End of the transition period for the MDR

On 26.05.2021, the Medical Device Directive 93/42/EEC (MDD) ceased to apply and only the Medical Device Regulation is applicable.

Although the MDD effectively expired on this date, you retain the right to market products (so-called "legacy devices") for the duration of the validity of your certificates.

> **Legacy Device**:
>
> Products that have already been certified under the MDD and will be placed on the market with the MDD certificate after 26.05.2021.

However, the following conditions must be met:

- You continue to be regularly audited by TÜV NORD CERT as a Notified Body under the MDD.
- You apply the requirements of the MDR applicable to your products. Some of the MDR requirements also apply to the products certified under the MDD, the so-called "legacy devices".
- You do not introduce "**substantial changes**" to your products.

Contractual Situation

Since 26.05.2021, no more changes to the existing certificates are possible. TÜV NORD CERT will however continue to perform its role in monitoring the certificates according to MDD. For this task, the existing contract was already adapted accordingly with your company in 2020.

Application of the MDR

As of 26.05.2021, you as a manufacturer must also apply the (EU) 2017/745 Medical Device Regulation (MDR) for the products for which you still use the MDD certificates of TÜV NORD CERT.

This means that, among other things, you must already have a market surveillance and notification system in place that meets the requirements of the MDR. However, it also means that you must not make any "*significant changes*" to the "legacy devices", because otherwise your MDD certificates will become invalid.

What if there are still changes?

Since manufacturers are not allowed to make any "*significant changes*" to their products after 26.05.2021 in order not to jeopardize the validity of the certificates, it becomes even more important that you record all changes to ensure the necessary transparency and traceability.

As your notified body, we provide you with a "TÜV NORD CERT Change Log" table in which you can record all changes.

- The auditors will look at these lists regularly in the course of the subsequent surveillance audits.

What is a "Significant change“?

Among the many possible reasons for a change, the MDR focuses on "significant changes" in design and intended purpose. In order to support you as a manufacturer in deciding whether it is a "significant Change", the European Commission has produced a guidance document

➔ MDCG 2020-3
Guidance on significant changes

The "TÜV NORD CERT Change Log" (P11F002) contains a column in which you can document your decision on the question: "Is this a "significant change"?" and justify it with reference to the decision tree of MDCG 2020-3.

We recommend the use of this guide to avoid that you cannot place your products on the market without applying for and undergoing a new certification under the MDR due to the implementation of a "Significant Change".

In Case of Changes

I. If, when using the guide, you come to the conclusion that you are planning a "Significant Change", please send us the completed form P11F002 immediately to the medical@tuev-nord.de .

- **Notification of changes to medical@tuev-nord.de before implementation**

It is important that you send us the notification before implementing these changes so that we, as the Notified Body, can take the appropriate action, such as a fee-based review and confirmation of the change.

II. Should you have difficulties in deciding on the correct classification, we recommend that you also complete the changelog P11F002 and submit it to the Notified Body for a chargeable assessment.

III. In case of non-significant changes, please document them in the changelog P11F002 and keep them available in the audit.

If you have any difficulties using the "TÜV NORD CERT Change Log" (P11F002), we recommend that you contact our team at an early stage. We will be happy to answer any queries you may have.