ELECTRONIC INSTRUCTIONS FOR USE
UNDER MEDICAL DEVICES REGULATION

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Reunião Anual do Colégio de
Assuntos Regulamentares

ORGANIZAÇÃO

COLÉGIO de ESPECIALIDADE ASSUNTOS REGULAMENTARES

REPÚBLICA PORTUGUESA
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SNS SERVIÇO NACIONAL DE SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

AGENDA

CE

MEDICAL DEVICE (MD) DEFINITION

any instrument, apparatus, appliance, software, implant, reagent, material or other article

intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

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

The following products shall also be deemed to be medical devices:
— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilisation of devices

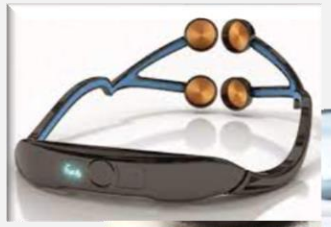
Art. 2 (1) of Regulation (EU) 2017/745, 5 of April (MDR)

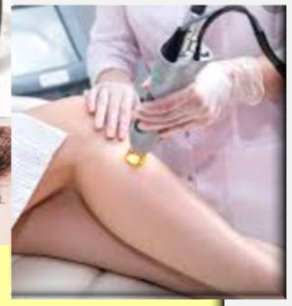
MEDICAL DEVICES REGULATION (MDR)

The scope of the MDR has broadened

Devices term (MDR) covers:

- Medical devices
- Accessories to medical devices;
- Products listed in Annex XVI, with non-medical intended purpose.

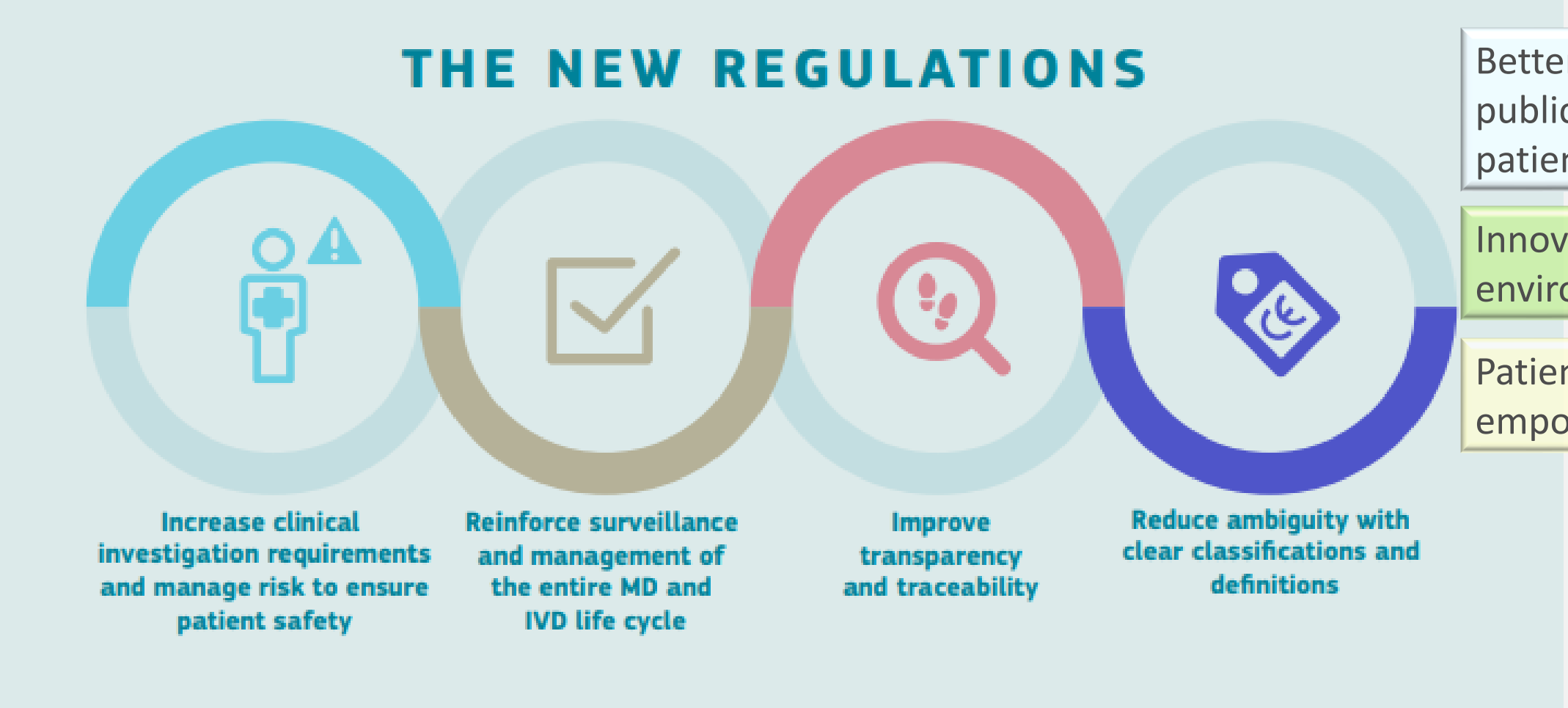




- **Contact lenses** or other items intended to be introduced into or onto the eye.
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as **equipment for liposuction**, lipolysis or lipoplasty.
- **lasers** and intense pulsed light equipment, for skin resurfacing, for tattoo or **hair removal** or other skin treatment.
- Equipment intended for **brain stimulation** (…

It is now explicit that devices and services sold online fall under the MDR scope

MEDICAL DEVICES REGULATIONS (MDR & IVDR)



Better protection of public health and patient safety

Innovation-friendly environment

Patient empowerment

https://ec.europa.eu/docsroom/documents/34908

MEDICAL DEVICES REGULATIONS (MDR & IVDR)

https://ec.europa.eu/docsroom/documents/34908

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NEW TECHNOLOGIES AND MEDICAL DEVICE REGULATION

INNOVATIVE SECTOR

- **Innovation is happening at an increasing speed**
  - Better Prevention AND Diagnostic AND Treatment
  - Big impact on health care delivery
- **Important Drivers:**
  - Nanotechnology
  - **Information and Communication Technologies**
  - Dissemination of high-tech care in less controlled environments
- **New generations of MD resulting from "Convergence Technologies"**
  - Increasing number of borderline products and combined products
  - The need of a multidisciplinary approach

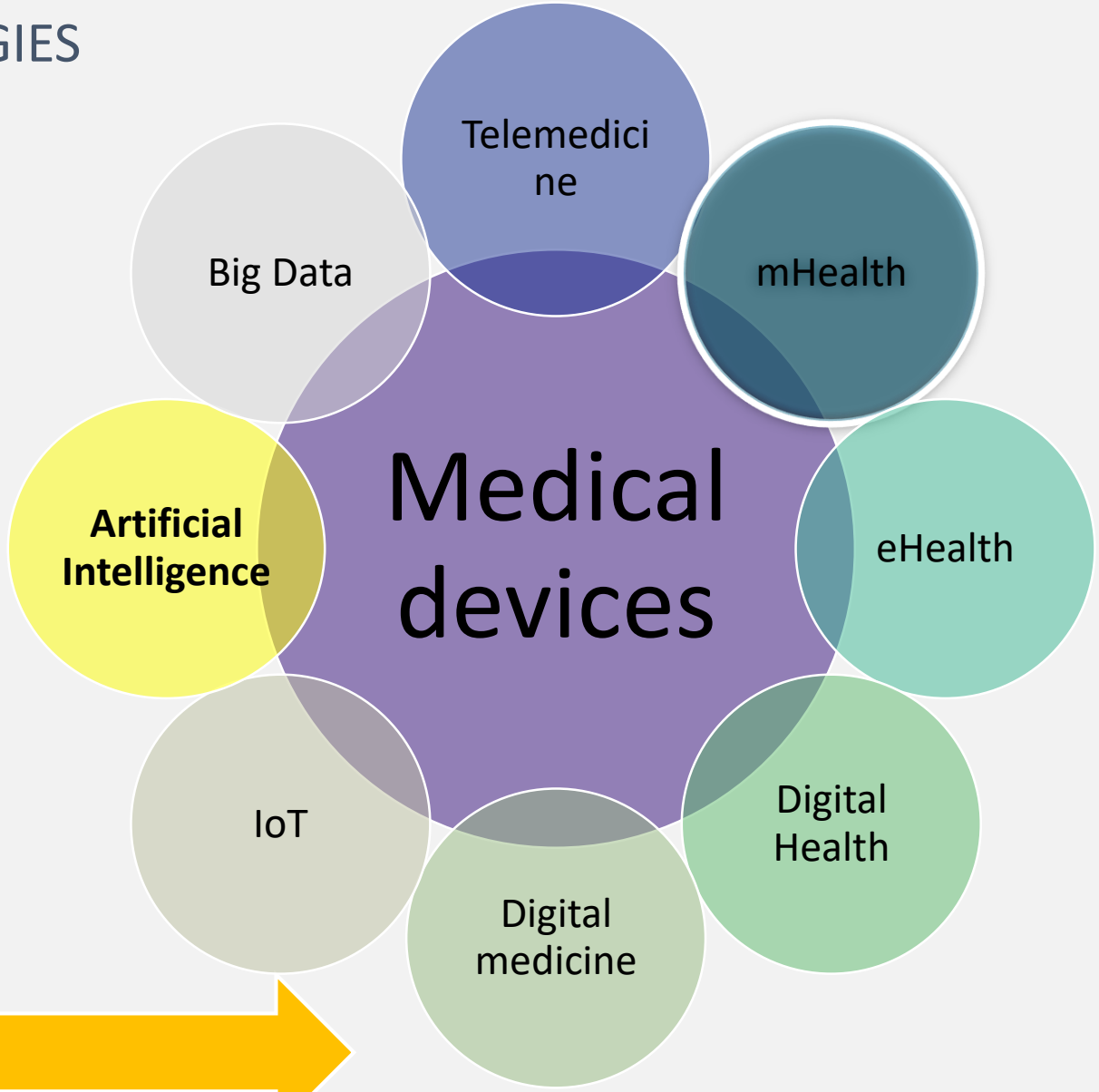
INFORMATION AND COMUNICATION TECHNOLOGIES

Diretive 2007/47/CE – MD Definition/“ …software, …, whether used alone or in combination…”

Regulation (EU) 2017/745 (MDR)

Regulation (EU) 2017/746 (IVDR)

10 years



INFORMATION AND COMUNICATION TECHNOLOGIES

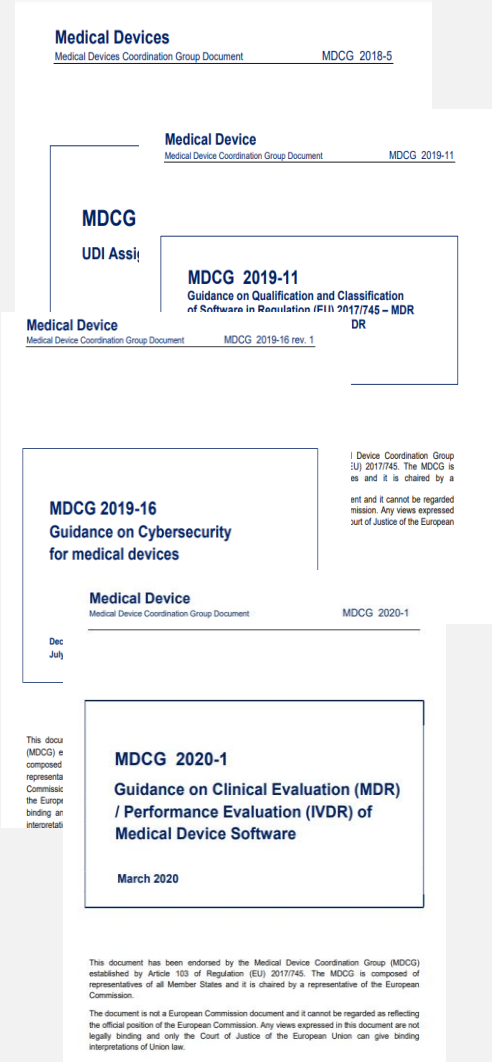
New provisions related to software/apps:

- Definitions: Compatibity, Interoperabilidade
- Classification rule for software- rule 11
- General Safety and Performance Requirements: software/hardware, security, data protection
- UDI for software device
- Distance sales (MD and services)

Clinical evaluation & Vigilance

- (...)

EU GUIDANCE



INFORMATION AND COMUNICATION TECHNOLOGIES

At EU level

NEW TECHNOLOGIES WORKING GROUP MEETING
23 OCTOBER 2020 (10:00-16:30)
WEBEX INVITATION

DRAFT AGENDA V2

N°	DESCRIPTION
1.0	Approval of the agenda
2.0	Update fro
3.0	Me
4.0	C
6.0	– COCIR analysis on Artificia

E-labelling

Software app providers

AI under MDR/IVDR

Drug/Device combinations (sensores, apps)

https://ec.e
dcg_workin

Proposal for a Regulation laying down harmonised rules on artificial intelligence
https://digital-strategy.ec.europa.eu/en/library/proposal-regulation-laying-down-harmonised-rules-artificial-intelligence-artificial-intelligence

At international level

IMDRF International Medical Device Regulators Forum

working item started:
- 1st meeting 13.08.2020

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About IMDRF
Work items
Consultations
Documents

Work items > Artificial Intelligence Medical Devices (AIMD)

Artificial Intelligence Medical Devices (AIMD)

The purpose of this Work Item is to achieve a harmonized approach to the management of artificial intelligence (AI) medical devices. This work item will cover machine learning-based medical devices representing AI technology applied to medical devices and further standardize terminology for machine learning-based medical devices among member jurisdictions.

Working Group Chair: Dr Young-kyu Kang, MFDS, South Korea

Working Group Membership: Regulators and stakeholder membership

http://www.imdrf.org/workitems/wi-aimd.asp

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

shop on Artificial Intelligence
April 2021 (Virtual)
T)

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INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

Placing on the market

- ✓ Declaration of conformity
- ✓ EU Certificate (where applicable)
- ✓ **Instructions for use** and labelling
- ✓ UDI
- ✓ …

Registration of devices and manufacturers in Eudamed/ or at National CA

INSTRUCTIONS FOR USE

- **Each device** shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging **or in the instructions for use**, and shall, if the manufacturer has a website, be made available and kept up to date on the website…- **Annex I (23) Requirements regarding the information supplied with the device**

- **Instructions for use -** means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken - **Article 2 (14) MDR**

INSTRUCTIONS FOR USE

Requirements regarding the information supplied with the device - Annex I (23)

- **Instructions for use shall be provided together with devices**. By way of exception, instructions for use shall **not be required for class I and class IIa devices if such devices can be used safely without any such instructions** and unless otherwise provided for elsewhere ….

- **Instructions for use may be provided to the user in non-paper format** (e.g. electronic) to the extent, and only **under the conditions, set out in Regulation (EU) No 207/2012** or in any **subsequent implementing rules** adopted pursuant to this Regulation.

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ELECTRONIC INSTRUCTIONS FOR USE

ELECTRONIC INSTRUCTIONS FOR USE

REGULATION (EU) NO 207/2012

Why

- **beneficial for professional users.**
- **to reduce the environmental burden**
- **reducing costs (industry),**

while maintaining or improving the level of safety

Limited scope

- **AIMD MD** and their **accessories used exclusively** for the implantation or programming of a defined AIMD;
- **Implantable MD** and their **accessories** intended **exclusively** for the implantation of a defined implantable MD;
- **Fixed installed MD**
- MD and their **accessories fitted with a built-in system visually displaying** the instructions for use;
- stand-alone software

AIMD – Active implantable medical devices

Conditions MD

- the devices and accessories are intended for **exclusive use by professional** users;
- the use by other persons is not reasonably foreseeable.

Other Conditions

Manufacturers

- shall undertake a documented **risk assessment…**
- shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of paper
- Shall provide information…
- **Ensure that users** have access and can request the instructions for use in paper form, …

ELECTRONIC INSTRUCTIONS FOR USE

Medical devices – online manuals replacing paper instructions

Have your say > Published initiatives > Medical devices – online manuals replacing paper instructions

In preparation

Draft act

Feedback period

27 April 2021 - 25 May 2021

FEEDBACK: OPEN

About this initiative

Summary

To ensure the smooth implementation of the new regulatory framework for medical devices (Regulation (EU) 207/2012), economic operators are now allowed to provide online manuals instead of paper instructions for certain device categories.

The new implementing regulation expands the scope of the Regulation to include medical device software.

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12954-Medical-devices-online-manuals-replacing-paper-instructions_en

ELECTRONIC INSTRUCTIONS FOR USE

- For some medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial. It can **reduce the environmental burden** and **reduce costs for the medical device industry** while maintaining or improving the level of safety.
- **Regulation (EU) 207/2012** has established conditions under which **instructions for use** of medical devices …could be provided in **electronic form instead of in paper form**…. The **rules** …should be **adapted to the new requirements of Regulation (EU) 2017/745** and **technological developments** in the field.

ELECTRONIC INSTRUCTIONS FOR USE

Article 1

This Regulation establishes the conditions under which information on safe and proper use, expected performances and precautions to be taken when using a medical device may be provided by manufacturers through the form of electronic instructions for use, as referred to in Annex I, Chapter III, point 23.1(f), to Regulation (EU) 2017/745.

It also establishes certain requirements concerning contents of and websites for instructions for use that are provided in electronic form in addition to instructions for use in paper form.

This Regulation does not cover products listed in Annex XVI of Regulation (EU) 2017/745.

Article 2

For the purposes of this Regulation, the following definitions shall apply:

(1) '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 made available through a software or a website;

(2) 'professional users' means persons using the medical device in the course of their work in the framework of a professional healthcare activity;

(3) 'fixed installed medical devices' means devices and their accessories which are intended to be installed, fastened or otherwise secured at a specific location in a health institution 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 institution.

ELECTRONIC INSTRUCTIONS FOR USE

REG. 207/2012 *VS* NEW DRAFT REG.

Article 3

(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

(a) implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745;

(b) fixed installed medical devices covered by Regulation 2017/745;

(c) medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the instructions for use.

(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:

(a) the devices and accessories are intended for exclusive use by professional users, and

(b) the use by other persons is not reasonably foreseeable.

(3) For software covered by Regulation (EU) 2017/745, manufacturers may provide instructions for use in electronic form by means of the software itself instead of in paper form.

Reg. 207/2012
….intended to be used exclusively for the implantation or programming of a defined active implantable medical device
….intended to be used exclusively for the implantation of a defined implantable medical device

Reg. 207/2012
Previously, the stand alone software have to fulfill the point 2 -> Applicable for exclusive use of professional users

ELECTRONIC INSTRUCTIONS FOR USE

REG. 207/2012 *VS* NEW DRAFT REG.

Article 4 of draft Regulation

(1) Manufacturers of devices referred to in Article 3, paragraphs 1 and 3, that provide instructions for use in electronic form to users instead of in paper form **shall undertake a documented risk assessment** which shall cover at least the following elements:

(i) evaluation of the period within which the instructions for use shall be provided in paper form at the user's request;

(j) assessment of the electronic instructions for use compatibility with different devices which could be used to display those instructions;

(k) management of different versions of the instructions for use, where applicable in accordance with Article 5 (8).

(2) The risk assessment for the provision of the instructions for use in electronic form shall be updated in view of the experience gained in the post-marketing phase

ELECTRONIC INSTRUCTIONS FOR USE

REG. 207/2012 *VS* NEW DRAFT REG.

Article 5 of draft Regulation

Manufacturers of devices, may provide instructions for use to users in electronic form instead of in paper form under the following conditions:

(…)

last device has been placed on the market;

(11) the instructions for use shall be available on their website in an official language of the Union determined by the Member State in which the device is made available to the user or patient;

(12) effective systems and procedures shall be in place to ensure that device users having downloaded instructions for use from the website can be informed in case of updates or corrective actions with regards to those instructions for use;

(13) all issued historical versions of the instructions for use shall be available on the website.

website

ELECTRONIC INSTRUCTIONS FOR USE

REG. 207/2012 *VS* NEW DRAFT REG.

Article 6 of draft Regulation

Article 6

(1) Manufacturers shall clearly indicate on the label 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.

In the case of software, the information shall be provided at the location from where access to the software is granted.

ELECTRONIC INSTRUCTIONS FOR USE

REG. 207/2012 *VS* NEW DRAFT REG.

Article 6 of draft Regulation (cont.)

(3) The information on how to access the instructions for use in electronic form shall contain the following:

(a) any information needed to view the instructions for use;

(b) the Basic UDI-DI and UDI-DI of the device, as respectively referred to in Article 27(6) and Article 27(1), point (a)(i), of Regulation (EU) 2017/745, and any additional information allowing the identification of the device, including its name and if applicable the model;

(c) relevant manufacturer contact details e.g. manufacturer's name, address and website;

(d) where and how instructions for use in paper form can be requested and within which time they shall be obtained at no additional cost in conformity with Article 5, point (3).

(4) Where, for devices and accessories referred to in Article 3 (1), point (a), a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form.

ELECTRONIC INSTRUCTIONS FOR USE

REG. 207/2012 *VS* NEW DRAFT REG.

Article 7 of draft Regulation

Article 7

(1) Where manufacturers provide the instructions for use in electronic form on an electronic storage medium together with the device, or where the device itself is fitted with a built-in system visually displaying the instructions for use, the instructions for use in electronic form shall also be made accessible to the users through a website.

(2) Any website containing instructions for use of a device which are provided in electronic form instead of in paper form shall comply with the following requirements:

(a) the instructions for use shall be provided in a commonly used format that can be read with freely available software;

(b) it shall be protected against unauthorised access and tampering of content in accordance with Article 4 (1), point (e);

(c) it shall be provided in such a way that the server downtime and display errors are reduced as far as possible;

(d) it shall fulfil the requirements of Regulation (EU) 2016/679;

(e) the Internet address as displayed in accordance with Article 6 (2) shall be stable and directly accessible during the periods set out in Article 5, points (9) and (10);

(f) all previous versions of the instructions for use issued in electronic form as referred to in Article 5, point (13), and their date of publication shall be available on the website.

General Data Protection Regulation

ELECTRONIC INSTRUCTIONS FOR USE

CHALLENGES

- **Enlargement of the scope to other medical devices**
- **Products used in combination (Medicines and Medical Devices)**

OBRIGADA
THANK YOU

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e Produtos de Saúde, I.P.