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Regulations of Medical Devices

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Table of contents

EBreast II

Introduction

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- European Union has laid down regulations on medical devices which are directly applicable throughout the EU:
  - Medical Device Regulation EU/2017/745
  - In Vitro Diagnostic Medical Devices Regulation EU/2017/746 (1).

Introduction

- Medical device regulations in EU:
  - improve the quality, safety and reliability of medical devices
  - strengthen transparency and information for patients and
  - enhance vigilance and market surveillance (2).

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Regulations

Medical Device Regulation EU/2017/745

"This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose

This Regulation does not apply to: in vitro diagnostic medical devices covered by Regulation (EU) 2017/746" (3.)

For more information on Medical Device Regulation please see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

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In Vitro Diagnostic Medical Devices Regulation EU/2017/746

"Directive 98/79/EC of the European Parliament and of the Council constitutes the Union regulatory framework for in vitro diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for in vitro diagnostic medical devices which ensures a high level of safety and health whilst supporting innovation.

This Regulation aims to ensure the smooth functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for in vitro diagnostic medical devices in order to meet common safety concerns as regards such products." (4.)

For more information on In Vitro Diagnostic Medical Devices Regulation please see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R07456

European Medicines Agency

European Medicines Agency (EMA)

- The European Medicines Agency (EMA) is a decentralised agency of the European Union.
- EMA is responsible for the scientific evaluation, supervision and safety monitoring of medicines. (5.)
- EMA's mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU (6).

For more information of EMA see: https://www.ema.europa.eu/en

Placing a medical device on the market

Placing a medical device on the market

- Medical devices can be placed on the market or put into service which conform with existing EU regulations.
- The manufacturer must be able to establish new product safety, suitability for intended use, performance and reliability before placing it on the market. (7)
- The manufacturer must issue an EU **Declaration of Conformity** (DoC) and affix **the CE marking** (Conformité Européenne) to the appliance to demonstrate compliance. (8)
- The CE marking shows that a product
  - meets all its essential requirements.
  - complies with all the requirements laid down in the applicable directives.
  - has been assessed in accordance with these requirements. (9)

Placing a medical device on the market

- The manufacturer must draw up the required documentation to enable to demonstrate that the apparatus meets the general safety and performance requirements. To be considered a medical device, the manufacturer must demonstrate that the intended use of the device complies with the definitions given in the Regulations. (8)
- The **conformity assessment** usually includes an audit of the manufacturer's quality system and, depending on the type of equipment, a review of the manufacturer's technical documentation on the safety and performance of the equipment.
- EU Member States designate accredited **notified bodies** s to carry out conformity assessments. (10)

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Special device groups; software

Special device groups; software

- The designation of software as a medical device or in vitro diagnostic (IVD) device almost invariably requires a case-by-case assessment. This is the responsibility of the software manufacturer.

- Guidance on definition and classification can be found in the EU MDCG 2019-11 and in the software guidelines issued by certain medical device regulatory authorities. Guidance on the classification of IVDs under the Regulation can be found in the MDCG 2020-16. As a rule, all software that controls a device or influences the use of a device must be classified in the same category as the device.

- The risk classification of medical software is guided by Classification Rule 11 of the Regulation (2017/745, Annex VIII). For software that is considered an IVD device, the classification follows the corresponding principles of the IVD Directive (98/79/EC) or the classification rules in Annex VIII of the IVD Regulation (2017/746). (11)

Manufacturer's incident reporting procedure

Manufacturer's incident reporting procedure

- Incident is defined as follows
  - events which have caused or could have caused a risk to the health of a patient, user or other person, resulting from
  - characteristics
  - malfunction or deterioration of performance
  - inadequate labelling
  - insufficient or incorrect instructions for use of a medical device.(12)

Manufacturer's incident reporting procedure

- The procedure for reporting medical device incidents varies depending on the regulatory framework under which the device is placed on the market.

- The Manufacturer Incident Report (MIR) form published by the Commission must be used for all manufacturer incident reports, and the requirement to use the International Medical Device Regulations Forum (IMDRF) codes also applies to all devices regardless of the regulatory basis. (12)

For more information on MIR form see: https://ec.europa.eu/docsroom/documents/32305/attachments/3/translations .

For more information on IMDRF see: https://www.imdrf.org/.

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References

References

1 Fimea. The new EU regulation on medical devices comes into force on 26 May 2021 [Internet]. 2021. [cited 2022 April 20]. Available from: https://www.fimea.fi/web/en/-/the-new-eu-regulation-on-medical-devices-comes-into-force-on-26-may-2021

2 European Comission. Public health: Stronger rules on medical devices [Internet]. 2021. [cited 2022 April 20]. Available from: https://ec.europa.eu/commission/presscorner/detail/en/IP_21_2617

3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.) [Internet]. [cited 2022 April 20]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

4 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance.) [Internet]. [cited 2022 April 20]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R07456

5 European Medicined Agency. About us [Internet]. [cited 2022 April 20]. Available from: https://www.ema.europa.eu/en/about-us

6 European Medicined Agency. What we do? [Internet]. [cited 2022 April 20]. Available from: https://www.ema.europa.eu/en/about-us/what-we-do

7 Fimea. Medical Devices. [Internet]. 2021. [cited 2022 April 20]. Available from: https://www.fimea.fi/web/en/medical-devices

8 Fimea. Placcing a medical device on the market. [Internet]. 2021. [cited 2022 April 20]. Available from: https://www.fimea.fi/web/en/medical-devices/placing-a-medical-device-on-the-market

9 Fimea. Ce marking. [Internet]. 2021. [cited 2022 April 20]. Available from: https://www.fimea.fi/web/en/medical-devices/placing-a-medical-device-on-the-market/ce-marking

10 European Medicined Agency. Medical Devices. [Internet]. [cited 2022 April 20]. Available from: (https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices

11Fimea. Sofware.[Internet]. 2021. [cited 2022 April 20]. Available from: https://www.fimea.fi/web/en/medical-devices/special-device-groups/software

12 Fimea. Manufacturer's incident reporting procedure. [Internet]. 2021. [cited 2022 April 20]. Available from: https://www.fimea.fi/web/en/medical-devices/manufacturer-s-incident-reporting-procedure

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