

Guidance on medical devices legislation

# Guidance on the regulations for electronic instructions for use of medical devices

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### Disclaimer

This document is intended as general guidance only. It should not be regarded as an authoritative statement of the law, nor as having any particular status. Manufacturers and others should not rely on the guidance alone to make decisions but should consult the legislation referred to and seek their own legal and professional advice on a case by case basis. The MHRA does not accept liability for any errors, omissions or other statements in this guidance whether negligent or otherwise. An authoritative statement on the interpretation of the legislation can only be given by the courts.

## 1 Introduction

[Commission Regulation \(EU\) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices](#) allows manufacturers of certain types of medical devices and accessories to provide electronic instructions for use if they wish, and lays down requirements that have to be met in order for this to fulfil the requirements of the Medical Devices Directive. EU regulations are directly applicable in UK law and do not therefore need to be transposed into domestic medical devices regulations to take effect.

The provision of instructions for use in an electronic form can be beneficial for certain professional users and the purpose of the Regulation is to reduce the environmental burden and improve competitiveness by reducing costs whilst at the same time maintaining safety. There is even a suggestion that electronic instructions for use could improve levels of safety, given that electronic storage of information is less susceptible to loss, providing that sufficient safeguards are used.

## 2 Definitions

'Instructions for use' means information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken as outlined in the relevant parts of point 15 of Annex I to [Directive 90/385/EEC](#) and of point 13 of Annex I to [Directive 93/42/EEC](#).

'Instructions for use in electronic form' means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or instructions for use available through a website.

'Professional users' means persons using the medical device in the course of their work and in the framework of a professional healthcare activity.

'Fixed installed medical devices' means devices and their accessories which are intended to be installed, fastened or otherwise secured at a special location in a healthcare facility so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare facility.

## 3 Applicable types of device

The types of medical device that the regulation can apply to are:

- a) active implantable medical devices and their accessories intended to be used exclusively for an indicated purpose and no other
- b) implantable medical devices and their accessories intended to be used exclusively for that purpose and no other
- c) fixed installed medical devices
- d) medical devices and their accessories (whether general medical devices or active implantable medical devices) fitted with a built in system visually displaying the instructions for use
- e) standalone software covered by Directive 93/42/EEC as amended by Directive 2007/47/EC.

It does not apply to In Vitro Diagnostic Devices for which guidance is available in MEDDEV 2.14/3 rev.1

## 4 Conditions

Manufacturers of the above types of device and accessories may provide electronic instructions for use on condition that:

- a) they are intended for exclusive use by professional users and the use by other persons is not reasonably foreseeable
- b) they have undertaken a risk assessment covering the elements detailed below which has concluded that the level of safety obtained by providing the instructions for use in paper form would be maintained or improved upon
- c) any parts of the instructions for use intended to be passed on to the patient are also available in paper form
- d) the text used, which can contain symbols and graphics is entirely the same as would be provided in paper form. Video and audio files may be offered in addition to the text, making clear what information this is and that it is optionally additional.

## 5 Risk assessment

A risk assessment of electronic instructions for use will be conducted covering the following elements:

- a) the knowledge and experience of the intended users
- b) the characteristics of the environment in which the device will be used
- c) the knowledge, experience of the user and their level of familiarity with the hardware and software needed to display the instructions for use that it would be reasonable to expect.
- d) the access of the user to reasonably foreseen electronic resources
- e) the performance of safeguards to protect the content from tampering
- f) the safety and back up mechanisms in the event of hardware or software fault particularly where integrated within the device
- g) the foreseeable medical emergency situation requiring a paper format
- h) the impact caused by the temporary availability of the website or Internet as well as any safety measures available to cope with the situation
- i) an evaluation of the time period within which professional users should also be provided with instructions for use in paper form on request
- j) that suitable measures are in place to ensure that the electronic instructions for use reach the professional user

The risk assessment shall also be updated in view of the experience gained in the post-marketing phase.

## 6 Requirements for the electronic labelling

Where instructions for use are to be provided electronically:

- a) the same format should be used in all Member States where the product is made available or put into service, subject to national regulations on the language of the labelling, unless justified in the risk assessment
- b) the manufacturer should have a system in place to provide instructions for use in printed paper form at no additional cost within 7 days of request. A receipt might be requested as proof that it's been provided
- c) information should also be provided on the surface of the device or where this is not practical in a leaflet about foreseeable medical emergency situations
- d) for devices fitted with a built in visual display of the instructions for use, this information should also include details of how to start the device
- e) their proper design and functioning should be ensured and verification and validation evidence provided to this effect
- f) failure of any built in display should not impede the functioning and safe use of the device in particular life monitoring or support functions
- g) information on software and hardware requirements in order to display the instructions for use should be provided in product catalogues and other device information support material
- h) a system should be in place to clearly indicate when the instructions for use have been revised and to inform each user if the revision was necessary for safety reasons
- i) the manufacturer should keep the instructions for use available in electronic format for two years after the expiry date of the last produced device except for implantable devices where they should be kept for 15 years after the last device has been manufactured. The use of technology that is independently supported and has back up in the case of failure might be considered
- j) the manufacturer should clearly indicate on the unit or sales packaging or in the case of fixed installed devices on the device itself that the instructions for use are provided in electronic instead of paper form and how they can be accessed
- k) the information referred to above on how the electronic instructions for use can be accessed should also include:
  - any information needed to view the instructions for use
  - a unique reference number giving direct access to the appropriate instructions for use and any other information needed to identify them
  - relevant manufacture contact details
  - where, how and by which time the instructions for use in paper form can be requested.

## 7 Website provision

Where instructions for use are provided in other electronic forms they should also be made accessible to users through a website. Where provided on a website the instructions for use should:

- a) be in a commonly used format that can be read with freely available software
- b) be protected against hardware and software intrusion
- c) be provided in such a way that server downtime and display errors are reduced as far as is possible
- d) mention in which EU languages the manufacturer they are provided
- e) fulfil the requirements of Directive 95/46/EC as amended
- f) display a stable and directly accessible Internet address subject to any code safeguards
- g) include all previous versions issued in electronic form and the date of publication making it clear which revisions or parts thereof are current and relate to which product.

## 8 Notified bodies

Where a Notified Body is involved in the conformity assessment of the device they will also review the requirements above for electronic labelling using a sampling method adapted to the class and complexity of the product.

## 9 Enquiries

If you have general queries about this guidance, contact us on:

[devices.compliance@mhra.gsi.gov.uk](mailto:devices.compliance@mhra.gsi.gov.uk) or [MB-MDA-ERA@mhra.gsi.gov.uk](mailto:MB-MDA-ERA@mhra.gsi.gov.uk)