THE MDR JOURNEY

«Let's make transparency a standard requirement»

NEWSLETTER N. 26 – *September 2022*

Subject: MDR readiness update at STS Medical Group

Dear Customer,

We are pleased to announce that as promised one year ago we are back with STS newsletter to provide you with the latest update on MDR status, challenges and preparation steps to develop the highest level of awareness among our customers and distributors.

Furthermore we will take this newsletter to constantly provide full transparency on STS efforts to ensure that our products will continue to be available in the market beyond MDR implementation deadlines with the usual highest safety and quality standard.

Recent regulatory changes

Over the last two years, the medical device actors in Europe have made great efforts to adapt to several regulatory changes:

- The date of application of the Medical Devices Regulation (EU) 2017/745 (MDR), initially stablished on 26 May 2020, was deferred to 26 May 2021 through Regulation (EU) 2020/561 in response to the COVID-19 pandemic. No changes to the MDR certification deadline for legacy products were included.
- New MDCG documents (over 100 documents to date) and EUDAMED guidance are being regularly published. These documents are not considered legally binding but are deemed state of the art and NBs across Europe daily encourage their adoption.
- UK and Switzerland have developed new legislative frameworks due to the Brexit and to the non-renewal of the mutual recognition agreement EU-Switzerland for the MDR, respectively. In both countries, the changes have involved appointment of authorized representatives (AR), quality management system (QMS) updates, technical documentation review by the ARs and registration with the National Competent Authorities.

These changes have been accompanied by multiple challenges such as:

- Covid-19 pandemic
- a global supply chain disruption
- raw material and component shortage
- and the portfolio optimization by all medical device suppliers due to MDR adoption.

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What is the status after MDR date of application?

1. After 26 May 2021, all new medical devices and the existing one class I non-sterile that keep the same risk class in MDR need to be MDR-compliant.
2. Additionally, all medical devices irrespective of risk class and MDD or MDR compliance need to fulfil additional obligations mainly related to vigilance and post-market surveillance system and undergo labeling updates.
3. Further updates have also been made to the QMS of the MDR actors, for instance fulfilling the additional obligations of the economic operators.

What about the legacy products?

Legacy products, which are the MDD-certified products, can continue to be placed in the market until the end of validity of the CE certificate according to MDD as described in Art.120 (3) of MDR.

Who is responsible for MDR certification?

The manufacturers have engaged or are engaging a Notified Body for the MDR certification process.

As we are all aware, many NBs have gone themselves at an earlier stage through the MDR assessment and designation although the number of accredited NBs which is today 32, looks insufficient for completing the MDR certification of all medical device producers accordingly to the regulation timeline.

The MDR certification is a long process involving the review of the QMS and technical documentation of the product families according to MDR upgraded requirements.

Where do we stand with EUDAMED?

Additional updates regarding EUDAMED (The European Database for medical devices) are being developed in parallel by the actors, such as:

- making specific company and device information publicly available
- updating the Database before the deadline currently established at the fourth quarter of 2024
- notifying vigilance reports through EUDAMED.

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Which actions is STS Medical Group taking?

STS is executing a corporate project that coordinates timely activities across STS companies for MDR transition according to the deadlines established by the European Commission and in agreement with all the stakeholders involved. The multiple activities are clustered into specific work packages led by different departments and STS sites. Focus is on execution.

The major work packages are related to the following:

- Technical documentation
- Labeling
- Post market surveillance and vigilance
- Quality System requirements
- EUDAMED registration & UDI

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.

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 October. We wish everyone productive and pleasant days.

Augusto Orsini
CEO
STS Medical Group

Meritxell Laguna
Group Manager Regulatory Affairs
STS Medical Group

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