

# Guide To Placing Medical Device Standalone Software on the Market

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## 1 SCOPE

This document applies to standalone software that falls within the definition of a medical device under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and related amendments 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 S.I. No. 252 of 1994.*

This document also applies to standalone software that qualifies as an *in vitro* diagnostic medical device (IVD) or as an accessory to an IVD in accordance with the Council Directive 98/79/EEC concerning IVD and related amendments that was transposed into Irish law by:

*S.I. No. 304 of 2001 European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001 that became mandatory on 14 June 1998 (amended by S.I. No. 576 of 2002 and S.I. No. 207 of 2012), which will hereafter be called S.I. 304 of 2001.*

This document also applies to standalone software that qualifies as an active implantable medical device (AIMD) in accordance with the Council Directive 90/385/EEC concerning active implantable medical devices and related amendments that was transposed into Irish law by:

*S.I. No. 254 of 1994 European Communities (Active Implantable Medical Devices) Regulations, 1994 that became mandatory on 14 June 1998 (amended by S.I. No 110 of 2009), which will hereafter be called S.I. No. 253 of 1994.*

In this guide, the term 'Regulations' is a reference to S.I. No. 252 of 1994, S.I. No. 304 of 2001 and S.I. No 253 of 1994.

Software incorporated into a medical device is outside the scope of this document.

## 2 INTRODUCTION

Standalone software plays an important role in the delivery of healthcare within healthcare institutions. For example, it may be used to control or monitor the performance of medical devices remotely, for patient management activities, or as an aid for treatment planning.

Standalone software, along with any associated mobile technology, is an integral part of eHealth, the integration of information and communication technology with delivery of healthcare. Advances in mobile technology in recent years, such as smart phones and tablets, have seen a large increase in the use of standalone software both within healthcare facilities and in patients' homes. Mobile devices allow users quick and easy access to the functionality provided by different 'mobile applications' (apps).

Standalone software may be considered a medical device in its own right when it is intended for a medical purpose that meets the definition of a medical device, as defined in S.I. No. 252 of 1994 and elaborated in section 4 of this document. Depending on the specific intended purpose, standalone software may qualify as an IVD medical device or an AIMD, in which case S.I. No. 304 of 2001 or S.I. No 253 of 1994 apply respectively.

Not all standalone software used in the healthcare sector are medical devices. For example, apps for general health and wellbeing that record lifestyle habits such as smoking and exercise are generally not considered as medical devices. It is essential that manufacturers of standalone software understand whether their product is a medical device or not.

Only medical devices that are compliant with the relevant legislation can be placed on the Irish and European market. The purpose of this document is to provide a general overview of the regulatory process involved in placing a medical device on the market for manufacturers and to provide additional guidance that is specifically relevant to standalone software.

### **3 DEFINITIONS**

#### **3.1 Medical device**

A 'medical device' is defined in S.I. No. 252 of 1994 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:

- 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,

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.

The definition of a medical device in S.I. No. 253 of 1994 differs slightly from the above definition as referred to in 4.3 below.

#### **3.2 In vitro diagnostic medical device**

'*In vitro* diagnostic medical device' (IVD) means any medical device which is 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:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

### **3.3 Active implantable medical device**

'Active implantable medical device' (AIMD) means any active 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.

The definition of a medical device in S.I. No. 253 of 1994 is such that an accessory to an AIMD (e.g. accessory software) intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for the proper application of the AIMD should be treated as an AIMD. Refer to MEDDEV 2.1/2 for more information. For example, standalone software that is intended to be used as an accessory to an AIMD (e.g. to communicate programming information with an implantable cardiac defibrillator) is treated as an AIMD and the manufacturer must follow the appropriate conformity assessment process (section 4.2) for an AIMD.

### **3.4 Accessory**

S.I. No. 252 of 1994 and S.I. No. 304 of 2001 define an 'accessory' as an article which whilst not being a medical device or an IVD is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device as intended by the manufacturer of the device.

### **3.5 Standalone software**

For the purpose of this guidance, 'standalone software' means software which is not incorporated into a medical device at the time of its placing on the market or its making available.

### **3.6 Medical device standalone software**

The term 'medical device standalone software' is used in this document as a general term that refers to standalone software (defined in section 3.5) that meets the definition of a medical device, IVD or an AIMD without being part of a hardware medical device. 'Without being part of' means software not necessary for a hardware medical device to achieve its intended medical purpose<sup>1</sup>.

### **3.7 Intended purpose**

The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

### **3.8 Manufacturer**

A 'manufacturer' of a medical device, as defined in the legislation, 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 his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

According to Regulation 13(1) of S.I. No. 252 of 1994, '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.'

For the purposes of this guidance, the above definition of a manufacturer may also apply to persons involved in activities such as software design, development, modification, initiation of specifications or requirements for standalone software or the creation of standalone software from 'off the shelf' software components.

### **3.9 Authorised representative**

Any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the European Community instead of the manufacturer with regard to the latter's obligations under the Regulations. Authorised representative is referred to in this document as European Authorised Representative (EAR).

### **3.10 Placing on the market of a medical device**

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<sup>1</sup> [IMDRF Software as a Medical Device \(SaMD\): Key Definitions](#)

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.

### **3.11 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.

### **3.12 Conformity assessment**

The process of demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.

### **3.13 Notified Body**

A certification body with relevant expertise that is responsible for ensuring that the conformity assessment procedures are followed by the manufacturer as well as establishing that devices conform to the relevant essential requirements of the Regulations and also to established standards in design and production.

## **4 GENERAL OVERVIEW OF PROCEDURE FOR AFFIXING A CE MARK**

All medical devices placed on the market, with the exception of devices that are custom-made or intended for clinical investigation, must bear a CE mark. Once a manufacturer has demonstrated that their medical device standalone software complies with the relevant regulations by the applicable regulatory procedure they may affix a CE mark to their product and place it on the Irish and European market.

The HPRA considers medical device standalone software that is offered for sale, or free of charge, for the Irish or any other European markets by online operators to be 'placed on the market' whether the operator is based inside or outside the EU.

The following sections provide an overview of the different steps involved in affixing the CE marking to a medical device, which is illustrated in the flow diagram below. Additional information that the HPRA considers relevant to standalone software is also provided throughout.

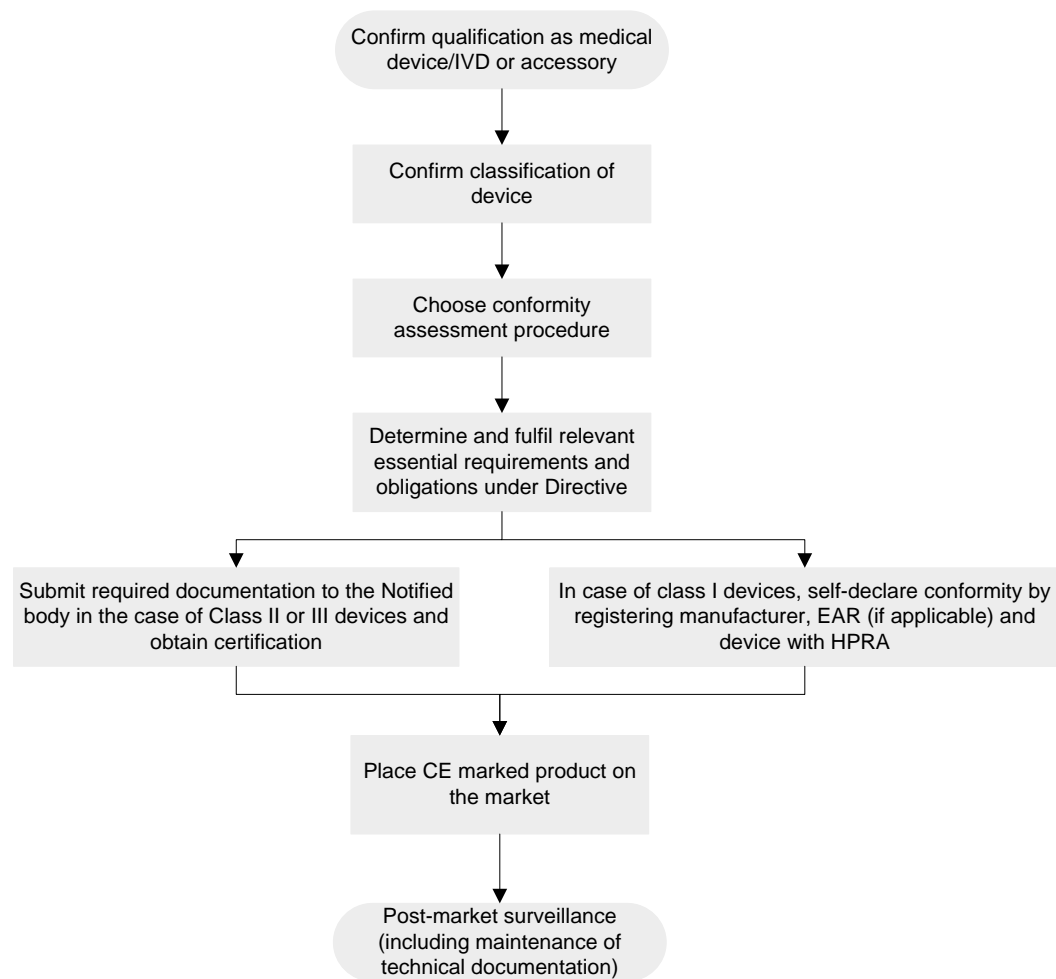


Figure 1: Process for placing medical device standalone software on the market

#### 4.1 Confirm the qualification of the product

A manufacturer must first confirm whether their product meets the definition of a 'medical device'<sup>2</sup>, an '*in vitro* diagnostic medical device'<sup>3</sup> an accessory to either of these or an AIMD<sup>4</sup>. Based on this assessment the manufacturer identifies which of the Regulations, if any, applies to their standalone software.

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<sup>2</sup> Regulation 2 of S.I. No. 252 of 1994

<sup>3</sup> Regulation 2 of S.I. No. 304 of 2001

<sup>4</sup> Regulation 2 of S.I. No. 253 of 1994



'Qualification' as a medical device is based on the intended purpose of the medical device that can be demonstrated and is defined by the manufacturer in the information provided with their product e.g. instructions for use, labelling and marketing material.

It is essential that the manufacturer has clearly defined the intended purpose of the software, taking into consideration all of the functions performed by the software. For example, if the standalone software allows a user to perform a number of different calculations, each calculation must be considered. Similarly standalone software may consist of several modules where only some of the modules have a medical purpose. In such cases, all modules must be considered when qualifying as a medical device and the manufacturer may CE mark those modules that meet the definition of a medical device.

When qualifying their standalone software a manufacturer must consider how the standalone software achieves its intended purpose. For example, consideration should be given as to whether:

- it is performing an action on data other than an action that is limited to storage, archival, lossless compression, communication or simple search,
- it is performing an action for the benefit of an individual patient,
- it is performing an action for a purpose included in the definition of a medical device,
- it is acting as an accessory to a medical device.

The process for qualifying standalone software as a medical device or an accessory is defined in the European Commission guidance document '[MEDDEV 2.1/6 Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices](#)' (at [www.ec.europa.eu](http://www.ec.europa.eu)). The HPRA recommends that manufacturers should refer to this document when qualifying their software.

The European Commission's 'Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices' also includes examples of standalone software qualifying as medical devices that may be useful references for manufacturers.

## **4.2 Confirm the classification**

General medical devices are classified into four categories depending on risk to the patient; Class I (low risk), IIa, IIb, III (highest risk). Schedule 9 of S.I. No. 252 of 1994 defines the set of rules that should be applied to a medical device to determine under which risk category the device falls. The Regulation states that standalone software is considered as an active medical device and as such the classification rules relating to active medical devices apply.

*In-vitro* diagnostic medical devices are classified into four categories based on risk: general IVDs, devices for self-testing, Annex II List B, Annex II List A.

MEDDEV 2.1/6 and the 'Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices' referenced above provide guidance on the classification of standalone software.

In cases where qualification and classification is difficult, please refer to the classification section of the HPRA website at [www.hpra.ie](http://www.hpra.ie).

### **4.3 Conformity assessment procedure**

A conformity assessment procedure is the process followed by a manufacturer in order to demonstrate that the relevant requirements under the Regulations that apply to their medical device have been met.

The risk classification of the medical device standalone software determines the conformity assessment procedure that the manufacturer must follow for their specific product. In selecting which conformity assessment procedure to apply a manufacturer must consider whether a particular conformity assessment procedure is appropriate for standalone software. For example, a conformity assessment procedure that only involves product testing may not be appropriate for standalone software as it may not adequately assess systematic failures that may be present in the software and therefore does not address all safety requirements of the standalone software.

#### **4.3.1 Class I Standalone software**

Medical device standalone software that is classified as Class I may bear the CE mark if the manufacturer follows the EC Declaration of conformity procedure set out in Schedule 7 of S.I. No. 252 of 1994.

This conformity assessment procedure does not require the intervention of a Notified Body.

For guidance on the processes involved in affixing a CE mark to Class I medical devices, refer to the HPRA Guide for Class I Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994.

Manufacturers and EARs of Class I medical devices based in Ireland must register with the HPRA, as per section 5.4 below.

#### **4.3.2 All other standalone software**

For medical device standalone software that does not fall under section 4.3.1, including Class I standalone software with a measuring function, the CE mark may be affixed if the manufacturer follows the conformity assessment procedure appropriate to its classification. These procedures are detailed in Regulations 8, 9, 10 and 11 of S.I. No. 252 of 1994, Regulation 8 of S.I. No. 304

of 2001 and Regulation 6 of S.I. No. 253 of 1994. For each of these procedures the intervention of a Notified Body is required.

For Class I standalone software with a measuring function the intervention of a Notified Body is limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

For IVDs, manufacturers should note specific references to software within the listed devices of Annex II e.g. software is specifically mentioned in List B regarding evaluating the risk of trisomy 21.

#### **4.4 Identifying relevant Essential Requirements**

Medical device standalone software must meet the Essential Requirements detailed in schedule 1 of the Regulations that apply to them, taking account of the intended purpose of the devices concerned. It is the responsibility of the manufacturer to review all of the Essential Requirements outlined in schedule 1 of the Regulations and identify those that are relevant to their standalone software.

The following are examples of Essential Requirements that are of particular relevance to standalone software:

- Essential Requirement 9.1 of S.I. No. 252 of 1994 relates to compatibility of the software, stating '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. Any restrictions on use must be indicated on the label or in the instructions for use'
- Essential Requirement 12.1a of S.I. No. 252 of 1994 relates to software validation stating for 'devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.'

Certain Essential Requirements may not be applicable to standalone software e.g. chemical composition or biocompatibility.

The manufacturer must maintain documentation of the solutions adopted to demonstrate conformity to the Essential Requirements. An Essential Requirements checklist, such as that included in the HPRA Guide for Class I Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994 is a useful means for documenting this information.

## 4.5 Technical documentation

In accordance with the Regulations, the manufacturer or his EAR must hold technical documentation that demonstrates the conformity of their products with the provisions of the Regulations and related directives that apply to them.

The manufacturer, or his EAR, must make technical documentation and the declaration of conformity available to the HPRA for inspection purposes for a period ending at least five years after manufacture of the product. This includes making the documentation available by a manufacturer to his authorised representative.

The information that is to be contained in the technical documentation is defined in the appropriate conformity assessment procedure. The following sections cover some specific considerations for manufacturers with regards to the technical documentation for medical device standalone software.

### 4.5.1 Harmonised standards

Products manufactured according to harmonised standards may benefit from the presumption of conformity to the related essential requirements. Manufacturers may choose whether or not to utilise applicable harmonised standards, but if these have not been applied in full, then this must be justified and additional data will be required detailing the solutions adopted to meet the relevant essential requirements.

Certain harmonised standards cover processes that are relevant to all medical devices while others are more directly relevant to standalone software. A manufacturer must determine which standards are applicable to their device. The following are examples (non-exhaustive) of harmonised standards that should be considered for medical device standalone software:

EN ISO 62304	Medical devices software – software lifecycle processes
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366	Medical devices – Application of usability engineering to medical devices

A list of relevant harmonised standards which have been applied in full or in part of the products should be maintained by the manufacturer. A complete and updated listing of all harmonised standards relevant to medical devices is maintained on the European Commission's website.

### 4.5.2 Software design and maintenance

The manufacturer should take into account the principles of a lifecycle approach to the design and maintenance of their medical device standalone software. The harmonised standard EN

ISO 62304 provides a framework for a life cycle approach for the safe design and maintenance of medical device software, including standalone software.

Key aspects that should be considered within this framework, and documented within the product's technical documentation, include:

- Software design planning to ensure repeatability, reliability and performance according to the intended purpose,
- Software development planning (e.g. verification and validation plan),
- Software requirement analysis (e.g. user, system and software requirements),
- Software implementation and verification,
- Software maintenance (e.g. modification plan),
- Software configuration management (e.g. change control and management),
- Security (refer to section 4.6).

### 4.5.3 Risk management

To ensure that any risks associated with the use of the device are compatible with a high level of protection of health and safety and are acceptable when weighed against the benefits to the patient or user, the manufacturer should have risk management systems for identifying hazards associated with their medical device standalone software, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of that control. While identifying these risks, it is important to bear in mind that the nature of clinical risk associated with medical device standalone software may lead to direct or indirect harm to the patient. Indirect harm that might be caused to the patient due to the level of influence that the standalone software has on the clinical intervention for e.g. misdiagnosis, delays in decision making and others due to design/implementation faults in the standalone software must be adequately addressed. The IMDRF publication "[Software as a Medical Device \(SaMD\)](http://www.imdrf.org)" [Possible Framework for Risk Categorization and Corresponding Considerations](http://www.imdrf.org) (at [www.imdrf.org](http://www.imdrf.org)) provides useful guidance on this topic.

The risk management systems should be based on international or other recognised standards, e.g. EN ISO 14971, and be appropriate to the complexity and risk of the device. Risk management systems may be designed for all elements of device life cycle including design, production and post-production phases.

The risk management processes should be integrated across the entire lifecycle of the standalone software.

### 4.5.4 Clinical evaluation

In accordance with Essential Requirement 6a of Schedule I of S.I. No. 252 of 1994 and S.I. No. 253 of 1994, demonstration of conformity with the essential requirements must include a clinical evaluation. This requirement applies to all medical devices that come under the above

legislation regardless of the risk classification that applies to the device. There is no requirement for clinical evaluation for IVD medical devices under S.I. No. 304 of 2001.

The clinical evaluation must follow a defined and methodologically sound procedure based on:

- 1 either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:
  - there is demonstration of equivalence of the device to the device to which the data relates, and
  - the data adequately demonstrate compliance with the relevant essential requirements,
- 2 or a critical evaluation of the results of all clinical investigations made,
- 3 or a critical evaluation of the combined clinical data provided in 1) and 2) above.

Guidance on performing a clinical evaluation is provided in [MEDDEV 2.7/1 Clinical evaluation: Guide for manufacturers and notified bodies](#). This guidance relates to all medical devices. However, standalone software differs from other medical devices and this should be reflected in the methods applied by the manufacturer in their clinical evaluation. For example, the risks and benefits posed by standalone software are often 'indirect', relating to patient management rather than 'direct' contact between the device and the patient.

#### **4.6 Data protection and cybersecurity**

Standalone software may as part of its functionality collect and store health data relating to a patient. Where this is the case, manufacturers must comply with relevant legislation concerning data protection so as to prevent threats to privacy of users. Data protection and security should be considered by a manufacturer from the design stage of their standalone software.

The Data Protection Acts<sup>5</sup> and the ePrivacy Regulations 2011<sup>6</sup> apply to standalone software, such as mobile apps, that are installed and used by users in Ireland. Manufacturers of standalone software must ensure they comply with the requirements of this legislation where it applies. Further information may be obtained from the Data Protection Commissioner at [www.dataprotection.ie](http://www.dataprotection.ie).

The manufacturer should describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorised access. Security tools such as data encryption and authentication mechanisms should be implemented by manufacturers<sup>7</sup>. A large number of software devices are designed to be networked and are thus vulnerable to cybersecurity threats. Manufacturers must implement appropriate measures

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<sup>5</sup> Data Protection Acts 1988 and 2003

<sup>6</sup> S.I. No. 336 of 2011

<sup>7</sup> European Commission green paper on mobile health

to protect their device against accidental or intentional exploitation of such vulnerabilities. Due to the constantly changing nature of cybersecurity threats, both pre-market and post-market measures will need to be adopted in order to ensure proper device functionality and security. Manufacturers must take cybersecurity measures into account during the development and design phase of the device as well as have detailed cybersecurity risk management procedures and communication protocols for post-market use.

#### **4.7 Instructions for use and labelling**

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users and the information needed to identify the manufacturer<sup>8</sup>. This information comprises the label and the data in the instructions for use (IFU). By way of derogation to the general principles, no IFU is required for Class I devices if they can be used safely without such instruction. A justification for not providing instructions for use should be documented within the technical documentation. For standalone software the manufacturer must consider all aspects of use of their software when considering the need for an IFU e.g. system requirements, downloading instructions, foreseeable medical emergency situations.

Standalone software may be made available to users on a disc that can include a copy of the IFU for the user. Other standalone software may only be available to users via download (e.g. mobile apps). The manufacturer of medical device standalone software should:

- ensure that the IFU is available to users, where required, and clearly identify where the IFU can be accessed by the user. e.g. on the app itself or via a website
- consider the information provided with the standalone software, and the format it is supplied in, as part of the risk assessment of the device (see section 5.5.3). For example:
  - o environment/setting in which the standalone software is intended to be used
  - o knowledge and experience of the intended users regarding the use of the device
  - o availability of the information online or offline
  - o whether the display of the information impedes the use of the device
  - o identification of the manufacturer/EAR in case of reporting of incidents
- ensure the information required on the device 'label' is provided, at a minimum, on the home screen of the standalone software. The user should be able to navigate to this information when using the software.
- ensure the label and IFU, regardless of its format (e.g. document, video, audio) is controlled within their documentation system, which also documents changes to the IFU.

National language requirements must be taken into account in relation to labelling and IFU. In Ireland, English must be used on all labelling and instructions for use. Competent Authorities

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<sup>8</sup> Section 13 of Schedule I of S.I. No. 252 of 1994

in Member States where the device is to be placed on the market should be contacted in order to determine any language requirements for their particular market.

#### **4.8 Affixing the CE mark**

The CE marking must<sup>9</sup> be in a visible, legible and indelible form on:

- the device or its sterile pack, where practicable and appropriate, and
- the instructions for use, as well as
- any sales packaging.

In the case of medical device standalone software the HPRA expects that the CE mark is visible, at a minimum, on the home screen/landing page of the standalone software.

In cases where a Notified Body assessment is required the CE marking must be accompanied by the identification number of the relevant Notified Body.

Note that Class I devices, with the exception of devices placed on the market in a sterile condition and devices with a measuring function, bear the CE mark without a Notified Body identification number as Notified Body intervention is not required.

It is prohibited to affix marks which are likely to mislead third parties with regard to the meaning of the CE mark. Other additional marks may be fixed to the device, to the packaging or the instructions for use provided the visibility or legibility of the CE mark is not impaired.

The CE mark format should be in compliance with the Regulations. Where the device is very small the minimum dimensions of the CE mark may be waived.

#### **4.9 Manufacturer's post-market surveillance**

Manufacturers must put in place and keep updated a system to review experience gained from their standalone software on the market and to implement necessary corrective actions, taking account of the nature and risks in relation to the product. This system is referred to as post-market surveillance (PMS) system. Information assessed as part of post market surveillance can include, for example, customer feedback and complaints.

Certain events, or 'incidents', involving medical device standalone software must be reported to the competent authority where the incident occurred. For further guidance in relation to obligations with regards to reporting of incidents, manufacturers should refer to the HPRA Guide to Vigilance System for Medical Devices at [www.hpra.ie](http://www.hpra.ie).

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<sup>9</sup> Regulation 6 of S.I. No. 252 of 1994, and S.I. No. 304 of 2001 and Regulation 5 of S.I. No. 253 of 1994.



Standalone software differs from other types of medical devices in how it is made available to users and distributed and this must be considered within a PMS system. For example, mobile applications are downloaded by users onto mobile devices via app stores. It is important for the effectiveness of the PMS system that the manufacturer of the mobile app can implement revisions to their mobile app, via apps stores, without delay where there is a potential risk to the safety of the user or patient (e.g. in case of a Field Safety Corrective Action). Similarly the manufacturer must ensure it is possible to distribute the associated Field Safety Notice to all affected impacted users without delay and receive reconciliation for all affected users. By design mobile apps can allow users to directly feed back to the manufacturer of the app and this can allow for efficient reporting.

#### **4.10 Registration of persons placing devices on the market**

Irish-based manufacturers of Class I medical devices, custom-made medical devices/AIMD and IVD medical devices, or their EAR, that place these devices on the market must<sup>10</sup> register with the HPRA by:

- informing the HPRA of their registered address, and
- supplying the HPRA with a description of the device which is sufficient to identify it.

Manufacturers of medical device standalone software that meets these requirements or their EAR must therefore register with the HPRA. Additional information on the registration process is available on the HPRA website at [www.hpra.ie](http://www.hpra.ie).

## **5 HPRA VIGILANCE AND MARKET SURVEILLANCE**

As the Competent Authority for medical devices in Ireland, the HPRA must establish and maintain a system for assessment of vigilance reports, including serious adverse incidents involving medical devices and to ensure these are appropriately addressed by the manufacturer. The HPRA must also conduct market surveillance in relation to products manufactured by Irish based manufacturers and those placed on the Irish market to ensure that they are in compliance with the relevant Irish and EU legislation relating to medical devices.

Market surveillance reviews can include a review of the manufacturer's technical documentation by the HPRA either as part of a desk review at the HPRA and/or by audit at the manufacturer's or authorised representative's premises. The aim of the market surveillance is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of medical device legislation.

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<sup>10</sup> Regulation 14 of S.I. No. 252 of 1994 and Regulation 10 of S.I. No. 304 of 2001

For additional information in relation to HPRA medical device audits please refer to the HPRA 'Guide for Medical Device Manufacturers on Auditing by the Health Products Regulatory Authority to the Medical Device Regulations'. This guide and associated documents can be found in the 'Publications and Forms' section of [www.hpra.ie](http://www.hpra.ie).

## **6 WHO TO CONTACT AT THE HPRA**

The HPRA encourages communication with the medical device sector. Should you have specific queries please address them to the Human Products Authorisation and Registration department of the HPRA at [devices@hpra.ie](mailto:devices@hpra.ie) or alternatively through the following contact details:

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