# MDR

## Information regarding the new MDR regulations in Europe

The Medical Device Regulation (MDR) is on the way to be implemented in Europe and we have since a couple of years back worked towards this. The implementation date is now May 26th 2021. Due to this you will soon start seeing changes in our documents and the use of new phrases and codes hence we want to keep you informed of changes to come. We believe this implementation will be a joint effort for everyone working in the Medical Device field and in our case the IVF-field in Europe. We will all play a role. We had originally planned to have a round the table discussion on the MDR at the ESHRE meeting but this year turned out different from all our plans. Instead we will from now on send a short information on the MDR to all our European distributors on a regular basis, this being the first.

Our suggested focus areas in the information e-mails (each e-mail presenting one focus area) are:
Eudamed
Basic-UDI-DI
New labeling (label- and insert example)
Classifications
Codes (MDS/MDT/MDN/EMDN) incl our excelsheet
Import responsibilities
(CE mark, decoding of basic UDI-DI, traceability, example of "reception routine" with two layers)
New contracts (explaining the differences)

If you have suggestions of other areas that would be interesting for you to have information on they are more than welcome! Maybe you would like us to prioritize the focus areas in a specific order, in that case just get back to us!

The full MDR is available on the EU commission website (https://ec.europa.eu/) but we have also found very handy versions that you can buy from the Qserve Group on the following link (https://www.qservegroup.com/eu/en/knowledge-center/eu-mdr-booklets). The MDR will be supported by further guidelines which are published as MDCG:s on the commissions website https://ec.europa.eu/health/md_sector/new_regulations/guidance_en . Note that also the coming MDCG:s are noted and good to keep track of.

We have also found a very helpful podcast called Medical Device made EASY (made by Monir El Azzouzi). They discuss all kinds of matters concerning medical devices and the new regulation. They also have episodes on the importer/distributor roles. We hope that you will find some of this information helpful in your endeavours towards the MDR.

# EUDAMED Economic Operator Registration

Time for a short information on the EUDAMED which we believe most of you have already heard of and might have experience of. The Eudamed is one of the key components of fulfilling the MDR. The EUDAMED is a web based platform that will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance. To this date only the section relating to Actor Registration has been made available. The following estimated timeline applies for the time being:

| Module | Release |
|---|---|
| **Actors** | Q1 2021 |
| **UDI Devices** | Q2 2021 |
| **Certificates** | Q2 2021 |
| **Vigilance** | Q3 2021 |
| **Clinical Investigations** | 2022 |
| **Post Market Surveillance** | 2022 |

We have now registered as an Economic Operator on the EUDAMED website and are now searchable on the following link: https://ec.europa.eu/tools/eudamed/#/screen/search-eo

The information included in the EUDAMED Economic Operator registration is very basic but as soon as you have registered you receive a Single Registration Number (SRN No) which will be very important from when the MDR is in place. Nidacon from now on has the SRN No: SE-MF-000001933. This will be a very important number for all active medical device companies in the European Union.

Everyone will be able to access the information in the EUDAMED. The IVF clinics will for instance be able to see the Post market surveillance and the vigilance data for every product and company registered. The same applies for you as a distributor. This will lead to an increased transparency throughout the European Union and we believe, if they get it rolling properly, it will be of great benefit for all of us. It has similarities to the system in the USA made available from the FDA.

Information series:

| No | Information | Sent out |
|---|---|---|
| 1 | Short introduction to MDR and our info plans | 2020-12-18 |
| 2 | EUDAMED | 2020-03-16 |
| 3 | Basic UDI-DI | |
| 4 | New labelling (incl. label and IFU example) | |
| 5 | Classifications | |
| 6 | Codes (MDS/MDT/MDN/EMDN) | |
| 7 | Import responsibilities | |
| 8 | New contracts | |

If you have any questions or need further information just get back to us!