# THE MDR JOURNEY

**NEWSLETTER No. 9 – December** 2019

*«Let's make transparency a standard requirement»*

In this newsletter we would like to inform you about:

- Two recent changes in the MDR context. One is the postponed implementation of the EUDAMED database and the other is the situation for devices which will be in Class Ir.
- STS strategy regarding the MDR transition.

## Changed Timelines

### EUDAMED

The EUDAMED database is required for multiple purposes by the MDR. The development of such a multi-purpose data base is very complex and need a long time. Right now it is just possible to apply for a test account. Based on this it was not a real surprise when the EU announces that the implementation of the EUDAMED database will be postponed to May 2022.
At first this means that a manufacturer cannot populate the database with the data for its medical devices. Which are good news, giving the manufacture more time to prepare the procedure for uploading this database. However, the fact that the data cannot be entered into the database does not mean that this information does not need to be available at the manufacturer. For sure, all the information required by the database has to be created, defined and stored within the Technical Documentation of a Medical Device.

### Extended Transition for some re-classified Class I products

Just a couple of days ago, the EU released the second corrigendum to the MDR. This corrigendum is mainly regarding those products which are classified as Class I according to the MDD and require the involvement of a Notified Body under the MDR. This kind of products can be made available on the market with a valid MDD certificate until 26 May 2024. But of course, the other responsibilities arising from the roles of the different economic operators, like post market surveillance or assigning a person responsible for regulatory compliance, are still required.

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## STS Transition Strategy

### Legal Framework

In general, all medical devices which are placed on the market need to be compliant to the MDR by 25th of May 2020. And all new developed medical devices which are placed on the marked will be compliant to the MDR by that date.
However, article §120 in the MDR defines transition periods for medical devices with an involvement of a Notified Body. This involvement is given for sterile medical devices (Class Is), products with measurement functionality (Class Im) and higher risk products (Class IIa, IIb, and III). Our Custom Procedure Trays, (CPT) also need the involvement of the notified body and are therefore also covered by this article §120.

Article §120 defines that all products that are placed on the market prior to 25th May 2020 can be made available on the market after that date if a valid MDD Certificate is maintained.

*"Making available on the marke*t" means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge; [MDR, §2, 27]
*"Placing on the market"* means the first making available of a device, other than an investigational device, on the Union market; [MDR, §2, 28]

In easy words, if the device is already sold prior to the end of the transition date and one has still a valid MDD certificate the medical device can still be sold after the date.

- The MDD Certificate expires after five years or according to §120 at latest at the 27th May 2024. The last time an MDD certificate can be issued is 25th May 2020. It is obvious that the required annual audits by the notified body have to be passed to maintain the validity of the issued certificate.
- No significant change to the Medical Device.
  Medical devices shall not be significantly changed in its design or intended purpose. Which rise the question what are significant changes? There is a consensus by the Notified Bodies that only changes which require an involvement of the notified body are considered as significant changes. Changes to a Procedure Pack like adding or removing components will most likely be no significant change – of course this depends on the kind of component and if it results in a changed intended purpose.
- Other obligations of an economic operator.

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Although the medical devices can be made available on the market based on a valid MDD certificate, this does not mean that one has no other obligations regarding the MDR. The other aspects arising from the respective roles as an economic operator has anyway to be fulfilled. This includes the Post Market Surveillance and Vigilance topics, nomination of a Person responsible for Regulatory Compliance, preparing EUDAMED data including the required UDI-DI and B-UDI-DI, and much more.

## Our Strategy

To benefit from the transition period defined in Article §120 we are focusing for an extension of our MDD Certificates. The required audits are already scheduled and will be in time prior to the deadline. Doing this we ensure that we can still make our medical devices available on the market until 27th May 2024. Of course, we will revise the Technical Files for these Medical Devices to be MDR compliant prior of the expiry of our MDD Certificates.

For our class I products without involvement of the Notified Body (not covered by §120) we are currently revising our Technical Files to be compliant to the MDR by 25th May 2020.

The other aspects and obligations which arise from our role as a manufacturer will be currently set up and will be in place till the 25th May 2020. These aspects and obligations comprise the Post Market Surveillance, Vigilance, appointment of a Person responsible for Regulatory Compliance, etc.

During the revision of the Technical Files we are assigning the required B-UDI-DI and UDI-DIs. The UDI-DIs are required by the MDR (§27) by different dates depending on the Risk Class of the Medical Device. These dates are addressed in our transition plan to ensure that every product is marked with an UDI by the respective deadlines.
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 arising from the MDR transition strategy for our Medical Devices.

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

We are confident we'll be able to continue to supply health care competently on customized surgical procedure sets and small kits.

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You want to know more about specific topics? Do you have any questions or comments? Write us **MDR2020@stsmedicalgroup.com**.

If you want to rewiew previus pubblished MDR newsletter use below link: MDR Newsletters.

The next MDR Newsletter will be issued in January. We wish everybody pleasant days.


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