Assessment Guideline For MDR

Contents

Introduction

Thank you for your interest for our MDR services. With this guideline we have tried to provide guidelines for MDR assessments however if you still have specific questions for which are not covered in this guidance you may reach us via mdsales@maltaca.com

Where To Find Guidance Documents

EU Commission publishes many useful guidance which will help manufacturers to use during the conformity assessment processes. Please check following website to see published guidance documents.
https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

Decision To Make Before Applying

There are several decisions to be made for a manufacturer before applying to MCA. In this part we will try to identify guidelines for these decisions.

Who Can Apply?

Manufacturers may apply for conformity assessment services and the application documents shall be submitted directly by them however if the manufacturer is not located in EU Union, the EU Authorized Representative may submit applications on behalf of the manufacturer.

When To Apply?

Conformity assessment process starts after a product finishes it's pre-clinical and clinical lifecycle and finishes before a product is made available on the market. Therefore, a manufacturer should have been finished all pre-clinical and clinical verifications and validations for the subject product before applying to a Notified Body. This includes finishing all necessary process validations in the manufacturing site.
Certain exceptions apply during the transition period between according to article 120 of MDR in which the manufacturer may submit a plan for final submission of missing technical documentation and MCA shall evaluate this plan. If MCA accepts this plan, the agreement will be initiated based on a condition to fulfill the deadline for submitting missing documentation.

Is The Device a Medical Device?

MDR applies to medical devices. The manufacturers shall make it sure that their device is a medical device according to MDR. To check the definition of the medical device please consult MDR Article 2. Borderline manual and MDCG 2020-5 will also provide guideline for deciding whether a device is a medical device or not.

Product Class

The obligations of the manufacturer and MCA as a Notified Body changes according to the product class. Deciding on the product class is one of the most important decisions to be made by the manufacturer. The product classes are as follows,
- class Is/Im/Ir
- class IIa
- class IIb

- Class III

The manufacturer shall use classification rules to define the product class. Detail explanation about classification is provided in MDR Annex VIII. For more guidance documents please refer MDCG 2021-14, Borderline manual and MDCG 2020-5.

EMDN

EMDN stands for European Medical Device Nomenclature. For every product the manufacturer shall assign one EMDN code. EMDN code is free and publicly available in following EU Commission website https://webgate.ec.europa.eu/dyna2/emdn/
The manufacturer shall state this code both in application forms and in their technical documentation. For more information please read MDCG documents published in following website https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

EUDAMED REGISTRATION

EUDAMED stands for European database on medical devices. This database will be used to regulate many new requirements of MDR. The manufacturers shall register themselves as an actor to EUDAMED and obtain SRN number. This number will be used by the MCA to identify the manufacturer. Additionally, all products shall be registered to EUDAMED together with their Basic UDI-DI code. The Basic UDI-DI will also be printed on the certificates. MCA will register information of certificates through EUDAMED. EUDAMED will have extending usage in MDR ecosystem. Until EUDAMED is fully functional the EU Commission has published MDCG 2021-1 Rev.1 to state possible alternatives.

CONFORMITY ASSESSMENT PROCEDURES

A conformity assessment process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled. There are several types of conformity assessment procedures as described in article 52 of MDR. A product is subjected to conformity assessment both during the design and production phase. In some cases, these phases can be covered by a single procedure and in some cases can be covered by different types of procedures. The procedures are divided into two main groups, these are Procedures based on type (EU-type examination) and procedures based on quality assessment. The manufacturer shall select a procedure to apply based on its own decision.

MCA's notification covers following quality assessment-based procedures,
- Annex IX Chapter I and III (EU Quality Management System). In this procedure MCA will focus on implementation of complete QMS (full quality) of the manufacturer to verify the system is capable of securing MDR requirements and ensuring safe and effective products are made available on the market.
- Annex IX Chapter II (EU Technical Documentation Assessment). In this procedure MCA will review technical documentation to verify the product contains necessary amount of objective evidence for complying with MDR requirement and whether they are safe and effective.
- Annex XI Part-A (EU Quality Assurance). In this procedure MCA will verify implementation of QMS of the manufacturer mainly by focusing on production part. Including manufacturing controls, quality controls, release controls etc. However, it shall be noted that for MCA this does not mean that the manufacturer may exclude design phase from its QMS.

For different product class, different variants of the conformity assessment procedures apply. Below section will provide a summary on them by mentioning only applicable ones for MCA.

PROCEDURES FOR CLASS IS/IM/IR

For these devices following options are applicable,
- Option 1: Annex IX Chapter I and III
- Option 2: Annex XI Part-A

For both options still the manufacturer will need to prepare a technical documentation according to Annex II and III of MDR however MCA will not systematically review them as a "technical documentation assessment". The review and verifications will focus on sterility for class Is devices, metrology for class Im devices and re-use aspects for class Ir devices.

Class Is/Im/Ir	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	N/A. MCA will not perform a full review. The available technical documentation will be verified for sterility, metrology, and re-use aspects.					
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A
Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	N/A	N/A	N/A	N/A	N/A	N/A
Post Market Clinical Follow-Up Report Assessment	The manufacturer shall update according to its PMCF plan. MCA will verify the reports.					
PSUR Assessment	N/A. PMS reports will be verified by MCA.					
SSCP Verification	N/A	N/A	N/A	N/A	N/A	N/A

PROCEDURES FOR CLASS IIA NON-IMPLANTABLE DEVICES

For these devices following options are applicable,
- Option 1: Annex IX Chapter I and III
- Option 2: Annex XI Part-A

For both options still the manufacturer will need to prepare a technical documentation according to Annex II and III of MDR and MCA will systematically review them as a “technical documentation assessment” per device category.

Class IIa Non Implantable	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Sampled per device category	Continuing Sampling				
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A
Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Post Market Clinical Follow-Up Reports based on its PMCF plan.					
PSUR Assessment	Yes, assessed according to sampling plan. Manufacturer shall update PSUR reports at least once every two years.					
SSCP Verification	N/A	N/A	N/A	N/A	N/A	N/A

PROCEDURES FOR CLASS IIA IMPLANTABLE DEVICES

For these devices following options are applicable,

- Option 1: Annex IX Chapter I and III
- Option 2: Annex XI Part-A

For both options still the manufacturer will need to prepare a technical documentation according to Annex II and III of MDR and MCA will systematically review them as a "technical documentation assessment" per device category.

Class IIa Implantable	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Sampled per device category	Continuing Sampling				
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A
Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Post Market Clinical Follow-Up Reports at least annually.					
PSUR Assessment	Yes, manufacturer shall update PSUR when necessary and at least every two years. Updates will be followed and assessed through EUDAMED.					
SSCP Verification	Yes, manufacturer shall update SSCP at least annually "if indicated." MCA will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS IIB REGULAR DEVICES

These devices include regular class IIb devices which are non-implantable, non-implantable wet devices and non-rule 12 Active Devices. For these devices based on MCA's notification scope there is only one available option which is Annex IX Chapter I and III.

Class IIb Regular	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Sampled per Generic Device Group	Continuing Sampling				
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A
Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Post Market Clinical Follow-Up Reports according to its PMCF plan.					
PSUR Assessment	Yes, manufacturer shall update PSUR at least annually. MCA will assess according to sampling plan.					

SSCP Verification	N/A

PROCEDURES FOR CLASS IIB RULE 12 ACTIVE DEVICES

These devices include class IIb Active devices under rule 12 which administer and remove medicines. For these devices based on MCA's notification scope there is only one available option which is Annex IX Chapter I and III.

Class IIb Rule 12	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Sampled per Generic Device Group	Continuing Sampling				
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	Yes. Except cases listed in article 54 2b and 2c	N/A Except in case of a modification which may affect risk-benefit ratio.				
Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Post Market Clinical Follow-Up Reports according to its PMCF plan.					
PSUR Assessment	Yes, manufacturer shall update PSUR at least annually. MCA will assess according to sampling plan.					
SSCP Verification	N/A					

PROCEDURES FOR CLASS IIB IMPLANTABLE WET DEVICES

These devices are class IIb implantable devices listed as WET devices in MDR. For these devices based on MCA's notification scope there is only one available option which is Annex IX Chapter I and III.

Class IIb Implantable WET	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Sampled per Generic Device Group	Continuing Sampling				
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A

Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed according to sampling plan. Manufacturer shall update the Post Market Clinical Follow-Up Reports at least annually.					
PSUR Assessment	Yes, manufacturer shall update PSUR at least annually. Updates will be followed and assessed through EUDAMED.					
SSCP Verification	Yes, manufacturer shall update SSCP at least annually "if indicated." MCA will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS IIB IMPLANTABLE DEVICES

These devices are class IIb implantable devices. For these devices based on MCA's notification scope there is only one available option which is Annex IX Chapter I and III.

Class IIb Implantable	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Every Device is reviewed	N/A	N/A	N/A	N/A	Every Device is re-reviewed
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A
Consultations for rule 14 and rule 21 products	N/A	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Report Assessment	Yes, assessed for every device. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed for every device. Manufacturer shall update the Post Market Clinical Follow-Up Reports at least annually.					
PSUR Assessment	Yes, manufacturer shall update PSUR at least annually. Updates will be followed and assessed through EUDAMED.					
SSCP Verification	Yes, manufacturer shall update SSCP at least annually "if indicated." MCA will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS III NON-IMPLANTABLE DEVICES

For these devices based on MCA's notification scope there is only one available option which is Annex IX Chapter I, II and III, which is the complete Annex IX procedure results EU Quality Management System Certificate + EU Technical Documentation Assessment Certificate.

Class III non-implantable	Initial Assessment	Surveillance 1	Surveillance 2	Surveillance 3	Surveillance 4	Re-Certification
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes

Technical Documentation Assessment	Every Device is reviewed	N/A	N/A	N/A	N/A	Every Device is re-reviewed
Testing During Surveillance	N/A	Yes	Yes	Yes	Yes	Yes
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	N/A	N/A	N/A	N/A	N/A	N/A
Consultations for rule 14 and rule 21 products	If applied	Repeating consultations may be applicable incase of a substantial change.				
Clinical Evaluation Report Assessment	Yes, assessed for every device. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed for every device. Manufacturer shall update the Post Market Clinical Follow-Up Reports at least annually.					
PSUR Assessment	Yes, manufacturer shall update PSUR at least annually. Updates will be followed and assessed through EUDAMED.					
SSCP Verification	Yes, manufacturer shall update SSCP at least annually "if indicated." MCA will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS III IMPLANTABLE DEVICES

For these devices based on MCA's notification scope there is only one available option which is Annex IX Chapter I, II and III, which is the complete Annex IX procedure results EU Quality Management System Certificate + EU Technical Documentation Assessment Certificate.

Class III non-implantable	**Initial Assessment**	**Surveillance 1**	**Surveillance 2**	**Surveillance 3**	**Surveillance 4**	**Re-Certification**
QMS Audit	Yes	Yes	Yes	Yes	Yes	Yes
Technical Documentation Assessment	Every Device is reviewed	N/A	N/A	N/A	N/A	Every Device is re-reviewed
Testing During Surveillance	N/A	Yes	Yes	Yes	Yes	Yes
Unannounced Audit	At least once every 5 years.					
Clinical Evaluation Consultation	Yes. Except cases listed in article 54 2b and 2c	N/A Except in case of a modification which may affect risk-benefit ratio.				
Consultations for rule 14 and rule 21 products	If applied	Repeating consultations may be applicable in case of a substantial change.				
Clinical Evaluation Report Assessment	Yes, assessed for every device. Manufacturer shall update the Clinical Evaluation reports based on its clinical evaluation plan.					
Post Market Clinical Follow-Up Report Assessment	Yes, assessed for every device. Manufacturer shall update the Post Market Clinical Follow-Up Reports at least annually.					
PSUR Assessment	Yes, manufacturer shall update PSUR at least annually. Updates will be followed and assessed through EUDAMED.					
SSCP Verification	Yes, manufacturer shall update SSCP at least annually "if indicated." MCA will verify initial version and the updates and upload to EUDAMED.					

REQUESTING OFFERS (PRE-APPLICATION)

When manufacturers want to receive an offer from MCA, they shall fill in MCA FR.MED.174 Pre-Application Form and MCA FR.MED.01 Annex-3, together with the requested documents in this form. Any type of communication shall be directly in between the MCA and the manufacturer or manufacturer's EU Authorized Representative. Consultancy companies, subcontracted individuals, MCA contact offices cannot submit pre-applications alone on behalf of the manufacturer. The manufacturers shall give special importance for using their official e-mails under their company domain as well as shall provide attention that the corresponding responses are coming from an e mail under maltaca.com domain. The filled in form and supporting documents shall be sent to mdsales@maltaca.com

Together with the above-mentioned pre-application form, the manufacturer shall provide user manuals or different type of supporting documentation providing details for the applied products. However detailed information may be requested for further evaluation.

In this phase MCA will try to get an overview of the manufacturer and it's products in order to estimate pricing.

All the currently used man/day fees and fixed price items will be publicly available in www.maltaca.com

It is important to know that MCA's prices will mainly depend on the time to be used for the assessment and this may vary when detailed review of the application is performed.

If the result of the initial control is positive MCA will provide an offer based on the estimated prices. If the manufacturer wants to accept the offer then the official application stage starts.

SUBMITTING APPLICATIONS

Once the offer is accepted, MCA will set up a team to perform a detailed application review. At this point the manufacturer shall fill in FR.MED.01 Application forms and its annexes and submit necessary documentation. An application review will be performed by MCA to do certain verifications, perform a completeness check, plan resources, and create plans to cover a certification cycle. If found acceptable MCA will draft a contract. Once the contract is signed by both parties the conformity assessment activities will start.
During the completeness check MCA may report some missing and incomplete documents. The manufacturer shall submit missing and incomplete documents within agreed deadline.
Application review will also include a sampling plan for the technical documentation and assessment program for the whole certification cycle. These documents will be shared with the manufacturer.

Refusal of the application by MCA and withdrawal of the application by the manufacturer will be reported through EUDAMED and manufacturer.

How Fees Are Calculated

Mainly the fees can be categorized in two main parts. Fixed fees and fees based on duration. Application fee and annual certificate usage fee have fixed prices based on product risk class. Audit and technical documentation review fees have man/day fees. For more detail please consult to MCA FR.MED.165 List of Standard Fees published in www.maltaca.com

Special Considerations In Contracts

It is important for a manufacturer to know that contracts mainly show pre-calculated fees. The resources to be used for conformity assessment tasks may change due to changing situations of the manufacturer or findings of the assessment. MCA will invoice the manufacturer based on the finally resources used and this may differ from the contract resulting either a lower or higher amount to be invoiced.

Additionally, the contract also mentions rates for travel fees or fees during the change assessments which can only be calculated if used and during the performance of the tasks.

MCA will also invoice manufacturers for reoccurring non-conformity response controls, time used for assessing appeals, time used for analyzing changes, time used to follow up expert panel opinions and for other possible used resources.

FR.MED.63 is the general terms which is a permanent annex for the contract. These terms generally set basic rules for conformity assessment tasks. These terms will always be available in the website and the manufacturer shall keep track of the changes on these terms.

Language Requirements

MCA accepts English for corresponding and for the language of documents/records for submitted documents.

The complete technical documentation content shall be in English. If especially third-party test reports are originally in other Languages, these shall be translated by a legally approved translation service provider. Please beware that a document which is not provided in English may be deemed as not existing therefore may lead to negative results.

The language of the QMS system securing compliance to MDR requirements shall be in English. These may include quality manuals, procedures, instructions, and records. The manufacturer may use some lower level of instructions in different language however this may require a translator to participate in audits.

Technical Documentation File Format

The files shall be in pdf format. The files shall be searchable. Titles and the locations of the documents shall be carefully and clearly organized and shall allow proper navigation and understanding. If not signed by legal electronic signatures (a valid electronic signature certificate appearing in the documents) the documents shall be signed by hand and the pages where these signatures exists shall be added to the searchable version of the documents. The files shall not be locked or protected.

TECHNICAL DOCUMENTATION CONTENT

The technical documentation content shall comply with MDR Annex II and III. In this part you may find a basic list of required documentation and certain guidelines. Please remember that each device requires specific concern to cover in order to show compliance to the MDR therefore this list and guidelines can not be taken as an exhaustive and complete list for every device.

Section 1 General and Device Description

Content	Guidance []shows possible documents to provide
Cover Page and Table of Content	
Revision History	
Description of the Manufacturer	*[Company History] [Legal Documents and Licences identifying locations]*
General Description of the Product, intended purpose, intended users	*Device description shall be clear and consistent. Misleading definition shall be avoided and as far as practical generic device definitions shall be used. Intended purpose, intended use and indications represent different terminologies and shall not be mixed. Intended users shall be clearly and correctly define such as medical professionals, nurses, lay person etc.*

Traceability Information, Product List, Model/Type List, Basic UDI-DI, EMDN, Catalogue Ref.	
The intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings. Intended use, clinical benefits, adverse effects	
Principles of operation of the device and its mode of action, scientifically demonstrated if necessary	
The rationale for the qualification of the product as a device the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;	*[Classification Checklist]* *(Proper justifications shall be provided for claiming that the device is a medical device and for selecting the applied rules. The justifications shall refer MDCG documents and borderline documents when applicable. More than one rule or sub rule may be applicable and the strictest shall apply)*
Explanation of any novel features	*Both scientifically proven technical and clinical novel features shall be clearly described*
Description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it	*Accessories or other devices shall be clearly defined with all possible variants. Packaging contents may be needed. Compatibility, performance and safety of the accessories and other products shall be proven.*
A description or complete list of the various configurations/variants of the device that are intended to be made available on the market	*[Table of Variants/Model]* *A table shall be provided with enough elements to differentiate each variant*
A general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition	*[Critical Component List] [List of Software Functions/Modules/Soups] [List of Chemical Composition/Formulation] [Evidences for safety and performance of components, parts, modules, compositions]* *(The information shall be provided as tables and shall allow matching each variant together with critical components, grades, parts, compositions etc. together with their suppliers). Manufacturer shall provide proper evidence for the safety and performance of sub parts such as proofs showing the part is a medical grade part, safety and performance reports, certificates etc.*
Photographs	*(Including each variant)*
Electrical Drawings Block Diagram	*Diagrams shall comply with engineering drawing rules*
Insulation Diagram	*Applied parts shall be identified*
Identification of Functional Safety Components	
Mechanical Drawings	*Tolerances, critical parts, material grades shall be identified*
Pneumatic Drawings	
Description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;	*[List/bill of Materials]* *(shall be provided as tables and shall allow matching each variant together with the materials, their grades, suppliers and shall be supported with proofs showing safety and performance of the materials.*
Identification of Substances	*(The manufacturer shall identify Human Blood and its Derivatives, Tissues of Animal Origin, Medicinal Products, and substances that are*

	systematically absorbed. Where the device does not contain such substances, a declaration shall be provided for their non-presence.)
Identification of Hazardous Chemical Substances	*(The manufacturer shall Hazardous Chemical Substances. Where the device does not contain such substances, a declaration shall be provided for their non-presence.)*
Technical specifications, such as features, dimensions, and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications	*(shall be provided as tables and shall allow matching each variant together with critical specifications, accessories, configurations, features)* *(the claimed specifications shall have proof documents provided in design related parts of the technical documentation.*
Overview of the previous generation or generations	*History of the device shall be clearly defined by outlining the differences between generations.*
Market History of the Device	*Please indicate the device is/was available in which markets since when together with the number of sold items. Please indicate current/previous device licences and certificates if there is any.*
Overview of identified similar devices available on the Union or international markets	

Section 2 Information To Be Supplied By The Manufacturer

Content	Guidance []shows possible documents to provide
Complete set of Labels and Markings	*[Label] [Markings] [Packaging Information] [Labelling instructions]* *Provide main label, sub labels, marking on the device, packaging label, information and illustrations on the label and packaging. The labels shall be lay out of actual labels.* *The labels or supporting documents shall provide information about dimensions, colour coding if used, position of the label and other relevant information*
IFU, Implant Card and other relevant informative documents	*[IFU] [Implant Card] [Service Manual] [Surgical Technique]* *IFU shall use a language for lay person. IFU shall contain consistent information about product description, product name, intended use, indications, contraindications, warnings etc.* *The warnings provided in the IFU shall be provided in a traceable way to Risk Analysis and shall not be provided as plain text.* *The manufacturer shall include other types of informative documents such as service manual, surgical technique etc. The documents shall be ready to publish lay outs. If electronic IFU's are used, these shall comply with relevant regulations and the documentation shall contain necessary explanations for reaching the documents.*

Section 3 Design and Manufacturing Information

Content	Guidance []shows possible documents to provide
Information on design stages applied to the device	*Provide information on which kind of activities are performed in each design stage preferably through a table by referring activities, plans, protocols, inputs, outputs. Documents proving internal and external reports/validation/verifications shall be referred.*
Design History	*Provide information, preferably through a table, on major design changes which are previously approved or waiting to be assed. The information shall clearly outline major design changes for previously MDD certified devices when they are in transition to MDR.*
Manufacturing Flow	*Provide an illustrative demonstration of manufacturing steps which in sequence describes activities starting from incoming inspection to release.*
Information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing.	*[Process tables] [Process Validation Master Plans]* *Provide information and identify specifications preferably through a table. Identify sites, locations and outsourced processes.* *The information shall outline critical parameters, adjuvants,*
Manufacturing Procedures and Instructions	*[Manufacturing Procedures] [Manufacturing Instructions]*
Product specification, packaging specification, storage specification, incoming inspection, continuous monitoring, in process controls, final product testing, installation specification	
Environmental Conditions	*Provide information about required environmental conditions such as clean rooms.*
Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed	*Through a table, identify all sites and match them with activities and suppliers/subcontractors if applicable.*
List of Critical Suppliers / Subcontractors	*Provide a list of critical suppliers by mentioning the activities they perform, the goods/services they provide. Justify why they are selected as critical.*
Critical Supplier Agreements	*Provide critical supplier agreement which secure compliance to MDR including unannounced site audits to critical suppliers.*

Section 4 General Safety and Performance Requirements

Content	Guidance []shows possible documents to provide

General safety and performance requirements	*[GSPR Checklist]* *Include a checklist provides following items as a table,* *- Requirement of MDR* *- Statement whether the requirement is applicable or not.* *- Justification in case a requirement is selected as non-applicable* *- Reference to Common Specifications, Harmonized Standards or other relevant solutions including a reference to their version.* *- method or methods used to demonstrate conformity with each applicable* *- Cross reference to controlled documents and precise reference to the location in the technical document* *- Unique summary of applied methods, major validation and verification outcomes.*
Essential requirements for Machinery Directive	*If your device is also a machinery according to 2006/42/EC, please provide a checklist to demonstrate compliance to machinery directive.*

Section 5 Benefit-Risk Analysis and Risk Management

Content	Guidance []shows possible documents to provide
Risk Management Documentation	*[Risk Management Procedure]* *[Risk Management Plan]* *[Risk Management Team][Supporting evidence for competency of the risk management team]* *[Risk Analysis]* *[Risk Management Report]* *(The documentation shall mainly consist of above listed items. The manufacturer shall indicate whether EN 14971 is applied or not. If not applied justification of the superiority of the selected methods needs to be provided.* *The risk methods need to identify gradings for risk levels in terms of probability and severity. Each individual risk shall be downgraded as low as possible by applying state of art risk control methods even though the risk is low before applying any risk control method. The possible counter effects of applied risk control measures need to be evaluated. The manufacturer shall provide risk-benefit assessment for each individual risks as well as an overall risk-benefit assessment.* *The manufacturer shall provide a residual risk assessment for each individual risk as well as an overall residual risk assessment.* *Especially for the design risks the risk control measures shall first apply risk control by design.* *The manufacturer shall provide risk analysis for design, manufacturing, post market related risks and each major part of the analysis shall easily be identified and separated.* *Each critical sub category such as clinical risks, usability risks, cybersecurity risks, biocompatibility risks, process risks, software risks shall be clearly identified. The whole risk management, including each individual risk shall have traceability information for connecting relevant documents and QMS of the manufacturer.*

Section 6 Product Verification and Validation

Section 6A Pre-Clinical Verification and Validation

In general, if a type is selected for testing, proper evidence shall be provided whether the worst-case scenario is covered. Where testing provided ISO 17025 accreditation certificate and scope of the laboratory shall be provided.(valid at the time of the testing)

Content	Guidance []shows possible documents to provide
Pre-Clinical Literature Evaluation	*Include a literature evaluation within a systematic approach to identify pre-clinical data that is applicable for the device. The pre-clinical literature evaluation needs to be updated periodically. Scientifically justify the ability to use data. The manufacturer may also decide to separate pre-clinical literature evaluation for below specific topics.*
Benchmarking Studies and Tests	
Validations and Justifications for Expected Lifetime	
Justification for transability of existing test evidence	*Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service;*
Key Design Verifications	*Provide results of key design verifications applied for devices especially for class IIb implantable and class III devices. Identify design inputs and outputs.*
Biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user	*[Biocompatibility Evaluation]* *[Biocompatibility Tests 10993 series]*
Chemical Characterization	
Physical Characterization	
Microbiological Characterization	
Mechanical Tests	
Electrical Safety Tests	*For example, type testing and testing according to 60601 series.*
Electromagnetic Compatibility Tests	
Other Performance and Safety Testing	
Functional Safety Engineering File	
Usability Engineering File	*[Usability Procedure][Usability Protocole/Plan][Usability Tests][Usability Report]* *Usability evaluation and results of the usability tests*
Software Verification and Validation	*[Software Lifecycle Procedures]* *[Software Definition, Classification, Information about functions and modules]* *[Software Requirements]* *[Software Traceability Matrix]* *[Identification of SOUPs]* *[Software risk assessment]* *[Software Unit Testing]* *[Software Validation/Test Results]*

	[Penetration Testing] *[Stress Testing]* *[Configuration Management]*
Stimulated Use Testing	
Cadaver Testing	
Product Stability Testing	*Results of the accelerated and real time testing need to be provided. If real time stability studies continue, a plan needs to be provided.*
Packaging Stability Testing	*Results of the accelerated and real time testing need to be provided. If real time stability studies continue, a plan needs to be provided.*
Transport Validation	*Provide results of simulated testing (such as according to ISTA standards) and real time testing results. Justify selected real time routes cover worst case scenario.*
Cleaning Validation	
Safe Disposal Validation	

Section 6B Special Requirements For Devices Incorporating a Substance Considered to be a Medicinal Substance

Content	Guidance []shows possible documents to provide
Intended Use and the Function of Medicinal Product(s) for the Medical Device	
Chemical and Pharmaceutical Information of Medicinal Product(s)	
Strength/Concentration and Presentation of Medicinal Product(s)	
Shelf Life Information (package unopened and in use)	
Manufacturer(s) of Medicinal Product(s)	
Description of Manufacturing Site(s) of Medicinal Product(s)	
Copy of Marketing Authorisation(s) or Equivalency of Manufacturing Authorisation in Accordance with Directive 2001/83/EC (If the manufacturing site(s) is outside of EEA.)	
GMP Compliance Document or Other Proof of GMP Compliance of the Manufacturer(s) (or EudraGMP Manufacturing Authorisation Reference)	
European Pharmacopoeia (Ph. Eur.) Certificate(s) of Suitability (If the medicinal product(s)/substance(s) is an active substance.)	
Active Substance Master File (European Drug Master File) (If the medicinal product(s)/substance(s) is an active substance or the active substance(s) is used during manufacturing.)	
Tests to confirm safety, quality and usefulness of the substance	
Results of Previous Consultations	

Section 6C Special Requirements For Devices Incorporating Materials to be Absorbed by or Locally Dispersed in The Human Body

Content	Guidance []shows possible documents to provide
Description of the materials intended to be absorbed by or locally dispersed in the human body	
Absorption, distribution, metabolism and excretion;	
Possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;	
Evaluation of the information of "the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action" on the Labels	
Evaluation of warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side-effects and risks relating to overdose in Information for Use.	
Resorption kinetic containing information such as; -resorption rate (mass loss and molecular weight reduction), decomposed material, mechanical strength changes over time, resorption completion time	
Evaluation of absorption, distribution, metabolism and excretion profiles of the device consisting of substance or combinations of substances *Pharmacokinetic studies of the resorbable product to determine the absorption, distribution, metabolism and excretion (ADME) route(s), mechanism(s), and timeline of excretion.*	
Evaluation of systemic absorption by the human body Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body but not systemically absorbed does not require consultation Medicinal Products Authorities. Devices, or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose a consultation to one of the Medicinal Products Authority. Medicinal Products Authority refers to one of competent	

authorities designated by member states in accordance with 2001/83/EC and EMA.	
Evaluation of possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions	
Evaluation of Local Tolerance (Evaluation of local tissue response during the degradation process to assess adverse reactions, such as inflammation, toxicity, or immune response to degradation by products during the device resorption period (biocompatibility evaluation of degradation by products)	
Evaluation of toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device local tolerance.	
To evaluate the justification given in the Clinical Efficiency and Safety Evaluation	

Section 6D Special Requirements For Devices Incorporating Substances which are CMR or Endocrine Disrupting Substances

Content	Guidance []shows possible documents to provide
Definition of Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) and/or endocrine disrupting substances	*Refer Annex I 10.4.2 for more detail*
Justification where CMR concentration above 0.1 % weight by weight	*Refer Annex I 10.4.2 for more detail*

Section 6E Special Requirements For Devices with a Measuring Function

Content	Guidance []shows possible documents to provide

Description of the methods used in order to ensure the accuracy as given in the specifications	
Validation for measuring accuracy through lifetime of the device	

Section 6F Special Requirements For Devices In Sterile or Defined Microbiological Condition

Content	Guidance []shows possible documents to provide
Bioburden Testing	
Pyrogen testing	
Description and Suitability Of Sterilization Method	
Sterilization Validation Documentation	
Validation For Sterile Barrier Systems	
Testing For Sterilization Residuals	
Aseptic Filling Validation	

Section 6G Special Requirements For Devices To Be Connected or Combined With Other Devices

Content	Guidance []shows possible documents to provide
Description of the combinations and accessories	
Validation for compatibility with other devices	

Section 6H Clinical Data

Content	Guidance []shows possible documents to provide
Clinical Evaluation Procedure	
Equivalent/Similar Devices	*If clinical data from equivalent/similar devices to be used provide evidence for proving equivalance/similarity.*
Clinical Evaluation Plan	
Clinical Evaluation Report Authors CV's and assessment of their conflict of interest	
Literature search protocol and report	
Appraisal Criteria	
List of selected and excluded articles including the reason for exclusion	
Full text of available clinical data	
Identification of other types of used clinical data	
Clinical Evaluation Report	

Clinical Investigation (including PMCF investigations)	*Complete clinical documentation including* *- Clinical investigation plan* *- Clinical investigation report* *- Ethics committee approval(s)* *- Competent Authority approval(s)* *Publications in scientific journals (if applicable)*
Transferability of Clinical Investigations performed outside EU	*Provide a justification for compliance and transferability of the data for EU Regulations and population.*
Previous Clinical Consultations	*Provide the result of the clinical consultation for class III implantable devices and class IIb Active Devices intended to administer and/or remove a medicinal product*
SSCP	*Provide SSCP for class III devices and implantable devices*

Section 7 Post Market Surveillance Documentation

Content	Guidance []shows possible documents to provide
Post Market System Procedures	
PMS Plan	
PMCF Plan/Protocol	
PMCF Report	
PSUR Report	
PMS Report for class I devices	
Procedures for Vigilance	
Summary of previous incidents and recalls	

Section 8 Declaration Of Conformity

Content	Guidance []shows possible documents to provide
Declaration of Conformity	*Provide draft declaration of conformity*

Section 9 Other Required Documentation

Content	Guidance []shows possible documents to provide
EU Representative Agreement	*For manufacturers outside the Union*

CONFORMITY ASSESSMENT TASKS

After signing the contract, the manufacturer shall provide all technical documentation and QMS documentation to MCA. Conformity assessment projects starts after initiating the contact and allocating resources. Conformity assessment tasks mainly consist of two main group of activities. These are audits and Technical Documentation Reviews. These two main group activities will be performed separately from each other.

Technical Documentation Pre-Review

Only during the initial application, MCA will perform a pre-review to technical documentation. The manufacturer shall provide brief explanation and document navigation by using FR.MED.80 form. MCA reviewers will use the same form to perform pre-review. At this stage the provided content is reviewed for their completeness and comprehensiveness. As a result of this review, MCA shall decide on continuation of the conformity tasks. If major issues are found, the manufacturer shall complete in maximum 6 months. If minor issues are reported these can be reviewed during the detailed technical documentation review. If the reported non-conformities are not properly corrected within defined timelines and conditions or if there are many major nonconformities found meaning that the device has not completed its pre-market lifecycle or meaning product safety and performance is not fully demonstrated, MCA will withdraw the application of the device in question. If findings are addressed properly MCA will continue with detailed technical documentation review. MCA will perform this review to the devices that are going to be reviewed initially and the manufacturer is responsible for reflecting necessary corrective actions if there are remaining technical documentation which is not yet sampled.

Stage 1 Audit

Only during the initial application, MCA will perform a stage 1 audit. This audit is an off-site audit. In this audit the preparedness of the manufacturer's QMS and readiness to the stage 2 QMS audit will be evaluated. The non-conformities reported during this audit shall be closed within maximum 4 months. The manufacturer shall provide corrections and corrective actions for each non-conformity reported during this audit however if MCA assessment team observes that all major non-conformities are downgraded to minor level, they may decide to check remaining issues during the stage 2 audit.

Detailed Technical Documentation Review

Detailed technical documentation reviews are part of initial and ongoing assessments. Especially where technical documentation is sampled, MCA will perform detailed technical documentation review during the surveillance and re-certification. At this stage the provided technical documentation will be reviewed by relevant product reviewer and/or clinical specialist deeply to verify the product complies with safety and performance requirements of MDR. All reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months.

Technical Documentation PMS and Change Review

If a technical documentation was subject to detailed review priorly, if the device falls into a category which sampling is not applicable or if there are too few devices in the same sampling category with this device, MCA will perform a limited technical documentation review focusing on PMS and changes during the ongoing assessments. All reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months.

Stage 2 Audit

During the initial application after stage 1 audit, MCA will perform stage 2 audit to verify effectiveness of QMS and suitability of technologies applied to the production of the device. Stage 2 audits are onsite audits. All reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months.

Surveillance Audit

Surveillance audits are onsite audits to verify applied QMS and production technologies continue to conform to the requirements of MDR. If all reported non-conformities are minor, the verification of the corrections and corrective actions will be checked by MCA during the next surveillance audit. If a major non-conformity exists, all reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months. The first surveillance audit shall be performed in maximum 12 months after the certification date. Other following routine surveillance audits shall be performed within maximum 12 months after

the previous surveillance audit. Surveillance audits may be performed at a time earlier than 12-month periods if necessary. For class III products; surveillance assessments shall include tests in accordance with Annex IX Section 3.5 of (EU) 2017/745 Regulation. The scope of this testing shall include a test of the approved parts and/or materials. Additionally, if appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices shall be performed.

Re-certification Audit

Re-certification audits are onsite audits to verify applied QMS and production technologies continue to conform to the requirements of MDR. All reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months. Since surveillance assessments will require re-review of certain devices the manufacturer shall provide special attention to apply for re-certification which is proper enough to complete all necessary activities

Unannounced Audit

Unannounced audits are special onsite audits that are normally performed once in every 5 years however MCA may increase the frequency based on certain parameters. Unannounced audits include testing relevant devices. If all reported non-conformities are minor, the verification of the corrections and corrective actions will be checked by MCA during the next surveillance audit. If a major non-conformity exists, all reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months.

Response To the Non-Conformities

Even though there are maximum available deadline limitations for each type of conformity assessment task, the MCA assessment team may enforce limitations for deadlines especially due to the criticality of the non-conformity.

Except for application review completeness check, technical documentation pre-review and clinical evaluation findings the client shall fill in FR.MED.53 form as a CAPA plan.

It is very important for a manufacturer to realize that CAPA plan will be a tool for the MCA assessment team to verify all actions to be initiated therefore which may allow complete resolution for the non-conformity. For this reason,
- CAPA plan shall be a result of several meetings, impact analysis, gap analysis performed after receiving the finding report.
- CAPA plan shall list all details of the activities to be performed within a sequence.
- CAPA plan shall document the actual changes to be provided in documents by mentioning section/page and other relevant information.
- CAPA plan shall not be oriented solely to the reported subject but all necessary effected activities shall be planned to solve root reason.

If the CAPA plan is prepared very generally, by providing policy or declaration level claims, this can cause failure.

General Considerations

- The manufacturer shall take possible workload of MCA for planning activities which comes with a specific deadline.
- The audits include supplier audits.
- Besides from routine conformity assessment tasks, MCA may raise non-conformities to the Manufacturer as a result of decision-making phase, internal control or as a result of external audits.
- MCA may take samples from the market for testing.

APPEALS ON CERTIFICATION DECISIONS

Manufacturer has right to appeal on the certification decisions taken by MCA. Once the appeal is received, it is evaluated that whether the appeal is related to the decision on/for certification.
If the appeal is not related to the decision on/for certification, then written information shall be provided by MCA to the appeal holder within 7 days.
If the appeal is related with the decision on/for certification, then the Quality Manager shall notify the issue to appeal committee and provides written information to the appeal holder within 7 days.
If accepted, MCA will set up a committee to evaluate the appeal and this committee will provide the recommended decision to the certification committee. The certification committee then will provide final decision and inform the appeal holder accordingly.