THE MDR JOURNEY

«Let's make transparency a standard requirement»

NEWSLETTER N. 27 – *October 2022*

Subject: MDR and new related documents. Impact to MDR actors.

Background

Following the publication of the Regulation 745/2017 (MDR) in May 2017, successive related documents have been released as:

- common specifications (CS) for specific device groups,
- updated list of harmonised European standards (hENs) to the MDR,
- MDCG guidance, which are documents that bring additional insights regarding MDR requirements.

In parallel, manufacturers are preparing or undergoing the MDR certification process, and Notified Bodies (NB) and Competent Authorities (CA) are supervising the manufacturers and the market.

Regulatory basis

The regulatory framework on medical devices including Directive 93/42/EEC and Regulation (EU) 2017/245 (MDR) are based on the "New Approach" and the "New Legislative Framework" policies.

In practice, the content of legislation establishes only essential requirements for the devices placed on the market and the technical details are provided in harmonised European Standards.

In addition, Article 103 MDR includes an expert committee, the Medical Device Coordination Group (MDCG), that assist the European Commission and the Member States in ensuring a harmonised implementation of the MDR through their contribution in the development of:

- scientific guidelines,
- common specifications
- and device standards,

The legal status of these documents is:

- Common specifications are mandatory 6 months after the date of their entry into force.
- MDR-hENs are voluntary but provide presumption of conformity to the MDR.
- MDCG documents are not legally binding but are considered state of the art and therefore recommended by NBs through regular audits.

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How do these documents affect MDR actors?

With the 100+ MDCG guidance documents and explanatory notes published so far, common specification development and ongoing harmonization process to European Standards for MDR, the actors with responsibilities in MDR need to allocate sufficient resources to timely search for new publications, assess impact and implement changes in their internal processes, products and technical documentation.

Conversely, for some MDR aspects where there is no specific document published the interpretation across the MDR actors may differ.

How does it affect medical device distributors?

Most of the MDCGs cover MDR requirements for manufacturers or notified bodies, but there are a couple of MDCG documents that are specific for importers and distributors. The documents are MDCG 2021-27 and MDCG 2021-26, that develop questions and answers (Q&A) on Articles 13 & 14 and 16 of MDR.

What can we expect over the next months?

According to the MDCG group plan, the number documents published is expected to increase. This may provide additional clarity to specific MDR requirements in terms of Q&A or additional insights to proof compliance.

Additionally, the increasing experience for manufacturers and Notified Bodies in MDR certification processes, and for the Competent Authorities with MDR market surveillance activities, along with the various coordination meetings to share experiences and develop common approaches, is supporting all actors involved to improve the understanding on the application of the MDR.

This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs".

We are already today all dependent on efficient cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supply to hospitals and patients in the future.

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We are confident we will continue to supply health care competently on customized surgical procedure sets and small kits.

Do you wish to know more about specific MDR topics? Do you have any questions or comments about STS newsletter? Write us at MDR2020@stsmedicalgroup.com.

The next MDR newsletter will be issued in November. We wish everyone productive and pleasant days.

Augusto Orsini
CEO
STS Medical Group

Meritxell Laguna
Group Manager Regulatory Affairs
STS Medical Group