Joint Medical Device Industry Guidance

on device, unit pack or sales packing information for the supply of eIFUs (electronic Instructions for Use)

as required by Commission Regulation (EU) No. 207/2012

Introduction

The Commission Regulation (EU) No. 207/2012 of the 9th March 2012 requires for medical devices which are placed on the market and made available with electronic Instructions For Use (eIFUs) in Art. 6.1:

"Manufacturers shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form.

That information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself."

The intention of the Regulation is to clearly show to the user that the IFUs, for a particular device, are supplied in an electronic form instead of in paper form.

Purpose

Due to national language requirements, and taking into account the limited space on medical device packaging, the requirement of Commission Regulation No. 207/2012 Art. 6.1 may be difficult to fulfil as *text*. Therefore this guidance proposes an approach to use an amended standardized *symbol* to address this provision. A harmonized industry approach will also help users and customers quickly adapt to a common labelling format indicating the availability of eIFUs.

References

Commission Regulation (EU) No. 207/2012 Art. 6.1

EN 980:2008

EN ISO 15223-1:2012

EN 60601-1:2006

Scope

This guidance is developed for all medical devices in scope of Regulation (EU) 207/2012 (see Art 3). This document does not apply to In Vitro Diagnostic Medical Devices.

Labelling

6.1 When to apply labelling?

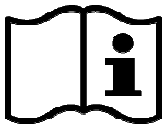
Labelling is required when an active implantable medical device, a medical device or a respective accessory falling under the scope of Commission Regulation (EU) No. 207/2012 is placed on the EU market and made available in the EU with eIFUs.

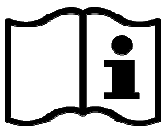
6.2 Where to label?

The label has to be placed on the device itself in case of “fixed installed medical devices” and/or on the packaging of each unit or on the sales packaging (Art. 6.1 of Commission Regulation (EU) 207/2012).

6.3 How to label?

Medical Device Industry advises to use the symbol **5.4.3** of **EN ISO 15223-1:2012 “Consult Instructions For Use”** in combination with an indicator for the use of eIFUs. This indicator may represent the address of the manufacturer’s eIFU website which is required by Commission Regulation (EU) No. 207/2012 or any other appropriate indication on the use of eIFUs. The “indicator” may be placed either alongside, beneath, or surrounding the symbol (as shown below)**.**





eIFU indicator

eIFU indicator

The symbol must be explained in the instructions for use or a leaflet provided with the medical device. In case an eIFU website address is provided as “eIFU indicator” the amended symbol should be read.” Consult instruction for use on this website” Note, the website address indicates the location of the instructions for use and not necessarily the exact section of the instructions for use referred by the amended symbol.

6.4 Exemptions

Where a manufacturer is required to label a medical device based on standard EN 60601-1:2006 with the “Follow instructions for use” symbol, Medical Device Industry advises to amend this symbol with the eIFU indicator in a similar manner as shown below:

eIFU indicator

eIFU indicator

If an eIFU website address is used, the amended symbol should be read.” Follow instructions for use on this website”

6.5 Additional information to be provided

The intention of the symbol is only to inform the user that the instructions for use are provided in electronic form instead of in paper form. Additional information must be provided to comply with Articles 6.2 and 6.3 of Commission Regulation (EU) 207/2012, especially if the eIfU is provided on an electronic storage medium and can be visually displayed by the device.

COCIR is the voice of the European Radiological, Electromedical and Healthcare IT Industry

Eucomed represents the medical technology industry in Europe

EUROM VI is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises

EUROMCONTACT: the European association of contact lens and care solutions manufacturers

FIDE represents the interests of the dental manufacturers in Europe