This EU Regulation Status Check May Actually Cheer You Up

We speak the language of the regulators and solve unsolvable problems.

DISCLAIMER

This presentation is intended for education purpose only and do not replace the legal text of the legislations, standards or guidance documents.

This presentation presents my personal opinion and interpretation as subject matter expert.

STATUS OF DESIGNATION/NOTIFICATION UNDER THE EU MDR

Where are we after 5 years from publication date? Status Update

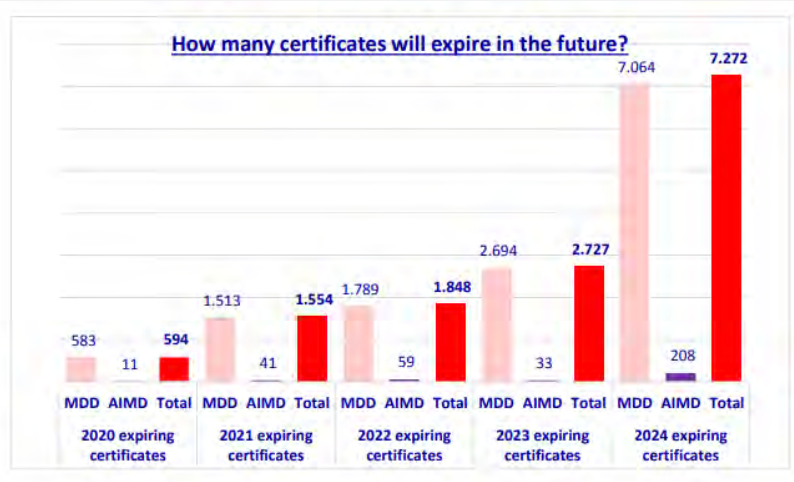
56 *Applications*

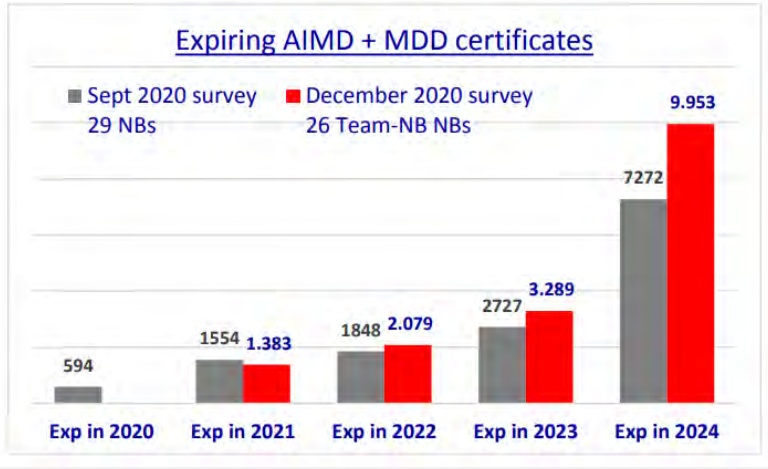
28 *Designated and Notified*

1 *Impacted by BREXIT*

STATUS OF DESIGNATION/NOTIFICATION UNDER THE EU MDR

SOURCE TEAM NB: *The distribution of certificates´ expiration over the transition period of Directives certificates will be challenging (15 Dec 2020)*





Where are we after 5 years from publication date? Status Update

REALITY

WE ARE HEADING TOWARDS A PROBLEM

COVID19 Travel Restrictions

Remote Audits are still not allowed

Less than 5-10% of Medical Device Certificates were issued

Devices are losing market availability:

1. *Higher clinical expectations*
2. *No pre-assessment possibility*
3. *Limited notified body availability*
4. *Lengthy conformity assessment process*
5. *Limited rounds of assessment*
6. *Etc.*

DID YOU FINALLY START TO READ IT?

Reading and Understanding the requirements is KEY

I

Chapter I (Art. 1-3):

Scope & definitions

II

Chapter II (Art. 5-24):

Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement

III

Chapter III (Art. 25-34):

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices

IV

Chapter IV (Art. 35-50):

Notified bodies

V

Chapter V (Art. 51-60):

Classification and conformity assessment, consultations, scrutiny

VI

Chapter VI (Art. 61-82):

Clinical evaluation & clinical investigation

VII

Chapter VII (Art. 83-100):

Post-market surveillance (PMS), post market clinical follow up (PMCF), vigilance, market surveillance, trends, periodic safety update report (PSUR)

VIII

Chapter VIII (Art. 101-108):

Cooperation between member states, expert laboratories, medical device coordination group, expert panels, device registers

IX

Chapter IX (Art. 109-113):

Confidentiality, data protection, funding, penalties

X

Chapter X (Art. 114-123):

Final provisions

DID YOU CLEARLY DEFINE YOUR ROLE?

ROLES WITHIN THE SUPPLY CHAIN

Distributor:

Natural or legal person in the supply chain who, on his behalf, furthers the availability of a medical device to the end user

Importer:

Natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

Manufacturer:

Natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on behalf by another person(s)

Authorized representative:

Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation

MDR: REQUIREMENTS FOR QMS DEFINED UNDER…

GENERAL OBLIGATIONS OF MANUFACTURER (Article 10)

1. Design and manufacture of devices according the requirements of this Regulation
2. Risk management according Annex I Section 3
3. Clinical evaluation according Article 61 and Annex XIV, including a PMCF
4. Technical documentation including the elements set out in Annexes II and III
5. *Requirement only for manufacturers of custom-made devices*
6. EU declaration of conformity
7. UDI system referred to in Article 27
8. Retention of technical documentation, EU declaration of conformity and any relevant certificate: 10 (15) years after the last device …
9. Procedures for conformity of series production and change control (design / standards / CS)

Most effective and continually improved quality management system

MDR: REQUIREMENTS FOR QMS DEFINED UNDER… (2)

GENERAL OBLIGATIONS OF MANUFACTURER (Article 10)

10 Post-market surveillance system in accordance with Article 83.

11 Information and labelling

12 Corrective action / withdrawal / recall

13 System for recording and reporting of incidents and field safety corrective actions

14 Access to information / documentation / device samples of the device

15 Cooperation with competent authorities

16 Information regarding outsourcing

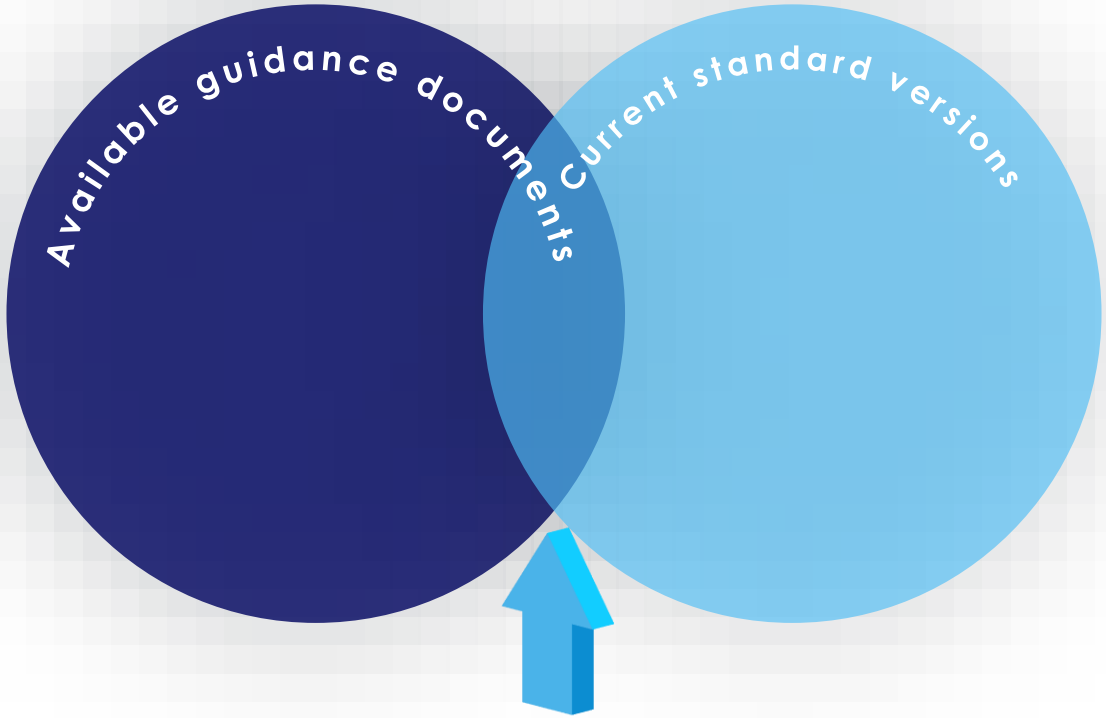
17 Compensation for damage caused by a defective device

MDR: THE QMS SHALL ADDRESS AT LEAST THE FOLLOWING ASPECTS…

- a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;
- clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;
- identification of applicable general safety and performance requirements and exploration of options to address those requirements;
- product realisation, including planning, design, development, production and service provision;
- processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
- responsibility of the management;
- verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;
- resource management, including selection and control of suppliers and sub-contractors;
- setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;
- processes for monitoring and measurement of output, data analysis and product improvement.
- risk management as set out in in Section 3 of Annex I;
- management of corrective and preventive actions and verification of their effectiveness;
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

STANDARDS & GUIDANCE

ISO 13485:2016 Medical devices



Harmonized

Relationship b/w EN ISO 13485:2016 and European Medical Device Regulation

ISO 13485:2016 Medical devices – Quality Management Systems; Requirements for regulatory purposes

HIGH VALUE

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)
2017/745	CEN	EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	05/01/2022	OJ L 1 - 05/01/2022

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