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Technical Documentation Checklist MDR

Before starting to check your technical documentation:

☐ **Applicability**

Check if your device will fall under the regulation. Pay attention to Article 1(2) on "devices without an intended medical purpose" (specified in the list in Annex XVI) that are also covered by the regulation.

Qualify your device as a medical device (see definitions in Article 2) and document the rationale.

Will your device be a service provided as explained in Article 6? In that case MDR will apply for your device as well.

Is your device an OBL (Own Brand Labelling)? You need to make sure that you have a full technical file for your device according to Article 10.

☐ **Classification**

Will your device change it's classification under MDR? Make an assessment of all your devices as regards to the new rules for classification in Annex VIII. Is your device a software – check out the new rules for software and the published MDCG guidance 2019-11, *Qualification and classification of software – Regulation (EU) 2017/745 and Regulation (EU) 2017/746*.

☐ **Conformity Assessment Route**

Choose an applicable Conformity Assessment Route that you will follow to demonstrate conformity with MDR.

Make sure that your Notified Body also is (or will be) designated according to that route. Also make sure that your device is within the scope of designation for your Notified Body.

☐ **Responsibilities**

Check out the updated responsibilities for a manufacturer (Article 10), importers (Article 13) and distributors (Article 14) and ensure that you include those in your QMS as applicable.

☐ **Manufacturer outside EU**

Review your agreements with your Authorized Representative and make necessary arrangements to comply with the requirements of Article 11.

Symbioteq Kvalitet AB
Box 1251
SE-131 28 Nacka Strand
Sweden

Street adress:
Augustendalsvägen 46
Nacka Strand
Sweden

Sahlgrenska Science Park
Medicinaregatan 8B
SE-413 46 Göteborg
Sweden

Phone: +46 8 621 05 02
Email: info@symbioteq.se
www.symbioteq.com

☐ **PRRC**

Assign the person responsible for regulatory compliance (PRRC). Verify that this person has necessary qualification as stated in Article 15?

☐ **Guidance documents, CS, harmonized standards**

Establish procedures to keep track of the publication of guidance documents (MDCG), common specifications (CS) and harmonized standards and assess their impact on your management system.

Technical documentation:

☐ **General Description**

Have a look at the general description of your device. Do you need to include more information? For example, an overview of identified similar devices. The basic UDI-DI as referred to in Annex VI, part C. See Annex II, chapter 1.

☐ **Design and Manufacturing Information**

Is your current Design and Manufacturing information complete and correct? Make sure to identify all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed. See Annex II, chapter 3.

☐ **GSPR**

The General Safety and Performance Requirements in MDR replaces the Essential Requirements in MDD. => Update the ER Checklist to a GSPR checklist. Identify all applicable requirements and decide on the method to comply with those requirements. Also make sure to provide evidence of compliance for each requirement. See Annex I.

☐ **Risk Management and Benefit/Risk Analysis**

The risk management system should be aligned with and reflected in the clinical evaluation for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. Risk management and clinical evaluation processes should be inter-dependent and regularly updated and the outcome shall be used as input for the Post-Market Surveillance Plan. See section 1, 3 and 8 of Annex I. Subsequently use the outcome of the Post-Market Surveillance to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

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☐ **Product Verification and Validation**

Make sure that you have traceability to evidence (e.g. test reports) to demonstrate conformity of the device with each requirement stated in the GSPR. For example; biocompatibility, usability, electrical safety and EMC, software verification and validation, stability (shelf-life), life-time and for the device performance and safety.

☐ **Labeling**

The technical documentation needs to include complete set of labels on the device and on its packaging and instructions for use. See Annex II, chapter 2 and Annex I, chapter III.

Also see UDI-DI requirements in Article 27 and Annex VI, part C.

Implantable devices – need to have an Implant card provided together with the device and information to the patient as stated in Article 18.

If the device is implantable or class III - Instructions for use need to have link to the summary of safety and clinical performance (SSCP) referred to in Article 32.

☐ **Biological Evaluation**

Make a Gap-analysis between the current biological evaluation and the new requirements in the MDR. Is an update required? Special attention should be given to the new demands in the MDR regarding Hazardous Substances and the GSPR´s applicable for your device.

If your current evaluation is performed according to earlier version of ISO 10993-1, it needs to be updated for ISO 10993-1:2018 to reflect the State of the Art. For example, regarding biological evaluation as part of a risk management process, demands of competencies of authors, the increased demands of material characterization, and which biological tests to consider. Don´t forget to consult the new versions of other parts of the ISO 10993 standard series, and to update according to the latest ones.

☐ **Clinical Evaluation and Clinical Investigation**

Make a Gap-analysis between the current evaluation and the new requirements in MDR. Does it need to be updated?

If your current evaluation is performed according to MEDDEV 2.7/1 rev.3 it needs to be updated to be at least in line with MEDDEV 2.7/1 rev.4 and the requirements set out in Article 61-82. Also see Annex XIV and XV.

If the device is implantable or class III, a summary of safety and clinical performance (SSCP) needs to be included. See Article 32.

☐ **PMCF**

Post Market Clinical Follow-up (PMCF) Plan and preparation of PMCF evaluation report need to be included in the technical documentation as referred to in Annex XIV or a justified rationale for why a PMCF is not applicable.

☐ **Post Market Surveillance and Vigilance**

Do a gap-assessment of the requirements set out in chapter VII of MDR (Also see Annex III) and for example make sure that you have a post-market surveillance plan that need to be part of your technical documentation.

Class I device manufacturers shall prepare a post-market surveillance report summarizing the results and conclusions of the data gathered during the activities planned according to Article 85.

Class IIa, IIb, and III device manufacturers shall prepare a periodic safety update report (PSUR) for each device according to Article 86.

See requirements on reporting of serious incidents and field safety corrective action and how to analyze those and vigilance data.

Be aware of new trend reporting according to Article 88.

☐ **EU Declaration of Conformity**

See Annex IV what a DoC shall contain, for example the Single Registration Number (SRN) as referred to in Article 31 and the basic UDI-DI as referred to in Annex VI, part C.