Complete MDR Assessment Guideline for Manufacturers

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Abbreviations

SZUTEST: SZUTEST Konformitätsbewertungsstelle GmbH
MDR: Regulation (EU)2017/745

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@szutest-germany.de

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 SZUTEST. 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 SZUTEST shall evaluate this plan. If SZUTEST 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 SZUTEST 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 SZUTEST 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. SZUTEST 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.

SZUTEST's notification covers following quality assessment-based procedures,
- Annex IX Chapter I and III (EU Quality Management System). In this procedure SZUTEST 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 SZUTEST 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 SZUTEST 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 SZUTEST 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 SZUTEST.

PROCEDURES FOR CLASS IS/IM/IR and Sterile Systems or Procedure Packs

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 SZUTEST will not systematically review them as a "technical documentation assessment".
The review and verifications will limit to the below parameters;
- In the case of devices placed on the market in a sterile condition, to the aspects relating to establishing, securing, and maintaining sterile conditions and/or,
- In the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements and/or,
- In the case of reusable surgical instruments to be placed on the market the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing, and the related instructions for use.
- In the case of a sterile systems or procedure packs aspects of the sterilization procedure for ensuring sterility until the sterile package is opened or damaged.

Class Is/Im/Ir and Sterile Systems/Procedure Packs	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. SZUTEST will not perform a full review. The available technical documentation will be verified for sterility, metrology, re-use aspects and sterilization procedure for ensuring sterility until the sterile package is opened or damaged.					
Testing During Surveillance	N/A	N/A	N/A	N/A	N/A	N/A
Unannounced Site 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. SZUTEST will verify the reports.					
PSUR Evaluation	N/A. PMS reports will be verified by SZUTEST.					
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 SZUTEST 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	Based on Sampling				
Unannounced Site 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 Evaluation	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 SZUTEST 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	Based on Sampling				
Unannounced Site 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 Evaluation	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.” SZUTEST 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 SZUTEST’s notification scope there is only one complete set of available option which is Annex IX Chapter I and III.
As a coupled conformity assessment route, if the manufacturer has EU Type Examination Certificate according to Annex X from another Notified Body, Annex XI Part-A Production Quality Assurance route may be followed.

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	Based on Sampling				
Unannounced Site 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 Evaluation	Yes, manufacturer shall update PSUR at least annually. SZUTEST 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 SZUTEST's notification scope there is only one complete set of available option which is Annex IX Chapter I and III.
As a coupled conformity assessment route, if the manufacturer has EU Type Examination Certificate according to Annex X from another Notified Body, Annex XI Part-A Production Quality Assurance route may be followed.

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	Based on Sampling				
Unannounced Site 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 during the initial assessment. 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 Evaluation	Yes, manufacturer shall update PSUR at least annually. SZUTEST 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 SZUTEST's notification scope there is only one complete set of available option which is Annex IX Chapter I and III.
As a coupled conformity assessment route, if the manufacturer has EU Type Examination Certificate according to Annex X from another Notified Body, Annex XI Part-A Production Quality Assurance route may be followed.

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	Based on Sampling				
Unannounced Site 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 Evaluation	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." SZUTEST will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS IIB IMPLANTABLE DEVICES

For these devices based on SZUTEST's notification scope there is only one complete set of 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.
As a coupled conformity assessment route, if the manufacturer has EU Type Examination Certificate according to Annex X from another Notified Body, Annex XI Part-A Production Quality Assurance route may be followed.

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	Based on Sampling				
Unannounced Site 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 Evaluation	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." SZUTEST will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS III NON-IMPLANTABLE DEVICES

For these devices based on SZUTEST's notification scope there is only one complete set of 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.
As a coupled conformity assessment route, if the manufacturer has EU Type Examination Certificate according to Annex X from another Notified Body, Annex XI Part-A Production Quality Assurance route may be followed.

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 Site 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 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 Evaluation	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." SZUTEST will verify initial version and the updates and upload to EUDAMED.					

PROCEDURES FOR CLASS III IMPLANTABLE DEVICES

For these devices based on SZUTEST's notification scope there is only one complete set of 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.
As a coupled conformity assessment route, if the manufacturer has EU Type Examination Certificate according to Annex X from another Notified Body, Annex XI Part-A Production Quality Assurance route may be followed.

Class III 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 Site 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 Evaluation	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." SZUTEST will verify initial version and the updates and upload to EUDAMED.					

REQUESTING OFFERS (PRE-APPLICATION)

When manufacturers want to receive an offer from SZUTEST, they shall fill in FR.MED.174 Pre-Application Form and FR.MED.01 Annex-3, together with the requested documents in this form. Any type of communication shall be directly in between the SZUTEST and the manufacturer or manufacturer's EU Authorized Representative. Consultancy companies, subcontracted individuals, SZUTEST 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 szutest-germany.de domain. The filled in form and supporting documents shall be sent mdsales@szutest-germany.de .

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 SZUTEST will try to get an overview of the manufacturer and its products in order to estimate pricing.

All the currently used man/day fees and fixed price items will be publicly available in www.szutest-germany.de as German and English Language.

It is important to know that SZUTEST'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 SZUTEST 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, SZUTEST 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 SZUTEST to do certain verifications, perform a completeness check, plan resources, and create plans to cover a certification cycle. If found acceptable SZUTEST will draft a contract. Once the contract is signed by both parties the conformity assessment activities will start.
During the completeness check SZUTEST 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 SZUTEST and withdrawal of the application by the manufacturer will be reported through EUDAMED.

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 FR.MED.165 List of Standard Fees published in www.szutest-germany.de .
Time spent will be calculated based on the product risk class. Following factors will increase the duration per device,
- PSUR, PMCF, SSCP, PMS Reviews
- routine reviews on Technical Documentation changes
- devices in sterile condition and number of applied sterilization methods.
- devices requiring biocompatibility review
- devices incorporating software
- devices that are absorbable or locally dispersed
- pre-market clinical investigation review
- Medicinal Product Authority Consultation
- Clinical Evaluation Consultation Procedure
- consultation procedure for devices that are systemically absorbed

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. SZUTEST 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.

SZUTEST 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

SZUTEST 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 exist 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 cannot 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 Licenses 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 defines 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	*(shall be provided as tables and shall allow matching each variant together with critical specifications, accessories, configurations, features)*

product specification made available to the user, for example in brochures, catalogues and similar publications	*(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 licenses 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, color 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 to claim state of art (Studies, Tests, Literature etc.)	*Manufacturer shall prove the applied device is state of art. Provide a comparison table with benchmarked devices to compare critical device characteristics. Especially, for the devices which does not have international standards where the safety and performance characteristics are defined, the manufacturer shall use literature or special tests to prove the device is state of art. Special tests may also be necessary where specifications or performance characteristics are unknown to the manufacturer. The manufacturer shall provide a report to summarize results of the benchmarking studies.*
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;	
Local tolerance	
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.	
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.	
In the absence of above studies, a justification shall be provided	
The label shall bear all of the following particulars; the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action	
The instructions for use shall contain all of the following particulars; 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;	

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 equivalence/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*

QUALITY MANAGEMENT SYSTEM DOCUMENTATION CONTENT

During the formal application the manufacturer shall submit the documentation that is prepared according to MDR.
Below you may find a list of minimum documentation required for the QMS but this may change from manufacturer to manufacturer based on its processes and applied products.

Content	Guidance [] shows possible documents to provide
Quality Manual	*Prepared based on MDR by using EN ISO 13485 as a base.*
Quality Policy	*Compatible to MDR compliance and based on applied products.*
Quality Plan	
Processes and their interaction	
List of Quality Documents (Procedures, Instructions, Lists, Plans, Forms, etc.)	
Organization Scheme	
Job Descriptions	*Covering tasks for MDR compliance, including PRRC*
Procedures based on EN ISO 13485	*Such as,* *Control of documents, control of records, management review meetings, infrastructure, customer communication, design and development, purchasing, control of production and service provision, assembly, service, particular requirements for sterile medical devices, validation of processes for production and service provision, particular requirements for validation of processes for sterilization and sterile barrier systems, identification, traceability, customer property, preservation of product, control of monitoring and measuring devices, feedback, complaint handling, reporting to regulatory authorities, internal audit, monitoring and measurement of product, control of nonconforming product, data analysis, CAPA procedures etc..*
Post Market Surveillance System Procedures	
Trend Reporting Procedure	
Post Market Surveillance Plans	
Post Market Clinical Follow-Up Procedures	
PMCF Plans	
Clinical Evaluation Procedure	
Clinical Evaluation Plans	

Procedures for handling SSCP and PSUR	*Including tasks to be fulfilled for Notified Body, for Authorities and for EUDAMED*
Procedure for handling Notified Body conformity assessment activities such as communication, surveillance activities, unannounced site audits, testing during surveillance, sampling from the market, etc.	
Produce for handling EUDAMED registration and data submission	
Procedure for handling UDI-DI	*Both for using traceability information in the QMS system and labeling aspects.*
Procedure for (EU)2017/745 Vigilance System	
Procedure for handling Technical Documentation creation	
Procedure for handling labeling according to (EU)2017/745	
Procedure for handling product risk management according to (EU)2017/745?	
Procedure for handling substantial changes according to (EU)2017/745	
Procedures for applied quality control tests	*Including their validation and acceptability of the results.*
A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under (EU)2017/745 Regulation and the undertaking by the manufacturer in question to apply those procedures.	
A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures	
A description of the procedures in place to keep up to date the post- market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures	
A description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.	
Documentation on the clinical evaluation plan	

CONFORMITY ASSESSMENT TASKS

After signing the contract, the manufacturer shall provide all technical documentation and QMS documentation to SZUTEST. Conformity assessment projects start 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, SZUTEST will perform a pre-review to technical documentation. The manufacturer shall provide brief explanation and document navigation by using FR.MED.80 Technical Documentation Pre-Review Checklist. SZUTEST 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, SZUTEST 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, SZUTEST will withdraw the application of the device in question. If findings are addressed properly SZUTEST will continue with detailed technical documentation review. SZUTEST 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, SZUTEST 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 SZUTEST 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, SZUTEST 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, SZUTEST 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, SZUTEST 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 on-site audits. All reported non-conformities, regardless from its classification, shall be effectively and completely closed within maximum 4 months.

Surveillance Audit

Surveillance audits are on-site 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 SZUTEST 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 Regulation (EU) 2017/745. 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 on-site 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 Site Audit

Unannounced site audits are special on-site audits that are normally performed once in every 5 years however SZUTEST may increase the frequency based on certain parameters. Unannounced site audits include testing relevant devices. If all reported non-conformities are minor, the verification of the corrections and corrective actions will be checked by SZUTEST 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 SZUTEST 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 Nonconformity Follow-up Report as a CAPA plan.

It is very important for a manufacturer to realize that CAPA plan will be a tool for the SZUTEST 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 SZUTEST for planning activities which comes with a specific deadline.
- The audits include suppliers audits.
- Besides from routine conformity assessment tasks, SZUTEST may raise non-conformities to the Manufacturer as a result of decision-making phase, internal control or as a result of external audits.
- SZUTEST may take samples from the market for testing.

APPEALS ON CERTIFICATION DECISIONS

Manufacturer has right to appeal on the certification decisions taken by SZUTEST. Once the appeal is received SZUTEST will check whether if it is related with a certification decision of SZUTEST or not within 7 days and inform the appeal holder. If accepted, SZUTEST will set up a committee to evaluate the appeal and this committee will provide the recommended decision to the certification committee within 7 days. If a decision cannot be taken within 7 days by committee, the justification shall be recorded. The certification committee then will provide final decision and inform the appeal holder accordingly.

STRUCTURED DIALOGUES

The structured dialogue meeting shall be established to ensure that both the company and SZUTEST effectively manage their conformity assessment processes and comply with requirements at every stage regarding to MDCG 2022-14 and MDCG 2019-6 Rev.5. This process ensures smooth communication and efficient decision-making through a well-defined series of discussions.

The structured dialogue aims to provide the manufacturer with necessary information and guidance regarding the process, not consultancy. Both parties shall follow the defined process and requirements, ensuring that applications and further process are completed more effective and smoothly. The structured dialogue process shall be conducted in accordance with the principles of independence, impartiality, and objectivity as per the requirements of MDR;
- Ensuring open and effective continuous communication between the manufacturer and SZUTEST.
- Increasing the efficiency and continuity of the conformity assessment process.
- Making the timeline and requirements of the assessment process transparent.

The main purpose of structured dialogue is to decode requirements but not the solutions. The manufacturer is ultimately responsible for fulfilling the requirements therefore the outputs of the structure dialogue cannot be a base of the assessment.

The company is responsible for providing all necessary information correctly and comprehensively, while SZUTEST reviews this information and follows the necessary steps for the conformity assessment. In the framework of the structured dialogue, the manufacturer's questions shall adhere to the SZUTEST's principles of independence, objectivity, and impartiality. This means that questions shall be specific rather than open-ended and shall not seek guidance on "how to comply," thereby preventing any consultancy services from being provided.

The structured dialogue cannot propose specific solutions and cannot provide conclusions that can only be provided as a result of routine conformity assessment tasks. The manufacturer shall be aware of this situation and shall accept that new/altered requirements may come into force after performing structured dialogues.

The structured dialogue cannot include topics that are under the responsibility of the authorities and expert panels.

Scope of Structured Dialogue
We can discuss below topics; **Prior to the application (pre-application):** • Timelines for conformity assessment until certification, including estimated timelines for possible special procedures, e.g. drug-device combinations, companion diagnostics or orphan devices • Clarification on the data /documentation to be provided with the application • If applicable, procedure related to the onboarding as a customer, including access to a possible portal, and relevant procedural guidance • Options of conformity assessment procedures and - for legacy devices - timing for submission of individual technical documentation, i.e. discussion about the manufacturer's "conformity assessment program" • Information on all necessary conformity assessment activities - e.g., initial audit, (annual) surveillance audits, technical documentation assessments, assessment of changes / change notification - and any special (process) audits or additional (sub-)assessments / reports for TD assessment not explicitly mentioned in the Regulations; it should be specified if such activities are required or not and if they will be performed once or more often • Pricing and fees • Exchange of information about involved persons for different conformity assessment activities on both sites (Notified body and manufacturer) including contact persons • Applicable standards and guidance documents • How to apply and reference standards or guidelines • Referring to the possibility of getting advice by EMA expert panels (Art. 106, Art. 61 (2) MDR) • Possibility of "modular approach" (e.g., review of specific parts of the technical documentation / clinical evaluation at different points in time, to allow (earlier) feedback on testing/evaluation strategies)

• General requirements regarding and acceptance of (third party) test reports / certificates • Leveraging evidence from previous assessment • Qualification and Classification of a product (Annex VII 4.2 (d) MDR) • Requirements for sampling of devices for technical documentation assessments • Best practice guidance for technical documentation (TD), including preferred structure of TD **During the conformity assessment activities (post-application):** • Clarification of missing data •If test reports were initially not accepted, next steps regarding the submission of new test data • Timelines for providing additional missing data • Early information / discussion on a planned significant/substantial change of a product (design) and the consequences for the certification process •Leveraging evidence from previous assessment • Appropriateness of equivalence claim (see Art. 61(4), second indent, MDR • Sufficiency of quality / quantity of clinical data • Applicability of Article 61(10) MDR • Appropriateness of PMCF plan • Clarification of non-conformities raised
We cannot discuss (non-exhaustive examples): – Complete gap analyses – Check for MDR/IVDR readiness – Review mock files for MDR/IVDR conformity – Provide technical solutions – Explain how the manufacturer should meet specific regulatory requirements – Provide answers that could only be answered by performing a complete review during the routine conformity assessment process – Verify the acceptability of existing clinical data.

In order to request a structured dialogue; The manufacturer shall first review MDR, other relevant guidelines, guidelines and documents published by SZUTEST to verify if the questions have clear answers for the relevant topics.

If there is no clear answer, the manufacturer shall comply the request and reach out SZUTEST by using FR.MED.206 Structured Dialogue Application Form and Meeting Minutes. The completed form shall send to mdsales@szutest-germany.de or the relevant head of audit team's e-mail address. FR.MED.206 Structured Dialogue Application Form and Meeting Minutes is published on SZUTEST's web page.

Following table shall be used to formulate the agenda;

Question/ Agenda Item	
Background Information *Refer relevant requirements of MDR or guidelines*	
Current Understanding / Proposed Answer	
Attachments	

If the proposed agenda/questions fall in a group where SZUTEST has got already a clear response from frequently asked questions, SZUTEST may suggest providing a response via e-mail instead of arranging a dedicated meeting.

If the proposed agenda falls into the scope of structured dialogue meeting, SZUTEST and the manufacturer will suggest on book the meeting for an available time. The time slots dedicated by the meetings shall be ideally half an hour. This duration can be increased based on the availability of the questions however it shall not exceed an hour.

The structured dialogue meetings shall be free of charge. However certain limitations apply. There is no limitation for the written responses however, SZUTEST may require from the company to comply the questions and handle them in a meeting. For the meeting following limitations apply;
- During the pre-application and application stage: Limited to 3 meetings.
- Changes and Scope Extensions: Limited to 2 meetings.
- Ongoing conformity Assessments: Limited to 2 meetings per project per year.

After executing the meeting, the manufacturer shall compile the summary of responses and meeting minutes on FR.MED.206 Structured Dialogue Application Form and Meeting Minutes and SZUTEST shall approve the meeting result.