are specific obligations placed on persons assembling system or procedure packs under the aforementioned Regulations, including the obligations to register with the HPRA and draw up specific declarations and documentation.

The purpose of this document is to provide guidance to enable persons placing medical device system or procedure packs on the market to meet the requirements of the Regulations.

3 BACKGROUND

Medical devices are often assembled and packaged together in order to place them on the market for use in a particular medical procedure, and the assembled configuration is referred to in the Regulations as a 'system or procedure pack'. For the purposes of clarity within this guidance document the medical devices assembled within a system or procedure pack will be referred to as 'component devices'.

'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose or specific procedures. The components of the procedure pack may not necessarily be used in combination or at the

same time. Some examples of procedure packs include first aid kits¹, surgical packs for specific procedures, theatre dressing packs, orthodontic procedure packs and skin traction kits.

'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose. These component devices are intended to be used together as a unit. Some examples of systems include joint replacement systems, orthopaedic drill systems, prosthetic systems and orthotic systems.

How a system or procedure pack is assembled and placed on the market can impact the role and obligations of the assembler. For example, assemblers may place a procedure pack on the market under their own name even though they do not manufacture any of the component devices themselves. A system or procedure pack may contain one or more component devices that do not bear their own CE mark or that may be intended by the assembler for a use other than that intended by the original manufacturer. In accordance with the Regulations these variations in how system or procedure packs are assembled can alter the conformity assessment route. It is therefore essential that all assemblers of system or procedure packs understand the requirements that apply to their specific product and their obligations under the Regulations.

This guide is not a definitive interpretation of the Regulations but aims to provide guidance to assemblers and manufacturers of system and procedure packs in understanding the Regulations.

4 DEFINITIONS

4.1 Medical device

A 'medical device' is 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:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

¹ Manufacturers of first aid kits must consider S.I. No. 44 of 1993, Safety, Health and Welfare at Work (General Application) Regulations, 1993.

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

4.2 Manufacturer

A 'manufacturer' of a medical device means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.

According to the Regulations², 'any obligation of a manufacturer under these Regulations shall extend to a person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.'

4.3 Placing on the market of a medical device

'Placing on the market' means the first making available, whether in return for payment or free of charge, of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, in the Community.

4.4 Putting into service of a medical device

'Putting into service' means, in relation to a device, making it available to the ultimate user for use in the State for the first time for its intended purpose.

5 CE MARKING OF SYSTEM AND PROCEDURE PACKS AND OBLIGATIONS OF MANUFACTURERS AND ASSEMBLERS

All medical devices when placed on the market must bear a CE mark, with the exception of devices that meet the definition of a custom-made device or those devices intended for clinical investigation. The CE mark may be affixed once a manufacturer has followed an appropriate conformity assessment procedure and demonstrated that the device complies with the requirements of the Regulations.

For system or procedures packs, the conformity assessment procedure that must be followed depends on how they have been assembled and configured. The Regulations³ identify two

² Regulation 13(1) of 252 of 1994

³ Regulation 11 of 252 of 1994

distinct scenarios which are described in the following sections along with the resulting obligations of the assembler or manufacturer.

5.1 System and procedure packs containing medical devices that all individually bear a CE mark

In this scenario the system or procedure pack solely consist of individual component devices each of which is CE marked and is to be used within its intended purpose and within the limits of use specified by their manufacturer⁴.

The person who puts the component devices into the system or procedure pack is referred to as the 'assembler'. It is important to note however that any obligation of a manufacturer under the Regulations extends to the assembler of a system and procedure pack who places it on the market under his own name⁵.

For these types of system and procedure packs, the following is an overview of the obligations that must be followed prior to placing on the market:

5.1.1 Declaration for system and procedure packs

The assembler shall⁶ draw up a declaration that:

- a) they have verified the mutual compatibility of the medical devices in accordance with the manufacturers' instructions and they have carried out their operations in accordance with these instructions. This is to ensure that the devices remain safe and effective in use e.g. the devices work well or fit well together and still work as intended as a whole/ in combination.
- b) they have included relevant information to users and relevant instructions from the component manufacturers within the packaging of the system or procedure pack, and
- c) that their assembly operations are subjected to appropriate methods of internal control and inspection.

The declaration shall be kept readily available for inspection, by the HPRA or by the assembler's chosen notified body, for a period of five years.

⁴ With the exception of Class I non-sterile or non-measuring medical devices, the CE marking shall in each case be accompanied by the identification number of the relevant Notified Body for that device.

⁵ Regulation 13 (1) of 252 of 1994

⁶ Regulation 11 of 252 of 1994

5.1.2 Information to be supplied with the system and procedure pack

In addition to the information referenced in 5.1.1 (b) above, the HPRA expects the following regarding the labelling and instructions for use for system and procedure packs:

5.1.2.1 Labelling information

The HPRA expects that the outer label of the system or procedure pack should contain the following information:

- A list of the medical device components/contents.
- If applicable, an expiry date based on the shortest dated component
- A specific lot number for the system or procedure pack to allow for traceability.

The devices and detachable components must be identifiable, in terms of batches and expiry dates, should any action relating to a potential risk be required.

The outer packaging of the system or procedure pack should not bear an additional CE marking.

5.1.2.2 Additional instructions

For system and procedure packs particular reference should be made to the requirements for instructions for use concerning installing or connecting medical devices together⁷ and additional treatment or handling before a device is used⁸. Where this information is not clear from the IFU of the individual devices, appropriate instructions must be drawn up and provided with the system and procedure pack. For devices within a pack that are reusable, instructions from the manufacturer on how to reprocess the device must be provided.

5.1.3 Registration

Any person who assembles a system or procedure pack and then places it on the market must register⁹ with the HPRA by:

- a) informing the HPRA of his place of business in the Republic of Ireland, and
- b) supplying the HPRA with descriptions of the system or procedure pack which are sufficient to identify it and the component devices contained within.

Registration with the HPRA should be completed on-line. Further details on how to register can be found in the HPRA 'Guide to the registration of persons responsible for placing

⁷ Schedule 1, 13.6(c) of 252 of 1994

⁸ Schedule 1, 13.6(i) of 252 of 1994

⁹ Regulation 14 of S.I. 252 of 1994

devices on the market in accordance with Directive 93/42/EEC and S.I. No. 252 of 1994', which may be downloaded from the 'Publications and Forms' section of the HPRA website www.hpra.ie.

5.1.4 Post market surveillance and vigilance

The HPRA expects assemblers to have in place an appropriate and robust quality system to ensure the post market surveillance (PMS) obligations, including vigilance reporting, of all manufacturers whose devices are included in their system and procedure pack can be fulfilled. This system should ensure effective communication of safety reports and other post-market information between assemblers and the component device manufactures (CDM) and to identify the activities and responsibilities for the assembler and each of the manufacturers for the following key issues:

- Vigilance and complaint reporting
- Incident investigations
- Field safety corrective action (FSCA) implementation

In relation to PMS the assembler of a system or procedure pack should consider their own declaration regarding mutual compatibility (section 5.1.1 above) and also the PMS and vigilance obligations of the CDM.

Regarding the declaration of mutual compatibility, it is expected that the assembler has a system to review experience gained from the use of his product. For example, this would include procedures for conducting investigations to determine whether a reported incident occurred as a result of a compatibility issue between the component devices or whether it was as a result of an issue with the individual CE marked device. Without having such a mechanism in place the assembler might not be aware of issues which could affect the validity of his declaration.

Regarding the PMS obligations of the CDM, the assembler of the system or procedure pack should immediately notify the CDM of any incident involving their device. This is essential to ensure the CDM meets their obligations for vigilance reporting.

Similarly, if an assembler is informed of a FSCA relating to a device contained within his system or procedure pack they must ensure that the necessary actions are carried out effectively and efficiently for all of their products containing the affected devices, including the component devices in a system or procedure pack. This may require issuing his own customer communication to ensure all affected users are aware of the CDM's FSCA.

5.2 System and procedure packs containing medical devices that do not all individually bear a valid CE mark and treated as a device in its own right

A system or procedure pack consisting of medical devices will be treated as a device in its own right and will be subjected to the relevant conformity assessment procedure where:

- a) it incorporates any device which does not bear a CE marking; or
- b) the chosen combination of devices is intended to be put to a different use to that intended by the original manufacturer for each individual device, as this would invalidate one or more of the original CE marks.
- c) one of the CE marked medical devices is assembled in the system and procedure pack in such a way that the CE mark of that device is no longer valid e.g. labelling and instructions for use requirements¹⁰ for the device is no longer satisfied.

For these types of system and procedure packs, the manufacturer (in this case the assembler) must follow the appropriate conformity assessment route based on the medical device component with the highest medical device classification within the system or procedure pack. The manufacturer must also ensure the Essential Requirements and all other requirements of the Regulations applicable to that medical device classification are satisfied e.g. registration requirements for class I medical devices. The following sections include HPRA guidance that should be considered.

5.2.1 Information to be supplied with the system and procedure pack

Where a system or procedure pack is treated as a device in its own right, the HPRA expects that the recommendations in section 5.1.2 should also be considered for all system and procedure packs in addition the information provided must comply with the Essential Requirements.

5.2.2 Post market surveillance

Manufacturers must put in place and keep updated a procedure to review experience gained from the system or procedure pack on the market and to implement necessary corrective actions, taking account of the nature and risks in relation to the product. Manufacturers should refer to the HPRA Guide to Vigilance System for Medical Devices at www.hpra.ie for further guidance.

When investigating a reported incident or complaint to determine whether a field safety corrective action (FSCA) is required for his product the manufacturer should consider each component device. For example, if it is determined that a component device involved in an incident was used as intended by the CDM and is suspected to be a contributory cause of the

¹⁰ Schedule 1, 13 of S.I. 252 of 1994

incident they should notify the CDM of the incident. This will allow the CDM investigate whether an FSCA is also required for their own device which may also be on the market on its own or as part of a different system or procedure pack.

In order to ensure this, the HPRA expects manufacturers of system or procedure packs to have in place an appropriate and robust quality system to ensure the post market surveillance obligations of all manufacturers whose devices are included in their system and procedure pack can be fulfilled per section 5.1.4.

6 TRACEABILITY

Accurate and accessible records are a key factor in effective medical device management and are required by the medical devices legislation. Any manufacturer or assembler of a system or procedure pack as described in section 5.1 and 5.2 above are expected to keep good records of the manufacturing of the system or procedure pack and have the ability to trace the system or procedure pack if a recall or other activity is necessary. Clear records should be kept from the outset, enabling the manufacturer to trace the individual medical devices within the system or procedure pack and the particular batches of the system or procedure packs throughout their lifetime. Assemblers need to consider unique device identification implications (UDI) for their system or procedure pack and the component devices.

7 SYSTEM AND PROCEDURE PACKS THAT REQUIRE STERILISATION

In certain cases a system or procedure pack may require to be sterilised prior to being used in a sterile environment. Article 12(3) of the Regulation states that 'any natural or legal person who sterilises, for the purpose of placing on the market, system or procedure packs or other CE-marked medical devices designed by their manufacturers to be sterilised before use, shall, at their choice, follow one of the procedures referred to in Annex II or V. The application of the abovementioned Annexes and the intervention of the Notified Body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions.'

The outer packaging of the system or procedure pack must bear the appropriate symbols and a CE mark indicating that a Notified Body has assessed it in relation to sterilisation. The steriliser must also make a written declaration that they have conducted the sterilisation in accordance with the manufacturer's instructions and must also register with the HPRA per the registration procedure referred to in section 5.1.3.

8 WHO TO CONTACT AT THE HPRA

This guide and associated documents can be found under the 'Publications and Forms' section of www.hpra.ie. Alternatively, they can be obtained from the HPRA directly as follows:

Telephone: +353-1-6764971

Fax: +353-1-6767836

E-mail: devices@hpra.ie