HealthManagement.org

LEADERSHIP • CROSS-COLLABORATION • WINNING PRACTICES

VOLUME 23 • ISSUE 2 • € 22

ISSN = 1377-7629

Medical Device & AI Regulations

THE JOURNAL 2023

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Standards in Support of the EU Medical Devices Regulations

The use of harmonised standards in support of the Medical Devices Regulations (MDR & IVDR) is a proven and trusted way to ensure compliance, quality, safety and efficiency of products, production processes, management systems, services and test-methods. They are developed as per the EU request to the European Standardisation Organisations (CEN & CENELEC) and cited in the Official Journal of the EU.

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key points

- European and International Standards are widely used in all sectors of economic and industrial activity, including the healthcare sector.
- Standards frequently are developed in response to market needs and assist with legislation gaps, thus the whole process is usually market driven and enhances free trade.
- The new European Regulations 2017/745 on Medical Devices (MDR) and 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) aim to ensure a robust, transparent and sustainable regulatory framework, and maintain a high level of safety while also supporting innovation.
- Using harmonised standards, is a proven way of ensuring that medical devices placed on the market comply with the regulations and are thus safe.
- The European and International standard EN ISO 13485:2016 “Medical devices - Quality management systems - Requirements for regulatory purposes” helps manufacturers comply with the requirements of the regulations regarding the implementation of a quality management system.

Useful Tools to Help Achieve MDR and IVDR Compliance

European and International Standards are widely used in all sectors of economic and industrial activity, including the healthcare sector, on which several active technical standardisation committees.

These standards are voluntary and define requirements and/or guidance regarding products, production processes, management systems, services or test-methods, ensuring quality, safety and efficiency.

They are trusted and appreciated worldwide, and as such, the European Commission uses them to assist manufacturers and economic operators to comply with EU regulations and eliminate barriers to trade.

Upon reflection, one could ask why? Why are standards so important?

As ISO, the International Organisation for Standardisation claims in one of its most popular quotes, “Great things happen when the world agrees!”. This is what standardisation is all about. It is a process based on very important principles such as consensus, transparency, accessibility, integrity, efficiency, and coherence in at the European and international level. Both International (ISO & IEC) and European (CEN & CENELEC) Standardisation Organisations, develop standards based on the above principles, with the voluntary participation of experts around the world, nominated by their members, the National Standards Bodies (e.g., BSI in the UK, AFNOR in France, CYS in Cyprus).

Additionally, across Europe all National Standards Bodies are governed by the European Regulation

1025/2012 and apart from developing and promoting the use of standards, they have the responsibility of managing the national standardisation system and participating in European & International Standardisation.

Standards usually are developed in response to market needs and assist with legislation gaps, thus the whole process is usually market driven and enhances free trade.

Removing barriers to trade was one of the main reasons why, back in 1985, the EU New Approach Directives were developed. Instead of specifying technical requirements, they laid down essential requirements, leaving it up to European standards to assist manufactures in complying with these directives. Then by citing these standards in the Official Journal of the European Union (OJEU), they evolve into Harmonised Standards.

Under the same philosophy, and in order to further improve this system, the EU has moved a few years ago to the New Legislative Framework, as a result of which the new European Regulations 2017/745 on Medical Devices (MDR) and 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) were developed. These new Regulations aim to ensure a robust, transparent and sustainable regulatory framework, and maintain a high level of safety while also supporting innovation.

As in the previous medical devices' directives, medical devices are classified according to their intended use and related risks, and different certification and registration requirements are set for each category. Additionally, the new regulations include several specific requirements for the economic operators of the supply chain of medical devices described in Chapter 1 in Article 2 (e.g. manufacturers, authorised representatives, importers, distributors), as well as notified bodies, expert laboratories etc. Also, the new regulations include requirements related to traceability, information provided by the manufacturer, as well as transitional provisions.

The new European Regulations 2017/745 on Medical Devices and 2017/746 on In Vitro Diagnostic Medical Devices have entered into force on 26th May 2021 and 26th May 2022 respectively. The transitional provisions are defined in Article 120 of the MDR and Article 110 of the IVDR. However, further extensions on time of implementation are expected to be granted and for this reason the European Commission initiated a consultation concerning the extension of this transition period in January 2023.

In order to assist all relevant stakeholders in complying with the new Regulations, the European Commission issued a Standardisation Request (SReq) to CEN & CENELEC, which was accepted by their members, requesting CEN & CENELEC to develop European standards in support of the regulations.

Implementation of harmonised standards gives presumption of conformity to the essential requirements of the Medical Devices Regulations

Once developed, these new standards are assessed prior to publication and, when published, they are offered to the European Commission for citation. It is important to note that compliance with harmonised standards is not compulsory (unless otherwise stated) and as per Article 8 of 2017/746 MDR, "Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof".

It is also important to note that the European Standardisation Organisations, which offer the standards for citation, cooperate very closely with the International Standardisation Organisations, under the Vienna Agreement (between CEN and ISO) and the Frankfurt Agreement (between CENELEC and IEC). This is achieved either through adoption of international standards or through development of standards in parallel.

In the healthcare sector and in relation to MDR and IVDR, most of the harmonised standards are based on or developed in parallel with ISO or IEC, leading to further coherence between European and international level.

All standards have a specific structure, however harmonised standards include some additional elements. More specifically, a harmonised standard typically contains:

- A European foreword providing the key references to the applicable EU legislation.
- The normative clauses, including scope, terms and definitions, technical methods, normative references etc.

It specifies requirements for a quality management system for organisations who need to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Implementation and certification of EN ISO 13185 can assist in the compliance with the Quality Management System requirements of MDR & IVDR

- One or more informative Annexes lettered Z (ZA, ZB,…,ZZ) describing the relationship between the clauses of the harmonised European Standard and the essential requirements of the legislation the standard aims to cover.

Finally, there is a standard, which, even though it is not harmonised yet, is very important in complying with the requirements of the regulations regarding the implementation of a quality management system by the manufacturers:
The European and International standard EN ISO 13485:2016 (+AC:2018+A11:2021) “Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)”.

In order to assist manufacturers, the standard also includes informative Annexes ZA and ZB which correlate the requirements of the standard with the relative requirements of MDR and IVDR.

Compliance with complex and demanding regulations can be challenging, both in large countries and economies but especially in smaller ones.
Using harmonised standards, is a proven way of ensuring that medical devices placed on the market comply with the regulations and are thus safe, both for patients as well as healthcare professionals and others.

Conflict of Interest

None. ■

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