The starter kits: information packages for a smooth application process under the MDR

On 17 April 2020, the European Parliament adopted a motion to postpone the transitional period of Regulation (EU) 745/2017 (MDR) by one year. The regulation itself has been in force since May 2017 and should have been implemented by 26.05.2020 this year.
This means that it is still possible to maintain certification for medical devices under the directives beyond the May 2020 deadline. This is achieved by means of a timely "recertification" in order to be able to continue to market existing products.
Due to the current crisis, all Notified Bodies are severely restricted in their service provision, the burden for manufacturers of medical devices is enormous.
Therefore, a postponement of the start date is a logical and welcome measure to give industry and Notified Bodies, but also authorities and other stakeholders enough time for an orderly transition to the MDR.

What exactly does this entail for you as a client of the DQS Medizintechnik GmbH?

DQS-Med is pleased to inform you that from now on we again are accepting requests for (early) recertification as well as the submission of new products and change notifications under the MDD.
Please be aware that we can only confirm these requests with the legally binding publication of the moratorium in the Official Journal of the European Commission.
At the same time, we expect the designation for the MDR by approx. end of June. We will of course keep you informed about the progress

What are the next steps?

We want to use this opportunity to make your transition to the MDR with DQS Medizintechnik GmbH as convenient and effective as possible. For this purpose, we provide you with two information packages that are built upon each other. You already received the Starterkit 1 with this email.
It contains:

- an overview of the conformity assessment procedure of DQS Medizintechnik GmbH in form of an informative timeline,
- a list of links with freely accessible information on medical devices, the directives, the regulation and the second corrigendum of the MDR,
- a description of the application process under the Regulation,
- explanations on the sampling of product files

Due to the current global situation and the extension of the transitional period, we would also kindly ask for your cooperation.
With the help of a capacity survey, we would like to know when and to what extent you as a company plan to submit your applications to us for the transition to the MDR. This will help us enormously in planning the conformity assessment procedures to be carried out and thus enable us to make your transition to the MDR as quick and uncomplicated as possible.
To this end, and based on your feedback, we will carry out very specific dummy planning at process level allocating our current resources. This will help us to detect possible capacity bottlenecks on the part of the assessors early and will give us the necessary run-up time to counteract these bottlenecks through additional authorisations.

Overview of the relevant client related processes of the DQS Medizintechnik GmbH

The regulation places high regulatory and procedural demands on industry and Notified Bodies alike. This can be seen, among other things, in the tight limits compared to the MDD/AIMDD and the very strict regulation of the application proceedings. In order to enable you, our existing clients, to be prepared in the most effective way, we will first like to describe how we as DQS med plan the implementation of these requirements:

Please note:
All points described below will only become effective at the time of the designation of DQS med for the implementation of conformity assessment procedures according to the Regulation (EU) 2017/745 (MDR). We will inform you in due time about changes of the status of our designation.

Also important:
For you as an existing client, the transition from the directives to MDR will always be carried out as an initial certification. This applies equally to audits and to all products that you wish to certify under the MDR. You will be accompanied as usual by our account managers and can contact us with all questions in confidence.

The complete application procedure under the MDR comprises two phases:

1. activities prior to the application (MDR, Annex VII, 4.2 Information of Notified Bodies and activities prior to the application) and
2. the actual application (MDR, Annex VII, 4.3 Review of the application and contract conditions)

Concretely this has the following implications for phase 1:
DQS Medizintechnik GmbH (DQS med) will publish the application procedure together with all relevant information (e.g. the fees and charges list, general terms and conditions, etc.) on the DQS med website. DQS med will conduct a preliminary review of your submitted information by a Regulatory Affairs Manager (RAM) prior to the actual application. The purpose of this preliminary review is to determine whether we, as a Notified Body, are still able to perform the conformity assessment for you.

If the preliminary review is positive, DQS med will prepare an offer.

List of relevant information for the feasibility assessment (MDR Annex II, section 1)

In order to carry out the feasibility study, the applicant is required to provide a range of information that enables us to identify and assess the essential characteristics of the medical device:

1. product description and specification, including variants and accessories
1.1. Product description, including
1.1.1. intended use
1.1.2. Is it an invasive / non-invasive product / implant?
1.1.3. Which substances / Medicinal products are used in combination with the product?
1.1.4. Are derivatives of human or animal origin used?
1.1.5. Which components / assemblies can be sterilised?
1.1.6. Is the product part of a medical system (system description)?
1.1.7. Technical data
1.2. Basis UDI-DI
1.3. Information on patient group, disease state, criteria for patient selection, indications, contraindications and warnings
1.4. principles relating to the operation of the device and its mode of action
1.5. Have external laboratories / service providers been consulted in the course of product testing (Activity, designation, and accreditation)?
1.6. Naming of critical suppliers and their activities (audit separately if necessary)
1.7. Description of accessories and other products included in the scope of certification, which are applied / used in combination with the medical device
1.8. List of existing variants and their differences
1.9. Has the product been / is it already certified according to MPG/MDD 93/42 EEC/EEC?

If you accept the offer, then phase 2 of the application and application review will begin:
DQS med provides its clients with application forms that enable them to submit an application according to the MDR.
With the submission of the application, all documents and evidence listed in Annexes IX and XI of the MDR must also be submitted, depending on the conformity assessment procedure you have decided on.
DQS med will review the application and inform you of the decision.

Please note that all rejected and withdrawn applications must be reported to the database (EUDAMED) described in Article 57 of the MDR by us as a Notified Body. We therefore ask you to ensure that all the information you provide is complete and correct and that all supporting documents are submitted in full; in particular:

- the specified documents relating to the quality management system,
- the product file (technical documentation),
- the preclinical and clinical documentation as well as
- the appropriate parts of the technical documentation regarding post-market surveillance (**Annex III, MDR**)

Incomplete documentation will inevitably lead to rejection of the application and entry in EUDAMED. Further information on this subject is provided in Starterkit 2, which is sent simultaneously with the information on successful designation.
Once the application has been approved, the corresponding conformity assessments, i.e. audits and document reviews, will be scheduled and carried out in cooperation with the applicants.

In this respect, the MDR also differs in some aspects from the directives:

1. The product file review must take place before the audits are carried out, as inputs from the review must be included in the audit program,
2. A maximum of three "loops" are available to DQS med and our clients for the review of the product files, after which the procedure must be restarted. In concrete terms, this means that new applications must be submitted for the products concerned

Sampling for the review of product files and during (unannounced) audits under the MDR

Until recently it has been uncertain whether sampling under the MDR is possible for Class IIa and IIb devices and if - how this sampling has to be carried out. The MDCG 2019-13 Guideline takes up this topic, even if a few questions still remain open.

Definitions:
As the MDR does not define certain terms or certain definitions are not suitable for the performance of a sampling, the MDCG paper introduces the definitions below or extends these definitions by certain aspects.

Please note:
These definitions are only valid in the context of sampling and cannot be applied to other aspects of the MDR without further elaboration!

- **'Classificazione Nazionale Dispositivi medici' (CND)**
  The CND is the official Italian classification and nomenclature for medical devices. Since then, the CND has been implemented not only in Italy, but also in Portugal and Greece. The CND is the basis for the future European Medical Device Nomenclature (EMDN)
- **The European Medical Device Nomenclature (EMDN)**
  The EMDN will be the nomenclature used by manufacturers to register their medical devices in the EUDAMED database. At the same time, it will be the basis for the generic product group and thus the sampling for Class IIa products.
- **Generic product group (MDR, Article 2 (7)):**
  The generic product group is the fourth level of the European Medical Device Nomenclature (EMDN), i.e. a combination of one letter plus 6 digits.
- **Product category:**
  Product Category means the relevant MDA/MDN codes according to Regulation (EU) 2017/2185 on the codes for the designation of notified bodies.
- **Product:**
  Product means the product(s) connected to a Basic UDI-DI (defined in MDCG 2018-1 v2 Guidance on BASIC UDI-DI and changes to UDI-DI).
- **Product range (MDR, Annex IX, 2.4):**
  The product range is a summary of all "product categories" for Class IIa products and all "generic product groups" for Class IIb products covered by a certificate.
- **QMS certificates:**
  QMS certificates are EU quality management system certificates and EU quality assurance certificates issued by notified bodies as a result of conformity assessments.

The criteria for sampling

The regulation distinguishes between quantitative and qualitative sampling criteria as well as between sampling before issuing a QMS certificate and during the surveillance phase. For illustration we provide you with the following table:

Criteria for the sampling of product files

	Before issuing a certificate	During surveillance	Objective at the end of a certification cycle
Class I	Notified Body is not involved	Notified Body is not involved	
Class I (m,r,s)	Limited to aspects m,r,s; minimum one product	Limited to aspects m,r,s; minimum one product	Representative coverage of all aspects considering the differences of the existing products
Class IIa	Minimum one representative product per product category covered by a basic UDI-DI	Minimum one representative product per product category covered by a basic UDI-DI	Representative coverage of the complete product range (all product categories) and at least 15% of all product files per product category (may be reduced to 5% in the first certification cycle under the MDR)
Class IIb	Minimum one representative product covered by a basic UDI-DI per generic product group	Minimum one representative product covered by a basic UDI-DI per generic product group	Representative coverage of the complete product range (all generic product groups) and at least 15% of all product files per generic product group (may be reduced to 5% in the first certification cycle under the MDR)
Class IIb, for the administration and/or removal of a medicinal product	Minimum one representative product covered by a base UDI-DI per generic product group Attention: all CERs of every product must be assessed.	Minimum one product	Representative coverage of the complete product range (all generic product groups) and at least 15% of all product files per generic product group (may be reduced to 5% in the first certification cycle under the MDR)
Class IIb implantable without exceptions	No sampling, all TDs must be assessed	Minimum one product	Coverage of all products (each product file) before the QMS certificate is issued plus additional annual reviews.
Class III	No sampling, all TDs must be assessed	Minimum one product	Coverage of all products (each product file) before the QMS certificate is issued plus additional annual reviews.
Additional rules and exceptions			
Generic product group	In cases where the 4th level of the EMDN does not exist, the Notified Body shall use the next higher level. If the notified body considers that for a given product the 4th level is not specific enough to define a generic product group, it may use the next lower level, if available.		
Products with multiple EMDN codes	If more than one EMDN code applies to a product, only the most appropriate of these EMDN codes shall be used for sampling purposes.		
Surveillance	The number of products to be assessed during the surveillance phase is determined by the Notified Body and may vary within the regulatory requirements. Reasons for this can be capacity bottlenecks, vigilance cases or suchlike. The follow-up of change notifications in accordance with section 4.9 of Annex VII (e.g. "the product range covered" in section 2.4 of Annex IX) and other surveillance activities in accordance with section 4.10 of Annex VII of the MDRs shall be carried out in addition to the sampling during surveillance.		