Contents

The Technical Documentation provided by the manufacturer shall be assessed regarding the aspects applicable from the following subsections.

General Aspects

Technical Documentation (TD) Structure and Content

If available provide an identification of the Technical Documentation in this section, manufacturers might revision control their Technical Documentation, if they do so, a reference to that revision or date of compilation shall be given here.

The Technical Documentation structure is preferably in order of MDR Annex II & III but must always cover all elements from MDR Annex II & III.

If a different structure is chosen by the manufacturer, a reference list linking the corresponding subsection of Annex II & III to the provided Technical Documentation can be helpful.

The Technical Documentation must be clear, organized, readily searchable and prepared in an unambiguous manner.

A Table of content must be available, sections and annexes shall be numbered, documents shall be traceable by document ID and / or other means such as e.g. title / version / revision, date.

The Technical Documentation must be correct, consistent, up-to-date and complete and it must cover all variants and trade names of the device as well as provided accessories with the device.

Project Management

This section shall provide an overview of the major milestones in a project. A table provides an overview of the key milestones and shall be completed with the dates when an activity was concluded.

The table given in the template shall be extended by additional lines where more milestones were passed during the project (e.g. 2nd Request for Additional Information / Deficiency Report).

1.1 Device Description and Specification, including Variants and Accessories

1.1.1 Device Description and Specification

1.1.1.1 Product or Trade Name

Include the product or trade name. The product name shall be consistent with the product displayed on the products' packaging and marketing brochures, and the application.

1.1.1.2 General Device Description, intended Purpose and intended User

Provide a general description of the device, including the intended purpose per MDR Chapter 1 and intended user for the device.

1.1.1.3 Basic Unique Device Identifier

Provide the Basic UDI DI attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by

means of product code, catalogue number or other unambiguous reference allowing traceability.

1.1.1.4 Intended Patient Population

Provide the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contraindications, warnings.

1.1.1.5 Principles of Operation of the Device and its Mode of Action

Provide a description of the principles of operation of the device and its mode of action. This shall be scientifically demonstrated by the manufacturer if necessary.

Justification whether it is a medical device according to the mode of action. Different mode of actions could be: absorption, degradation.

1.1.1.6 Qualification of the Product as a Device

Provide and check the rationale for the qualification of the product as a medical device per MDR.

1.1.1.7 Risk Class of the Device

Check if the device falls under the medical device regulation (MDR) and is correctly classified (Annex VIII. The justification for product classification has to be sufficiently robust. Document if the device under assessment is without an intended medical purpose (listed in Annex XVI).

1.1.1.8 Novel Features / Changes to Predecessor

In case there are no novel features, e.g. the device is already on the market under MDD/AIMDD state such information in this section and remove the table from the report.

Otherwise provide an explanation of all novel features of the device compared to the predecessor and provide an overview of the relevant verification / validation reports applicable to these features.

All novel features and changes need to be verified in a specific way, applicable test report(s) need to provide evidence of the successful and safe implementation of the specific novel feature. This is also applicable for changes.

You can choose to identify every novel feature in the report and reference this ID through the final technical report (where applicable).

1.1.1.9 Accessories and Device Combinations

Provide a description of all accessories, other medical devices and other products (generic, batteries, covers, bags,…) that are not medical devices, which are intended to be used in combination with it.

If the device is to be connected to other device(s) in order to operate as intended, a include a description of this combination/configuration including proof that it conforms to the general safety and performance requirements. When connected to any such device(s) having regard to the characteristics specified by the manufacturer.

Note: Where tools, equipment, accessories, products are put on the market separately as individual packed devices document if they are a medical device or not.

If they are a medical device and shall be marketed separately check that there is evidence for compliance of these medical devices provided in this Technical Documentation.

Especially for active implants manufacturers minor accessories (like screw drivers, stylets, plugs, etc) are often regarded non-relevant by the manufacturer while compiling the Technical Documentation and might not have their own labelling, risk management, and all other necessary documents according to MDR. In such cases further investigation through a deficiency might be necessary.

1.1.1.10 Configurations and Variants of the Device

Provide a complete list of the various configurations/variants of the device that are intended to be made available on the market.

1.1.1.11 General Description of the key functional Elements

Provide a 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.

Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings) which clearly indicate key parts/components, including sufficient explanation to understand the drawings and diagrams.

1.1.1.12 Materials incorporated in Key Functional Elements

A 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.

This section is not intended to cover biocompatibility, chemical properties and other elements covered by section 1.6.1.3 in this Work Instruction. However, the information here should be consistent with the information provided for biocompatibility assessment.

1.1.1.13 Technical Specifications

Technical specifications (features, dimensions and performance attributes) of the medical device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, e.g. in brochures, catalogues, IFU or similar publications; including if applicable information on:

- Storage conditions and shelf life
- Preventive inspection and maintenance to be performed including the frequency of such maintenance measures for non-implantable parts
- Information on cleaning, disinfection – how the device was designed to allow cleaning and disinfection, when device is intended to be cleaned, disinfected or re-sterilized
- Information on microbiological state (sterile, non-sterile, specific information on bioburden)
- Information on packaging
- Information on sterilization method
- Information on reusable device
- Specific Information on the MRI Safety level of the device.

Especially for active implants but also for other devices where it is applicable the MRI safety status of the device or device system shall be presented here as well. The MRI safety status can be either:

- MR Unsafe
- MR Conditional
- MR Safe
- Untested

Note: There is no MRI safety status "MR Compatible".

1.1.1.14 Reference to previous and similar Generations of the Device

Provide an overview of the manufacturer's previous generation(s) of the device, if such exist, or an overview of the manufacturer's identified similar devices available on the EU or international markets, if such exist.

Also provide information on the similar characteristics, it needs to be understood which characteristics the previous and similar devices have in common such as e.g. materials, design, function, intended use.

1.2 Information supplied by the Manufacturer

Provide here all information if the device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system. Check that the the information is understandable to the user and, as appropriate, to the patient.

Provide information about the question if the information are written in a way that is readily understood by a lay person when the device is intended to be used by a lay person.

The product description and the intended use which the manufacturer intends to use to identify the device when placed on the market need to be sufficiently detailed and accurate.

When symbols are used they need to be in compliance with the MDR and with applicable standards, also in regard to colour if this is required (e.g. "read instruction for use" icon on non-implantable active medical devices).

Markings for the device:

Prominent display of warnings, identification of implantable parts and component parts without surgical intervention.

Markings on the device provide all required information.

Assessment of requirements on UDI Information in the labelling (labels, and instruction for use, patient information) can be postponed until EUDAMED is functional (see MDR Article 123 f / g).

1.2.1 Labels

Check if a complete set of labels is provided with the Technical Documentation. For all device models / variants the applicable labels shall be included in the file. Representative labels are only accepted, if the variable information is of minor importance (e.g. serial number, dimension, quality of single devices in a multipack).

Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

The label(s) on the device and on its packaging (single unit packaging, sales packaging, transport packaging in case of specific management conditions) need to be presented in the languages accepted in the member states where the device is envisaged to be sold;

It is not necessary to provide verification results on languages here. An overview of market access countries / applicable languages / reference to the Technical Documentation is acceptable. A list of marketed EU countries and evidence that the national requirements of the languages used are adhered to shall be part of the Technical Documentation.

In case, the marketed countries in the EU are not finally defined at the moment of assessment, a master template in either English or German language can be assessed.

> *Rationale for this approach: Adherence to implemented procedures on translation of labels / IFU is part of the QMS process and its surveillance and is randomly verified on-site in the course of QMS audits.*

Check if the labels and markings on the device and the packaging provide all information required by the MDR Annex I, all applicable MDR articles, and by applicable standards. Check that the markings on all packaging provide all relevant information.

Specific labels for transport packaging are only required in case the device must be transported at controlled conditions (e.g. temperature, upright, no vibration etc.).

If applicable, restrictions on use applying to combinations of the device under assessment with other medical devices need to be presented in the labelling.

1.2.2 Instruction for Use / accompanying Documentation

Check if the instructions for use is presented in the languages accepted in the member states where the device is envisaged to be sold.

In case, the marketed countries in the EU are not finally defined at the moment of assessment, a master template in either English or German language can be assessed.

> *Rationale for this approach: Adherence to implemented procedures on translation of labels / IFU is part of the QMS process and its surveillance and is randomly verified on-site in the course of QMS audits.*

The accompanying documentation must provide all relevant information. In cases the device (active implantable, but also non-active implants) has a specific MRI Safety level the accompanying documentation need to provide information if the patient can undergo an MRI scan and under which conditions.

If instruction for use is provided to the user in non-paper format (e.g. electronic) Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices is applicable, too and needs to be assessed if not already an assessment for compliance to 207/2012 was performed. Check in these cases if access to the electronic instruction for use has been verified.

The instruction for use includes all information required by the MDR Annex I and by applicable standards.

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use The information shall, if the manufacturer has a website, be made available and kept up to date on the website of the manufacturer.

1.2.3 Implant Card and Information for Patient

Check if the following is fulfilled and provide an overview of the applicable patient information and implant card applicable to the device.

The manufacturer of an implantable device shall provide together with the device the following:

a) Information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

b) Any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

c) Any information about the expected lifetime of the device and any necessary follow-up;

d) Any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I: “in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed”.

The information referred to in (a), (b), (c), and (d) shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned member state.

The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate.

Updates of the information shall be made available to the patient via the website mentioned in point (a).

In addition, the manufacturer shall provide the information referred to in point (a) on an implant card delivered with the device.

1.3 Design and manufacturing Information

1.3.1 Design Stages applied

Check if information is provided to allow the design stages applied to the device to be understood.

This information may include the specific design stages applied by the manufacturer and the techniques that are used to control, monitor and verify the design of the device during these stages. Typical compliance proof could be design review protocols specifically for the device showing the design stages applied to the device.

A summary on the design process (SOP) with reference to the applied implemented documented procedure(s) and versions date shall be included. But reference alone is not sufficient to comply to this requirement as long as the design stages applied to the device cannot be understood by the SOP. Check if the provided SOP is applicable to the device under assessment.

1.3.2 Manufacturing Process and Process Validation

Check if the Technical Documentation provides complete information and specifications, including the manufacturing processes and their validation, their adjuvants (e.g. process aids, agents), the continuous monitoring, and the final product testing. Data shall be fully included in the Technical Documentation.

Manufacturing includes production, assembly, packaging, sterile packaging, sterilization, final packaging (as applicable) until dispatch of the final device.

The Technical Documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of the MDR and in particular the applicable General Safety and Performance Requirements.

Information can be provided in terms of a flow chart including individual operation steps, time points of in-process controls (monitoring) and final controls, reference of manufacturing procedures (ID numbers sufficient for traceability).

A summary of manufacturing processes allowing an understanding of the critical process steps and utilities and process chemicals required to produce the device can be helpful to get an overview of the activities in manufacturing.

An overview of all validations and manufacturing processes as well as test methods which require validation activities can be helpful to understand the validation approach and all the validation steps.

A summary list with references of manufacturing process validations and test method validations (Document ID no.) shall be part of the Technical Documentation.

Validation documentation (Validation Protocols / Validation Reports) for production process validation and test method validation shall be part of the Technical Documentation.

Verification documentation for continuous demonstrating efficacy on a periodic basis (if applicable) is also part of the Technical Documentation.

In case of sub-contracted (outsourced) processes:

For non-critical component suppliers (e.g. bulk) identification of the supplier or subcontractor is acceptable.

For critical component suppliers (e.g. outsourced manufacturing of sterile device / implants) information of manufacturing processes and corresponding control measures (e.g. references to verification and validation activities, copy of the certificate shall be included) needs to be part of the Technical Documentation.

Key life cycle steps that can be considered during the assessment of a device are for example:

- Design
- Verification
- Validation
- Manufacturing and Assembly
- Storage
- Transport
- Use
- Reuse
- Disposal

1.3.3 Design and manufacturing Sites

Provide an identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

1.4 General Safety and Performance Requirements

Assess if the correct General Safety and Performance Requirements were selected by the manufacturer. Check for those which are not applicable, that a rational is provided why they are not applicable to the device.

For in depth assessment of the GSPR use the current revision of the PPP “NAM AMP MDR General Requirements” and all applicable device / technology specific PPPs.

A GSPR checklist is not specifically required by the MDR. To provide information by means of other documents like risk management, design verification, etc. might be acceptable to provide the relevant information. However, a cross reference to the respective evidence documents in the Technical Documentation must be available.

1.4.1 Applicable general Safety and Performance Requirements

Include evidence for General Safety Performance Requirements compliance, e.g. a checklist.

Consider multiple lists if multiple products shall be certified. When there are accessories which are marketed individually separate proof needs to be provided.

Check that all applicable General Safety and Performance Requirements are identified and fulfilled. In case certain requirements do not need to be considered or are not applicable a rationale has been provided by the manufacturer.

1.4.2 Methods used to demonstrate Conformity

Check which methods have been used (verification or validation).

Check that the methods used to demonstrate conformity with the requirements and documented evidence for conformity with each of these methods is adequate.

1.4.3 Harmonized Standards, common Specifications, or other Solutions applied

Check if the harmonised standards, Common Specification (CS), non-harmonized standards, common technology standards, SOPs for non-standardized methods etc. which have been applied are documented.

The manufacturer employed the Harmonised Standards, Common Specifications (CS) or other solutions as described in the following documents, e.g. List of Harmonised Standards, Common Specifications, Standards. Check that the standards, CS, or other specifications employed by the manufacturer are suitable and applicable to fulfil the General Safety and Performance Requirements.

1.4.4 Controlled Documents offering Evidence of Conformity

Demonstration of conformity includes a precise identity of the controlled documents offering evidence of conformity with harmonised standards, common specification or other method employed to demonstrate conformity with the General Safety and Performance Requirements. A cross-reference to the location of such evidence documents shall be provided.

1.5 Benefit – Risk – Analysis and Risk Management

1.5.1 Design and Construction Risks

Check the risk management file for completeness and for reference of EN ISO 14971 (including a chapter or reference of benefit-risk analysis).

Check if:

- all known and foreseeable hazards have been identified by the manufacturer and that all risks associated with these hazards occurring during intended use and during reasonable foreseeably misuse have been estimated and evaluated.
- Risk control measures adopted by the manufacturer for the design and construction conform to safety principles, taking account of the generally acknowledged state of the art.
- All these risks have been reduced as far as possible by the manufacturer. The manufacturer positively evaluated that reducing the risks did not adversely affect the risk benefit ratio of the device.
- Where appropriate the manufacturer has taken adequate protection measures in relation to risks that cannot be eliminated (residual risks).
- The manufacturer provides information for safety (warnings, precautions, contraindications) in information supplied by the manufacturer
- If appropriate and necessary, the manufacturer provides training to users.
- The residual risk associated with each hazard as well as the overall residual risk is assessed and concluded to be acceptable by the manufacturer.
- The manufacturer informs the user(s) of any residual risks.

The Risk Management File in the Technical Documentation typically covers several documents such as hazard analysis, risk analysis, risk assessments, risk management plan, risk management report, and other. Check that all relevant and applicable risk management documents are provided and assess for suitability and acceptability of the risk management.

1.5.2 Analysis of Risks due to Use Error (Usability)

Check if there are risk control measures adopted by the manufacturer related to use errors and that these conform to safety principles, taking account of the generally acknowledged state of the art.

Check if risks related to the ergonomic features of the device and the environment in which the device is intended to be used have been reduced as far as possible by the manufacturer.

Where applicable, check if the manufacturer considered the technical knowledge, experience, education, training and use environment – also if a lay person uses the device, if that is included in the intended use.

Additionally that the manufacturer considered the medical and physical conditions of intended users.

1.6 Product Verification and Validation

The Technical Documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the

requirements of this Regulation and in particular the applicable general safety and performance requirements.

Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications.

Detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council shall be demonstrated.

For in depth assessment of the general safety and performance requirements use PPP NAM_AMP MDR General Requirements and all applicable device / technology specific PPP´s.

1.6.1 Pre-clinical and clinical Data

Asses results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications.

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.

1.6.1.1 Animal Studies

The results obtained in animal studies (excluding studies according EN ISO 10993) and conclusions made supporting and providing evidence for compliance with the design specifications and performances claimed.

Assessment of animal studies for the high risk devices (class III and implantable IIb devices) are included in the clinical assessment of the Clinical Evaluation Report (CEAR), MED_T_09.05 by the CLR.

1.6.1.2 Simulated Use Test

Assess the detailed information on any simulated use testing.

Asses if the key assumptions made as the basis for acceptance / verification have been challenged and the manufacturer provided sufficient and acceptable rationales.

The results obtained and conclusions made support and provide evidence for compliance with the design specifications and performances claimed.

1.6.1.3 Biocompatibility of the Device

The biocompatibility need to include the identification of all materials in direct or indirect contact and a classification according to EN ISO 10993-1 Table A1.

The devices need to be designed in such a way that the risks posed by substances leaking from the device are reduced to a minimum.

The documentation provided by the manufacturer needs to contain detailed information on biocompatibility testing and biological evaluation. The review of the presented data must

indicate that the materials used are safe for their intended use within the meaning of EN ISO 10993-1.

The review of the presented data must indicate that the materials used ensure the compatibility between materials and substances used and biological tissues, cells, body fluids taking in account the intended purpose. Where relevant the review of the presented data must indicate that the materials used ensure defined and safe absorption, distribution, metabolism and excretion.

An assessment by a E-BC is mandatory for:

- Class III devices
- Implantable devices of class IIb, other than excepted implants: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors
- Active devices with assessment of additional parts to ISO 10993-5 / ISO 10993-10 (TD for MDA can only assess the results related to ISO 10993-5 and -10)

Assessment result for these devices to be documented in MED_T_09.37 by the Expert E-BC.

1.6.1.4 Physical, chemical and microbiological Characterisation

The chemical and physical properties of the devices need to be adequately addressed by the manufacturer in the Technical Documentation. The materials and substances used need to be safe regarding toxicity and flammability.

The documentation needs to contain detailed information on chemical and physical evaluation. The materials used must ensure the characteristics and performance regarding mechanical and chemical properties.

The material of the device must meet the defined chemical and/or physical specification.

1.6.1.5 Electrical Safety

Check that the applicable standards were applied to the device. Assess if the device was tested for all foreseeable external influences and environmental conditions regarding electrical safety. Provide information who (laboratory) conducted testing on electrical safety, if applicable.

The manufacturer must provide detailed information regarding test design, the complete test protocols, methods of data analysis, data summaries, and test conclusions.

Assess if devices for supplying the patient with energy or substances are designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

An assessment by an E-ES is mandatory for:

- Class III devices
- In case the evidences provided (test reports) do not originate from an accredited test lab or in case of doubts about their validity exist.

Assessment result for these cases to be documented in MEDF0988.04E by the Expert E-ES.

1.6.1.6 Electromagnetic Compatibility / ionizing and non-ionizing Radiation

Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent must be

included in the Risk Analysis and Clinical Evaluation. The design of the emissions control by the user has to be evaluated regarding functional safety. The design of such devices shall ensure reproducibility and tolerance of relevant variable parameters.

1.6.1.7 MRI Safety Testing of the Device / Device System

Provide an overview of the medical device system or mention which devices are MR Conditional.

You can use tables or other formats to explain the MR Conditional Device / System and the requirements applicable to the MRI Scanner to safely undergo an MRI examination.

MRI Scanner Conditions

The following conditions are applicable for all systems.

- MRI Scanner Type
- Magnet Strength
- Spatial Gradient
- Head SAR
- Whole Body SAR
- Gradient Slew Rate
- Scan Time Limitation
- Scan Zone Restrictions
- MRI Testing of implantable parts of active implantable medical devices

Clauses from ISO T/S 10974:2010 apply for this assessment module for active implantable devices.

1.6.1.8 Functional Safety, Software, Cybersecurity

Devices supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

The device must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

Devices must have a protection against risks associated with the possible negative interaction between software and the IT environment within the device operates and interacts.

Apps need to be compatible with the medical device (mobile computing platforms) and need to be designed and manufactured considering specific features and requirements for the platforms related to their use (e.g. iOS, Android).

The Software (also incorporated into the device) must be developed according to the state of the art. Considering the principles of development life cycle, risk management, including information security, verification and validation.

Software that is intended to be used in combination with mobile computing platforms must be designed and manufactured considering the specific features of the mobile platform.

The manufacturer needs to describe and provide information about minimum requirements on hardware, IT networks characteristics, and IT security measures necessary to run the software as intended. Including protection against unauthorised access,.

Electronic programmable systems, including software, need to be designed to ensure repeatability, reliability and performance according to the intended use.

A Functional Safety assessment by a E-FS is mandatory for:

- Class III devices
- In case the applicable PPPs contain requirements for functional safety and no functional safety report issued by TPS could be provided by the manufacturer.

Assessment result for these cases to be documented in MEDF0988.02E by the Expert E-FS.

A Cybersecurity assessment by a E-FS or a software auditor (TA for MDS1009) is mandatory for:

- Class III devices
- In case unauthorized access to the device via an IT network could result in death or serious injury of human beings or in compromise of date privacy.

Assessment result for these cases to be documented in MEDF0988.03E by the Expert E-FS or TA for MDS1009.

1.6.1.9 Software Verification and Validation

Describe the software design and development process and provide evidence of the validation of the software, as used in the finished device.

This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer.

1.6.1.10 Packaging

Describe the packaging system of the terminally sterilized device and assess if it follows the applicable requirements of the relevant standards and guidelines.

The integrity of the sterile packaging must be clearly evident to the final user.

An indication permitting the sterile packaging to be recognised as such need to be present.

The packaging system for non-sterile devices intended to be sterilized prior use must be suitable for the sterilization indicated by the manufacturer. The packaging must not adversely affect the device characteristics and performances during the lifetime of the device.

Where the the high risk device (class III and implantable IIb devices) is supplied sterile, detailed information on packaging validation according relevant standards and guidelines needs to be provided and documented. Assessment result to be documented in MED_T_09.39 by the Expert E-PK.

Assess that the device characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

The packaging system for non-sterile devices allows maintaining the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination.

1.6.1.11 Stability and Shelf Life of the Device

Shelf life to be evaluated for the device and, if applicable, for the sterile packaging system.

Qualification demonstrating that the device characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

Stability and lifetime of implants in human beings have to be also considered during the assessment process in the clinical evaluation.

1.6.1.12 Performance and Safety

The documentation shall contain the results of all the verification and validation testing and / or studies undertaken and their critical analysis to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

The documentation shall contain detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding performance and safety.

Key laboratory studies, verification and validation studies, and testing results as presented by the manufacturer shall be included in the FTR (MED_T_09.21 / MED_T_09.19).

1.6.1.13 Constructional and Mechanical Safety

The device is designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices.

Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person must handle are designed and constructed in such a way as to minimise all possible risks.

Errors likely to be made when fitting or refitting certain parts which could be a source of risk are made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

1.6.1.14 Clinical Data, Clinical Evaluation Report, PMCF Plan, and PMCF Evaluation Report

The assessment of the clinical evaluation report, PMCF plan and report is performed according to MED_P_09.08.

1.6.1.15 Consultation of Clinical Evaluation

For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, a consultation of the clinical evaluation is required.

The consultation is performed according MED_W_09.21.

The conclusion of this assessment (consultation) needs to be documented and, if applicable, discussed by the clinical reviewer in the CEAR. The project reviewer needs to check if the conclusion by the expert panel was taken into consideration and shall select which basic conclusion is applicable.

Some devices may not require a clinical evaluation consultation, such devices are:

- Where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has

demonstrated to the CLR that the modifications do not adversely affect the benefit-risk ratio of the device; or

- Where the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the CLR confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device.

1.6.2 Additional Information required in specific Cases

1.6.2.1 Substances Considered to be a Medicinal Product

For medical devices incorporating, as an integral part, a medicinal substance with an ancillary function to the device, the usefulness of the respective substance for the intended purpose of the device has to be verified (MED_T_09.07) followed by consultation of a 'Medicinal Products Competent Authority' or the European Medicines Agency 'designated by the member states on quality and safety of the substance including clinical benefit / risk profile (see MED_W_09.07 and MED_T_09.11).

1.6.2.2 Substances derived from Human Blood or Human Plasma

For medical devices incorporating, as an integral part, a medicinal substance derived from human blood, the usefulness of the respective substances for the intended purpose of the device has to be verified followed by consultation of EMA on quality and safety of the substance including clinical benefit / risk profile (see MED_W_09.08).

1.6.2.3 Tissues or Cells of Human Origin

For medical devices manufactured utilizing tissues of human origin the assessment is performed and documented according to MED_W_09.20.

Assessment by the expert for inactivation of viruses and infectious agents to be documented in report.

Additionally, for medical devices manufactured utilizing tissues of human origin as referred in MED_W_09.20 a consultation of respective national Competent Authorities is required.

1.6.2.4 Tissues or Cells of Animal Origin

For medical devices manufactured utilizing tissues of animal origin the assessment is performed and documented according to MED_W_09.04.

Assessment by the expert for inactivation of viruses and infectious agents to be documented in MED_T_09.45.

Additionally, for medical devices manufactured utilizing tissues of specific animal origin as referred in MED_W_09.04 a consultation of respective national Competent Authorities is required.

1.6.2.5 Other Materials of biological Origin

For medical devices manufactured utilizing tissues of biological origin other than from animal origin or from human origin, the device and materials have to be evaluated on:

- processing, preservation, testing
- and handling of the substances
- safety for patients, users, and where applicable, other persons

- safety within the waste disposal chain
- safety with regard to viruses and other transmissible agents
- appropriate methods of sourcing
- validated methods of elimination or inactivation in the course of the manufacturing process

1.6.2.6 Devices incorporating or consisting of Nanomaterial

For medical devices using particles with at least one dimension below 100 nm, further characteristics as agglomeration state / aggregation, composition (e.g., chemical composition and structure), particle size / size distribution, purity/impurity, shape, solubility (hydrophobicity, liposolubility, water solubility), stability, surface area, surface chemistry, surface charge and coating characteristics need to be documented and the related risk analysis need to be evaluated.

1.6.2.7 Substances or Combinations of Substances that are absorbed by or locally dispersed

In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

- 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; and 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 such studies, a justification shall be provided.

MED_W_09.22 applies for the consultation and assessment process.

1.6.2.8 CMR or endocrine-disrupting Substances

In the case of devices containing substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) or endocrine-disrupting substances referred to in Section 10.4.1 of MDR, Annex I, the justification referred to in Section 10.4.2 of Annex I needs to be assessed.

For substances which are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, or substances having endocrine disrupting properties under this regulation (see section 10.4.1 of MDR, Annex I), contained in the device which are over 0.1% weight by weight: Check that the justifications are adequately addressed and considered by the manufacturer.

The manufacturer provides appropriate labelling on the device and/or on the packaging for each unit, where appropriate, on the sales packaging, with the list of such substances.

The manufacturer provides appropriate precautionary measures in the instructions for use to protect children, pregnant or nursing women or other vulnerable patient groups, if they fall in the intended use of the device.

1.6.2.9 Sterile Devices or Devices with defined microbiological Condition

In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps shall be provided. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility is required. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

Where the device is supplied sterile, detailed information on sterilization validation including bioburden testing, pyrogen testing, testing for sterilant residues, if applicable, has to be evaluated and documented in respective report template MED_T_09.38 / MED_T_09.40 / MED_T_09.41.

For devices assessed on a representative sample this test module will be reviewed by an authorized expert according to MED_F_09.83 MDR Audit Testing Plan.

1.6.2.10 Infection Risk and reusable Device

Assessment criteria are:

- The design of the device allow easy and safe handling.
- The design of the device reduces as far as possible and appropriate the risk from unintended cuts and pricks.
- The design of the device reduces as far as possible any microbial leakage from the device and / or microbial exposure.
- The process to control microbial contamination is in compliance with the applicable requirements of the relevant standards and guidelines.
- Processes descriptions and validations to allow reuse, including cleaning, disinfection, packaging are available and, if applicable, the validated method of re-sterilisation.
- IFU includes information to identify when the device should no longer be reused. Include the relevant information e.g. signs of material degradation, maximum number of allowable reuses, etc.
- Reusable devices requiring cleaning, disinfection, sterilisation bear a permanent UDI Carrier on the device itself. The UDI Carrier is validated to be readable after each process.

For devices assessed on a representative sample the test module Reusable Device will be reviewed by an authorized expert (STA) according to MED_F_09.83 MDR Audit Testing Plan. This review shall be documented in MED_T_09.53.

1.6.2.11 Devices with a measuring Function

In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications shall be included.

Taking account of the intended purpose, check that the device provides sufficient accuracy, precision, and stability, within appropriate limits of accuracy for their intended purpose.

Accuracy limits are to be indicated in the labelling or in the IFU.

Check that the measurements, monitoring and display scale is designed in line with ergonomic principles taking into account the intended purpose, users and the environmental conditions in which the devices are intended to be used.

Measurements are to be expressed in legal unites conforming with Directive 80/181/EEC.

1.6.2.12 Devices with Connection to other Device(s)

If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer has to be evaluated.

In case of connections to be handled by the user, check that the connections are designed and constructed in such a way as to avoid misconnection.

1.7 Additional Regulations, Procedures, Directives, Commission Decisions

1.7.1 Summary of Safety and Clinical Performance (SSCP)

In the case of implantable devices and class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a Summary of Safety and Clinical Performance (SSCP). The Product Reviewer and CLR evaluate the draft SSCP provided with the Technical Documentation. After positive assessment the PH will inform the manufacturer and request the final version of the SSCP. The assessment result based on the final SSCP is documented in the SSCP Validation Statement MED_T_09.15.

The SSCP shall include at least the following aspects and shall be written in a way that is clear to the intended user and, if relevant, to the patient:

a) The identification of the device and the manufacturer, including the basic UDI-DI and the single registration number;

b) The intended purpose of the device, including indications, contra-indications and target populations;

c) A description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;

d) Possible diagnostic or therapeutic alternatives;

e) Reference to harmonized standards and common specifications;

f) The summary of the clinical evaluation as referred to in MDR, annex XIII, and relevant information on the post-market clinical follow up;

g) Suggested profile and training for users;

h) Information on any residual risks and any undesirable effects, warnings and precautions.

The bullet points a), c), and e) will be evaluated by the Product Reviewer; the remaining bullet points will be addressed by the CLR (MED_P_09.08).

The SSCP Validation Statement MED_T_09.15 together with a recommendation to up-load the SSCP into the EUDAMED database will be send to MHS-CRT by the PH.

1.7.2 Periodic Safety Update Report (PSUR)

The assessment of the Periodic Safety Update Report (PSUR) for all class III devices and all implantable devices (class IIa / IIb) is documented in MED_T_09.14 Evaluation of PSUR.

The assessment of the Periodic Safety Update Report (PSUR) for all other devices is documented in the MDR Clinical Evaluation Assessment Report (CEAR) for class IIa / IIb devices, MED_T_09.57.

The assessment of PSUR starts after the initial MDR certification following the minimum reporting timelines as specified in MDR and shall be annual for class III devices and class IIb implants. For class IIa implants the minimum reporting timeline is biennial.

It is the responsibility of the manufacturer to ensure a timely submission of the PSUR and to inform the notified body that a PSUR has been uploaded to the electronic system (EUDAMED).

Where the evaluation of the PSUR by a notified body is not applicable, the relevant text in the final technical report (FTR) template can be removed.

1.7.3 Environmental Protection, Safety of Disposal

Manufacturers shall identify and test procedures and measures of which their devices can be safely disposed after use. These procedures shall be described in the instructions for use.

1.7.4 Personal protective Equipment Directive 89/686/EEC

Define if the personal protective equipment directive 89/686/EEC is applicable to this device in combination to the medical device regulation.

1.7.5 Hazardous Substances, REACH, biocidal Products

Devices, or those parts thereof, or those materials used therein:

- That are invasive and to come into direct contact with the human body, or
- that (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- that transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

containing:

- Substances which are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, or
- substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in Regulation (EC) No 1907/2006 (REACH) or in Regulation (EU) No 528/2012

shall be identified and quantified in % weight by weight (w/w).

And if the concentration is above 0.1% w/w a justification for the presence of these substances has to be evaluated.

Justification shall be based on:

- An analysis and estimation of potential patient or user exposure to the substance;
- An analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer reviewed studies, scientific opinions from relevant Scientific Committees and an analysis of the availability of such alternatives;
- Argumentation why possible substance and/ or material substitutes or design changes, if available, are inappropriate to maintain the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and / or materials;
- Where applicable and available, the latest relevant Scientific Committee guidelines.

1.7.6 Other regulatory Requirements

This section shall contain reference and document compliance to all other regulatory requirements which were not already mentioned in this work instruction, e.g.

RED: 2014/53/EU Radio Equipment Directive

And/or other applicable specific procedures, supplementary directives, regulations, and commission decisions.

1.8 Additional Surveillance Activities

Include requirements for additional surveillance activities such as audits, follow-ups, or actions from the Technical Documentation assessment. Indicate when a follow-up needs to be fulfilled and if the remark or follow-up has any influence on the recommendation for certification.

If no additional surveillance activities are required, it is acceptable to delete the subsections which are not applicable.

1.8.1 Extra Audit of the QM-System

In case an extra audit of the QM system is required, list the items, processes, and elements which have to be addressed in that audit in the applicable table in the Technical Documentation Assessment Report (MED_T_09.21 / MED_T_09.19). In the column “Extra Audit Scope”, provide information on the extra audit’s scope and in the column “To be audited by”, define the role of the person that shall conduct the audit.

1.8.2 Items for the next regular Audit

In case an item shall be given to the audit team of the next upcoming audit, this item shall be documented in the applicable table in the Technical Documentation Assessment Report (MED_T_09.21 / MED_T_09.19). Note, this is not an extra audit but only an assessment item for the regular scheduled audit.

This information has to be transferred into the CBW Database for the related facility as “To Do” for the next audit (see MED_P_09.03). This initial entry is done by the assistant of the project handler.

During the certification process the Senior Technical Certifier (STC) checks these CBW Database entries and, if deemed necessary, adds further follow-up actions, or modifies existing

entries. This additional entry or change is done by the assistant of MHS-CRT in the CBW Database.

1.8.3 Follow-up Project

In cases where a follow-up is defined, a follow up project shall be requested from the manufacturer. The applicable table in the Technical Documentation Assessment Report (MED_T_09.21 / MED_T_09.19) needs to specify the follow-up from the manufacturer. The follow-up must be combined with a date until when the specific -information and/or documentation must be provided.

Additionally the follow-up project is entered in the project database (e.g. PSE, or project handling database like SAP) as follow-up project (by Project Coordinator or PH) and shall be linked with the due date indicated in the FTR. If possible this follow-up project number shall be already mentioned in the FTR.

After response by the manufacturer and assessment of the response the FTR shall be revised or amended (e.g. Technical Short Report MDR MED_T_09.24) with the result by the PH. A new submission file (e.g. amendment to the original submission file) shall be up-loaded to MHS-CRT by the PH or Project Coordinator. Up-load shall be made with MEDICI (or where MEDICI is not feasible up-load in PSE or other local project handling database). In case that the follow-up project number is different to the project number of the origin project a clear linkage between these project numbers needs to be described in the follow-up project file.

Details for submission to MHS-CRT are defined in MED_W_10.06.

1.8.4 Recommended Conditions on Certification

A recommendation for a Condition on the Certificate shall apply in cases where a limitation or condition must be stated **on the certificate** (e.g. additional contraindication, device distribution limited to study centres of PMCF study, or if within the certification the suspension of certificate has to be announced, certificate validity limitation, etc.).

Final decision regarding conditions is made by the STC according MED_P_10.23. The information in the applicable table in the Technical Documentation Assessment Report (MED_T_09.21 / MED_T_09.19) is a recommendation and shall identify the source for a recommended condition (e.g. PH, CLR, PR, or other involved parties).

1.9 Summary

The summary section of the FTR (MED_T_09.21 / MED_T_09.19) concludes the assessment. Select the conclusion statement according to the conformity assessment route and classification of device. Delete not applicable statements.

2 TECHNICAL DOCUMENTATION ASSESSMENT MODULES FOR IVDR

Technical Documentation Assessment

The Technical Documentation must be verified for conformity with Annex II and Annex III, the relevant General Safety and Performance Requirements (according to Annex I), the applicable requirements of the IVDR, and in accordance to the applicable PPPs and Common

Specifications (CS) with knowledge and experience regarding the technology concerned and the intended purpose of the device.

It is possible that the review of single aspects (assessment modules) is documented in separate technical reports which are signed by the responsible Product Reviewer (PR) / IVD Clinical Reviewer (ICR) / Expert.

The project handler must verify that the data and descriptions in the technical reports of the module assessments is consistent with the tasks from the project planning sheet (PPS MED_F_03.03), the application by the manufacturer, the complete device incl. its accessories as stated in the overarching FTR and on the draft certificate.

The FTR must clearly indicate which features, dimensions, and / or performance attributes of the device, including variants and accessories, are covered by the assessment.

These reports and their individual conclusions (including additional surveillance activities if applicable) must be referenced in the Technical Documentation Assessment Report (FTR) by the Project Handler (see IVDR report template MED_T_09.20 or MED_T_09.22). Please note that the report template MED_T_09.20 (IVDR Technical Assessment Report) used for MDR / IVDR Technical Documentation Assessment includes the Performance Evaluation Assessment Report as specified in IVDR Annex IX section 4.8.

Within the final technical report it must be clear who performed an assessment of a specific module. Reviewers shall be documented in the specific section in the FTR together with a reference to the report from the PR / ICR / Expert.

The PH shall verify prior finalizing the FTR that the assessments of the involved PR / ICR / Expert still meet the current regulatory requirements (especially if the assessment result is older than 6 months).

The FTR shall document the level of compliance with the respective requirements of IVDR and in particular with the applicable General Safety and Performance Requirements depending on the applicable Conformity Assessment Procedures.

The FTR is signed by the Project Handler, signatures from the PR / ICR / Expert on the FTR are not required, if separate assessment reports (partial reports) are signed.

Each report (FTR and PR / Expert reports) needs to have a declaration of non-consultancy and impartiality signed by the involved PR / Expert / ICR and in case of the FTR by the Project Handler.

IVDR required Expert Levels (Authorizations)

The Project Handler considers the following criteria for the selection of product specialist and if necessary an IVD clinical reviewer (ICR), which are determined on a case-by-case decision, based on the expert support needed (see MED_P_09.15) e.g. for

- a high risk and complex device to be assessed,
- unfavourable test results presented in the TD,
- justification and rationale by the manufacturer for acceptance and compliance, which requires more specialised knowledge,
- borderline device to be assessed,
- concerns from authorities regarding this kind of devices / therapy / technology / materials to be assessed,
- unclear state-of-the-art related to the benefit/risk evaluation,
- in case a clinical study on human subjects regarding the clinical condition of patients has to be assessed; involvement of CLR (Clinical Reviewer) shall be considered for assessment of this study,
- general concerns of the TD assessor regarding own subject matter expertise.

An assessment by an ICR is mandatory in following cases:

- Performance evaluation of a class D device
- Performance evaluation of a class C Companion Diagnostics device
- Performance evaluation of an innovative class C devices

The Project Handler has to consider to involve an ICR in following cases:

- any assessment related to innovative device or innovative technology,
- new indication for this type of medical device,
- dubious indication or mechanism of action,
- justification and rationale by the manufacturer for acceptance and compliance, which requires more specialized clinical knowledge,
- unclear state-of-the-art related to the benefit/risk evaluation.

Table 1: IVDR required expert levels (authorizations)

Assesment Module	IX.4 for Class D and IX.4 – IX.5 for Class D (ST + NP) and X and XI for Class D (including ST + NP)	IX.4 – IX.5 for Class B and C (including for ST + NP) and X and XI for Class C (including ST + NP)	IX.4 – IX.5 for Class D and C Companion Diagnostics (including ST + NP)
Device Description and Specification	PS-IVD	TD-IVD	PS-IVD
Information Supplied (Labelling and IFU)			
Design and Manufacturing Information			
General Safety and Performance Requirements			
Benefit-Risk Analysis and Risk Management			
Requirements for Self-Testing and Near-Patient Testing			
Verification and Validation excluding following Sections: **a) Clinical Performance** **b) Software Verification and Validation**			
Clinical Performance	PS-IVD / ICR		
Software Verification and Validation	E-SW (SPC4)		
Chemical, Physical and Biological Properties excluding following Sections: **a) Nanoparticle Technology** **b) Sterile Devices and Devices with defined Microbiological Condition** **c) Constructional Safety** **d) Devices with Measuring Function**	PS-IVD	TD-IVD	PS-IVD
Nanoparticle Technology	PS for MDS 1007		
Sterile Devices or Devices with Defined Microbiological Condition	STA		
Constructional Safety excluding following section: **a) Electrical Safety / Electromagnetic Compatibility**	PS-IVD	TD-IVD	PS-IVD
Electrical Safety / Electromagnetic Compatibility	E-ES (SPC3)		

Assesment Module	IX.4 for Class D and IX.4 – IX.5 for Class D (ST + NP) and X and XI for Class D (including ST + NP)	IX.4 – IX.5 for Class B and C (including for ST + NP) and X and XI for Class C (including ST + NP)	IX.4 – IX.5 for Class D and C Companion Diagnostics (including ST + NP)
Devices with a Measuring Function	PS-IVD	TD-IVD	PS-IVD
Summary of Safety and Performance (SSP)			
Post-Market Surveillance			
Consultation of novel Class D IVDs		n.a.	
Consultation of Companion Dx (Class D and C)	n.a.		PS-IVD
Consultation of Reference Laboratories	PS-IVD	n.a.	
Other Regulatory Requirements	Selected by PH for IVD depending on regulatory requirement		

The Technical Documentation provided by the manufacturer shall be assessed regarding the aspects applicable from the following subsections.

General Aspects

Technical Documentation (TD) Structure and Content

If available provide an identification of the Technical Documentation in this section, manufacturers might revision control their Technical Documentation, if they do so, a reference to that revision or date of compilation can be given here.

The Technical Documentation structure is preferably in order of IVDR Annex II & III but must always cover all elements from IVDR Annex II & III.

If a different structure is chosen by the manufacturer, a reference list linking the corresponding subsection of Annex II & III to the provided Technical Documentation can be helpful.

The Technical Documentation must be clear, organized, readily searchable and prepared in an unambiguous manner.

A Table of content must be available, sections and annexes shall be numbered, documents shall be traceable by document ID and / or other means such as e.g. title / version / revision, date.

The Technical Documentation must be correct, consistent, up-to-date and complete and it must covers all variants and trade names of the device as well as provided accessories with the device.

Project Management

This section shall provide an overview of the major milestones in a project. A table provides an overview of the key milestones and shall be completed with the dates when an activity was concluded.

The table given in the template shall be extended by additional lines where more milestones were passed during the project (e.g. 2nd Request for Additional Information / Deficiency Report).

All Experts and Product Specialists involved in the Assessment shall be recorded in a dedicated table specifying for part of the Technical Documentation they have been responsible.

Test-/ Assessment Specification according PPP_IVDR_General Requirements, as well as any restrictions and amendments to the applied Test Program(s) shall be documented.

2.1 Device Description and Specification

2.1.1 Product or Trade Name

Include the product or trade name. The product name shall be consistent with the product displayed on the products' packaging and marketing brochures, and the application.

In case of companion diagnostic include the associated medicinal product(s).

2.1.2 Basic Unique Device Identifier

Provide the Basic UDI DI attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability.

2.1.3 General Device Description, intended Purpose and intended User

Provide a general description of the device, including the intended purpose per IVDR Chapter 1 (Article 2) and intended user for the device.

2.1.4 Intended Testing Population

Provide the intended testing population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contraindications, warnings.

2.1.5 Qualification of the Product as a Device

Provide and check the rationale for the qualification of the product as a medical device per IVDR.

2.1.6 Risk Class of the Device

Check if the device falls under the medical device regulation (IVDR) and is correctly classified (Annex VIII. The justification for product classification has to be sufficiently robust.

2.1.7 Configurations and Variants of the Device

Provide a complete list of the various configurations/variants of the device that are intended to be made available on the market.

2.1.8 Composition of the Device

Provide an overview of the device component packed.

2.1.9 Principles of Action

Provide a description of the principles of assay and, if in combination with instruments, also the principle of operation of the instrument.

2.1.10 Accessories and Device Combinations

Provide a description of all accessories, other medical devices and other products which are intended to be used in combination with the device.

If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration. Include proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

Note: Where tools, equipment, accessories, products are put on the market separately as individual packed devices describe if those products are medical devices or not.

Note: Accessories provided separately need to have their own labelling, instruction for use, packaging and certification.

2.1.11 Accessories / Equipment required for Use but not provided with the Device

Provide a description of accessories required for use, but not provided with the device.

2.1.12 Reference to Previous and Similar Generations of the Device

Provide an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist.

Also provide an overview of identified similar devices available on the Union or international markets, where such devices exist.

2.2 Information supplied by the Manufacturer

Provide here all information if the device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system and the information is understandable to the user and, as appropriate, the patient.

Provide information about the question if the information are written in a way that is readily understood by a lay person when it is applicable to a lay person.

The product description and the intended use which the manufacturer intends to use to identify the device when placed on the market need to be sufficiently detailed and accurate.

When symbols are used they need to be in compliance with the IVDR and with applicable standards.

Markings on the device provide all required information.

Assessment of requirements on UDI Information in the labelling (labels, and instruction for use, patient information) can be postponed until EUDAMED is functional (see MDR Article 113 f.).

2.2.1 Labels

Check if a complete set of labels is provided with the Technical Documentation. For all device models / variants the applicable labels shall be included in the file. Representative labels are only accepted, if the variable information is of minor importance (e.g. serial number, dimension, quality of single devices in a multipack).

Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

The label(s) on the device and on its packaging (single unit packaging, sales packaging, transport packaging in case of specific management conditions) need to be presented in the languages accepted in the member states where the device is envisaged to be sold.

It is not necessary to provide verification results on languages here, an overview of market access countries / applicable languages / reference to the Technical Documentation is acceptable. A list of marketed EU countries and evidence that the national requirements of the languages used are adhered to shall be part of the file.

In case, the marketed countries in the EU are not finally defined at the moment of Assessment, a master template in either English or German language can be assessed.

> *Rationale for this approach: Adherence to implemented procedures on translation of labels / IFU is part of the QMS process and its surveillance and is randomly verified on-site in the course of QMS audits.*

Check if the labels and markings on the device and the packaging provide all information required by the IVDR Annex I, all applicable IVDR articles and by applicable standards. The markings on all packaging provide all relevant information.

Specific labels for transport packaging are only required in case the device must be transported at controlled conditions (e.g. temperature, upright, no vibration, etc.).

If applicable, restrictions on use applying to combinations of the device under assessment with other medical devices need to be presented in the labelling.

2.2.2 Instructions for Use / accompanying Documentation

Check if the instructions for use is presented in the languages accepted in the member states where the device is envisaged to be sold.

In case, the marketed countries in the EU are not finally defined at the moment of Assessment, a master template in either English or German language can be assessed.

> *Rationale for this approach: Adherence to implemented procedures on translation of labels / IFU is part of the QMS process and its surveillance and is randomly verified on-site in the course of QMS audits.*

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website.

If instruction for use is provided to the user in non-paper format (e.g. electronic) Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices is applicable, too and needs to be assessed if not already an assessment for compliance to 207/2012 was performed. Check in these cases if access to the electronic instruction for use has been verified. If device is for self-testing consider additional requirements according Annex I, 20.4.2.

2.3 Design and manufacturing Information

2.3.1 Design Information

Check if information is provided to allow the design stages applied to the device to be understood. This information may be on the specific design stages applied by the manufacturer, the techniques that are used to control, monitor and verify the design of the device during these stages. A summary on the design process (SOP) with reference to the applied implemented documented procedure(s) and versions date shall be included.

The Technical Documentation shall contain at least a description of critical ingredients (provided or recommended for use), description of major subsystems, analytical technology, dedicated computer hardware / software (for instruments), an overview of the entire system (for instruments and software, a description of data interpretation methodology, i.e. algorithm (for software, description of design aspects concerning suitability for self-testing or near-patient testing (for self-tests and near-patient tests

2.3.2 Manufacturing Information

Check if the Technical Documentation provides complete information and specifications, including the manufacturing processes and their validation, their adjuvants (e.g. process aids, agents), the continuous monitoring and the final product testing. Data shall be fully included in the Technical Documentation.

Manufacturing includes production, assembly, final product testing, and packaging of the finished device to be understood.

Information can be provided in terms of a flow chart including individual operation steps, time points of in-process controls (monitoring) and final controls, reference of manufacturing procedures (ID numbers sufficient for traceability). A summary of manufacturing processes allowing an understanding of the critical process steps and utilities and process chemicals required to produce the device.

In case of sub-contracted (outsourced) processes: For non-critical component suppliers (e.g. bulk) identification of supplier only.

2.3.2.1 Description of the manufacturing Process / Process Flow

Provide a general description of manufacturing process.

2.3.2.2 Quality Control Testing

Important in process and final quality control measures, defined acceptance criteria for final product testing.

2.3.3 Design and manufacturing Sites

Provide an identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed in this section.

2.3.3.1 Critical Component Supplier

For critical component suppliers overview of manufacturing processes and corresponding control measures (e.g. references to verification and validation activities, copy of the certificate shall be included).

Provide Information on incoming control of critical materials etc.

2.3.3.2 Outsourced critical Processes

Provide Information on incoming control of provided goods / services etc.

2.4 General Safety and Performance Requirements

Assess if the correct General Safety and Performance Requirements were selected by the manufacturer and check for those which are not applicable that a rational is provided why they are not applicable to the device.

For in depth assessment of the GSPR use the current revision of the "PPP_IVDR_General Requirements" and all applicable device / technology specific PPPs.

A GSPR checklist is not specifically required by the IVDR. To provide information by means of other documents like management, design verification, etc. might be acceptable to provide the relevant information. However, a cross reference to the respective evidence documents in the Technical Documentation must be available.

Include multiple lists if multiple products shall be certified. When there are accessories which are marketed individually separate proof needs to be provided.

Check which methods have been used (verification or validation).

The methods used to demonstrate conformity with the requirements and documented evidence for conformity with each of these methods is adequate.

Check if the harmonised standards, Common Specification (CS), non-harmonized standards, common technology standards, SOPs for non-standardized methods, etc., which have been applied are documented.

The manufacturer employed the Harmonised Standards, Common Specifications (CS), or other solutions as described in the following documents, e.g. List of Harmonised Standards, Common Specifications, Standards.

Standards, CS, or other specifications employed by the manufacturer are suitable and applicable to fulfil the General Safety and Performance Requirements.

Demonstration of conformity includes a precise identity of the controlled documents offering evidence of conformity with harmonised standards, common specification, or other method employed to demonstrate conformity with the General Safety and Performance Requirements. A cross-reference to the location of such evidence shall be provided.

2.5 Benefit – Risk – Analysis and Risk Management

2.5.1 General

Check the risk management file for completeness and for reference of EN ISO 14971 (and Annex H; including a chapter or reference of benefit-risk analysis).

Check if:

- All known and foreseeable hazards have been identified by the manufacturer and that all risks associated with these hazards occurring during intended use and during reasonable foreseeably misuse have been estimated and evaluated.
- Risk control measures adopted by the manufacturer for the design and construction conform to safety principles, taking account of the generally acknowledged state of the art.
- All these risks have been reduced as far as possible by the manufacturer. The manufacturer positively evaluated that reducing the risks did not adversely affect the risk benefit ratio of the device.
- Where appropriate the manufacturer has taken adequate protection measures in relation to risks that cannot be eliminated (residual risks).
- The manufacturer provides information for safety (warnings, precautions, contraindications) in information supplied by the manufacturer
- If appropriate and necessary the manufacturer provides training to users.
- The residual risk associated with each hazard as well as the overall residual risk is assessed and concluded to be acceptable by the manufacturer.
- The manufacturer informs the user(s) of any residual risks.

The Risk Management File in the Technical Documentation typically covers several documents such as hazard analysis, risk analysis, risk assessments, risk management plan, risk management report, and other. Check that all relevant and applicable risk management documents are provided and assess for suitability and acceptability of the risk management.

2.5.2 Specific Usability Risks

Check if there are risk control measures adopted by the manufacturer related to use errors and that these conform to safety principles, taking account of the generally acknowledged state of the art.

Check if risks related to the ergonomic features of the device and the environment in which the device is intended to be used have been reduced as far as possible by the manufacturer.

Where applicable, check if the manufacturer considered the technical knowledge, experience, education, training and use environment – also of a lay person using the device if that is applicable.

The manufacturer considered the medical and physical conditions of intended users.

Consider also possible use errors by a patient during self-testing and/or near-patient testing.

2.6 Requirements for Self-Testing and Near-Patient Testing Devices

Requirements for self-testing and near-patient testing devices with regards to labelling and risk management are included in the chapters 2 (Information supplied by the manufacturer) and 5.2 (Specific Usability Risks) of this work instruction, respectively.

Usability of the devices is to be covered in specific studies for the intended user group (under consideration of appropriate patient selection) where the understandability / readability of the instructions for use, handling of the device and interpretation of the results are investigated.

In the case of blood glucose monitoring devices for self-testing, compliance to standard EN ISO 15197:2015 is to be assessed and documented in the Amendment to Evaluation Result template MED_F_09.29.

2.7 Product Verification and Validation

The Technical Documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

For in depth assessment of the general safety and performance requirements use PPP_IVDR_General Requirements and all applicable device / technology specific PPP´s.

2.7.1 Specimen Type / Handling

Provide a description of the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such as duration, temperature limits and freeze/thaw cycles

2.7.2 Analytical Performance Characteristics

The analytical performance characteristics shall be demonstrated by different means according to IVDR Annex II.

2.7.2.1 Accuracy

The Technical Documentation shall contain results to show trueness and precision of measurement. The data shall be provided in sufficient detail to allow an assessment of the adequacy of the means selected to establish the trueness and precision.

Trueness measures apply to both quantitative and qualitative assays only when a certified reference material or certified reference method is available.

Precision shall describe repeatability and reproducibility of the studies.

2.7.2.2 Analytical Sensitivity

The Technical Documentation shall include information about the study design and results of the claimed analytical sensitivity. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.

2.7.2.3 Analytical Specificity

The Technical Documentation shall include information about interference and cross-reactivity studies performed to determine the analytical specificity Check if the studies contain the analysis on potential interfering and cross-reacting substances or agents on the assay, on the tested substance or agent type and its concentration, specimen type, analyte test concentration, and results.

Interferents and cross-reacting substances or agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:(a) substances used for patient treatment such as medicinal products; (b) substances ingested by the patient such as alcohol, foods; (c) substances added during specimen preparation such as preservatives, stabilisers; (d) substances encountered in specific specimen types such as haemoglobin, lipids, bilirubin, proteins; (e) analytes of similar structure such as precursors, metabolites or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that can mimic the test condition.

2.7.2.4 Metrological Traceability of Calibrator and Control Material Values

Check if metrological traceability of applied calibrator(s) and/or control material(s) is given and is part of the Technical Documentation.

2.7.2.5 Measuring Range of the Assay

The Technical Documentation shall include information about the measuring range (linear or non-linear) including the limit of detection and shall describe on how the range and detection limit were established.

The information shall include a description of specimen type, number of specimens, number of replicates, and specimen preparation including information on the matrix, analyte levels and how levels were established. If applicable, a description of any high dose hook effect and the data supporting the mitigation such as dilution steps shall be added.

2.7.2.6 Definition of Assay Cut-Off

The Technical Documentation shall include information about a summary of analytical data with a description of the study design including methods for determining the assay cut-off, such as: (a) the population(s) studied: demographics, selection, inclusion and exclusion criteria, number of individuals included; (b) method or mode of characterisation of specimens; and (c) statistical methods such as Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

2.7.2.7 Analytical Performance Report

The Technical Documentation shall include a summary of the analytical performance which was demonstrated on the basis of analytical performance studies and which is documented in the analytical performance report.

2.7.3 Clinical Performance

2.7.3.1 Studies

The Technical Documentation shall contain information on clinical performance and shall include documents as referred to in Section 2 of Part A of Annex XIII (study purpose, study plan, study analysis and study results).

Clinical performance such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected population shall be demonstrated and documented.

Demonstration of clinical performance of a device shall be based either on clinical performance studies, scientific peer-reviewed literature or published experience gained by routine diagnostic testing or a combination of the above mentioned sources.

Describe Compliance with CS if available.

Note: Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data

Check if a clinical performance study plan (including the purpose of the study) is provided according Annex XIII 2.3.2 is documented

Furthermore, verify the compliance with the applicable Common Specification (CS) according IVDR. As long as no applicable CS exist, the current version of the Common Technical Specifications as laid down in Decision 2009/886/EC amended by Decision 2011/869/EU are used as “state of the art”.

2.7.3.2 Clinical Performance Report

Clinical performance shall be demonstrated and documented in the clinical performance report, which shall be part of the Technical Documentation

Check if a clinical performance study report is documented and signed by a medical practitioner or any other authorized person responsible. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents.

The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

2.7.4 Scientific Validity

Scientific validity shall be demonstrated and documented in the scientific validity report, which shall be part of the Technical Documentation. Check if available.

Demonstration of scientific validity of a device shall be based either on one or a combination of the following sources (check if applied):

- Relevant information of devices measuring the same analyte or marker
- Scientific (peer-reviewed) literature
- Consensus expert opinions / positions from relevant professional associations
- Results from proof of concept studies

  Results from clinical performance studies

2.7.5 Performance Evaluation Report

The Technical Documentation shall contain a performance evaluation report according Annex XIII. Check if available.

The Performance Evaluation Report shall include the scientific evaluation report, the analytical performance evaluation report, the clinical evaluation report and an assessment of those reports allowing demonstration of the clinical evidence.

Check in particular if the performance evaluation adequately addresses the relevant safety and performance requirements as specified in Annex I, if the performance evaluation is

appropriately aligned with the risk management requirements, if the performance evaluation is appropriately reflected in the information supplied my the manufacturer, and if the items according Annex XIII section 1.3.2 are covered in the report. Finally, clinical evidence shall scientifically demonstrate that the intended clinical benefit and safety is achieved according to the state of the art in medicine.

2.7.6 Usability of self-testing / near-patient testing Devices

If a medical devise in intended for self-testing / near-patient testing usability shall be shown by respective clinical data. Usability verification and /or validation shall be part of the Technical Documentation and shall also become part of the risk management documentation.

2.7.6.1 Blood Glucose monitoring Devices for Self-Testing

For evaluation of additional requirements regarding Blood Glucose Monitoring Systems for self-testing in managing Diabetes Mellitus refer to “Amendment to Evaluation Result: Assessment according to specific requirements of EN ISO 15197:2015 (MED_F_09.29) for blood glucose measuring systems for layperson use only”.

2.7.6.2 Other self-testing Devices

Suitability for self-testing at all stages of the procedure must be shown for the device by test reports including results of studies carried out with lay persons or individuals representing respective users.

Means to reduce the risk of user error in the handling of the device and in the interpretation of the results as far as practicable, e.g. by a user control to show that the product performs as intended at time of use.

2.7.6.3 Near-patient testing Devices

Suitability for near-patient testing must be shown for the device by test reports of studies conducted in relevant environments (for example, patient home, emergency units, ambulances).

Means to reduce the risk of user error in the handling of the device and in the interpretation of the results as far as practicable, e.g. by a user control to show that the product performs as intended at time of use.

2.7.7 Stability

This Section shall describe the claimed shelf life, in use stability and shipping stability studies.

Qualification demonstrating that the device characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

2.7.7.1 Claimed Shelf Life

This Section shall provide information on stability testing studies to support the shelf life that is claimed for the device. Real-Time Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions. The three lots do not need to be consecutive.

Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claims but shall be followed up with real time stability studies.

Stabilities studies (real-time) shall include a study plan and study report (including study protocol, number of lots, acceptance criteria and testing intervals with the conclusions and claimed shelf life.

In case accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described.

2.7.7.2 In-Use Stability

This Section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device, regardless of whether real or simulated.

This may include open vial stability and/or, for automated instruments, on board stability.

In case of open vial stability, studies may reflect the actual storage conditions following the first opening of the e.g. primary container.

In the case of automated instrumentation, if calibration stability is claimed, supporting data shall be included.

The Technical Documentation shall include a respective study report (including the protocol, acceptance criteria and testing intervals) and the conclusions and claimed in-use stability which have been made.

2.7.7.3 Shipping Stability

This Section shall provide information on shipping stability studies for one lot of devices to evaluate the tolerance of devices to the anticipated shipping conditions.

Shipping studies may be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold.

The Technical Documentation shall include a respective study report (including the protocol, acceptance criteria), the method used for simulation conditions and the conclusion and recommended shipping conditions.

2.7.8 Software Verification and Validation / Functional Safety / Cybersecurity

This section shall describe the software design and development process and provide evidence of the validation of the software, as used in the finished device.

This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer.

2.8 Chemical, Physical and Biological Properties

2.8.1 Nanoparticle Technology

For medical devices using particles with at least one dimension below 100 nm, further characteristics as agglomeration state / aggregation, composition (e.g., chemical composition and structure), particle size / size distribution, purity/impurity, shape, solubility (hydrophobicity, liposolubility, water solubility), stability, surface area, surface chemistry, surface charge and coating characteristics.

2.8.2 Hazardous Substances

This section shall describe if any potential hazardous substance according applicable regulations are included in the device.

Check if applicable:

- Regulation (EC) No 1272/2008 in accordance with Part 3 of Annex VI
- Regulation (EC) No 1907/2006 (REACH)

Check if a Material Safety Data Sheet is issued and does contain the ingredients of the device. If applicable consider appropriate labelling and / or warnings and precautions requirements.

2.8.3 Substances of Animal / Human / Microbiological Origin

2.8.3.1 Human Origin / Human Blood or Plasma

This section shall provide information of origin of substances from human origin. Conditions in which it was collected should be available for assessment and conclusions should be recorded.

Check if appropriate warnings or precautions were taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any.

This information shall also cover, where appropriate, infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin.

Check if appropriate virus-inactivation methods were validated.

Check if appropriate testing for infectious diseases are documented.

2.8.3.2 Microbiological Origin

This section shall provide information of any substance from microbiological origin (e.g. bacterial expression systems, hybridoma purified antibodies etc.). If applicable, control measures and / or validation method(s) for transmissible agent shall be described and evaluated.

2.8.3.3 Animal Origin

This section shall provide information of any substance from animal origin. If applicable, control measures and / or validation method(s) for transmissible agent of animal origin (e.g. BSA, TSE) shall be described and evaluated.

2.8.4 Sterile Devices or Devices with defined microbiological Condition

In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps shall be described in this section.

The sterilization methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility, shall be part of the Technical Documentation. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

2.8.5 Constructional Safety

2.8.5.1 Mechanical Safety

The device is designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices.

Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person must handle are designed and constructed in such a way as to minimise all possible risks.

Errors likely to be made when fitting or refitting certain parts which could be a source of risk are made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

2.8.5.2 Electrical Safety / Electromagnetic Compatibility

Check that the applicable standards were applied to the device. Assess if the device was tested for all foreseeable external influences and environmental conditions regarding electrical safety. Provide information who (laboratory) conducted testing on electrical safety, if applicable.

The manufacturer must provide detailed information regarding test design, the complete test protocols, methods of data analysis, data summaries, and test conclusions.

Assess if devices for supplying the patient with energy or substances are designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

The design of the emissions control by the user has to be evaluated regarding functional safety. The design of such devices shall ensure reproducibility and tolerance of relevant variable parameters.

2.8.5.3 Ionizing and non-ionizing Radiation

Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent must be included in the Risk Analysis and Clinical Evaluation.

2.8.5.4 Environmental Protection and Safe Disposal

Manufacturers shall identify and test procedures and measures of which their devices can be safely disposed after use. These procedures shall be described in the instructions for use.

2.8.5.5 Packaging

This section shall describe the packaging system of sterile and non-sterile devices of finished products and/or kit components included in an IVD Kit.

For non-sterile devices:

Enter a description of the packaging system (finished product and kit components) and verify whether packaging allows maintaining the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination.

For sterile devices:

Describe the packaging system of the terminally sterilized device and assess if it follows the applicable requirements of the relevant standards and guidelines.

The integrity of the sterile packaging must be clearly evident to the final user.

An indication permitting the sterile packaging to be recognised as such need to be present.

The packaging system for non-sterile devices intended to be sterilized prior use must be suitable for the sterilization indicated by the manufacturer. The packaging must not adversely affect the device characteristics and performances during the lifetime of the device.

Assess that the device characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

2.8.5.6 Devices with Connection to other Device(s)

If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

In case of connections to be handled by the user: check that the connections are designed and constructed in such a way as to avoid misconnection.

2.8.6 Devices with a measuring Function

In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications shall be described in this section.

Taking account of the intended purpose the device provides sufficient accuracy, precision, and stability, within appropriate limits of accuracy for their intended purpose.

Check if Accuracy limits are indicated in the labelling or in the IFU.

Check if measurements, monitoring and display scale is designed in line with ergonomic principles taking into account the intended purpose, users and the environmental conditions in which the devices are intended to be used.

Measurements are to be expressed in legal unites conforming with Directive 80/181/EEC.

2.9 Summary of Safety and Performance (SSP)

This section is only applicable for class C and class D devices. The Technical Documentation shall contain a summary of safety and performance (SSP) and shall be part of the conformity assessment. For assessment details please refer to MED_P_09.04.

2.10 Post Market Surveillance

The Technical Documentation shall contain a post market surveillance plan as specified in Annex II and III.

Check if the post market surveillance plan does cover items as specified in Annex III.

2.10.1 Periodic Safety Update Report / Post-Market Surveillance Report

For class C and class D devices, the Technical Documentation shall contain a periodic safety update report (PSUR) for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market

surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken.

The PSUR shall be updated at least annually and shall be part of the technical documentation as specified in Annexes II and III. Please check for last update.

For assessment details please refer to MED_P_09.04. The evaluation results of the PSUR shall be documented in the respective PSUR-Evaluation Report IVD (MED_T_09.36).

For class B devices a post-market surveillance report shall be part of the Technical Documentation summarising the results and conclusions of the analyses.

2.10.2 Post-Market Performance Follow-Up (PMPF)

Post-Market Performance Follow-Up shall be performed by the manufacturer according a PMPF Plan. A PMPF plan shall be part of the Technical Documentation and shall demonstrate compliance to requirements according Annex XIII, Part B.

2.11 Further regulatory Steps required

In the course of Conformity Assessment according to IVDR Annex IX or X consultation activities may be required. If one of the following three cases apply refer to.

Consultations apply in the following three cases:

1. Conformity assessment of class D IVD devices - consultation of Reference Laboratories (IVDR Article 48 (5).

2. Conformity assessment of novel class D IVD devices - consultation of EU expert panel (IVDR Article 48 (6).

3. Conformity assessment of Companion Diagnostics (CDx) – consultation of the European Medicines Agency (EMA) or competent authorities of EU member states in charge of medicinal product (IVDR Article 48 (8).

If consultation applies please follow the work instruction MED_W_09.23 and describe all results in the respective section(s) of the IVDR Technical Documentation Assessment Report as “non-applicable”.

If no consultation is applicable it is acceptable to mark the respective sections of the IVDR Technical Documentation Assessment Report as “non-applicable”.

2.12 Other regulatory Requirements, supplementary Directives, Regulations and Commission Decisions

This section shall provide information of any other applicable regulatory requirement, supplementary directives, regulations and commission decision, which have not been already covered in the previous section(s) of the IVDR Technical Documentation Assessment Report.

If additional requirements conformity shall be demonstrated and documented in this section.

If no additional requirements apply it is acceptable to mark this section as “non-applicable”.

2.13 Proposed Parameters for Product Verification Program

In case of Conformity Assessment of Class D products please refer to MED_P_09.07 Product Verification Process Flow for IVD Devices for details.

For Products classified as Class A / B / C, this chapter does not apply.

2.14 Additional Surveillance Activities

Include requirements for additional surveillance activities such as audits, follow-ups, or actions from the Technical Documentation assessment. Indicate when a follow-up needs to be fulfilled and if the remark or follow-up has any influence on the recommendation for certification.

If no additional surveillance activities are required, it is acceptable to delete the following subsections which are not applicable.

2.14.1 Extra Audit of the QM-System

In case an extra audit of the QM system is required, list the items, processes, and elements which have to be addressed in that audit in the applicable table in the Technical Documentation Assessment Report MED_T_09.20. In the column “Extra Audit Scope”, provide information on the extra audit’s scope and in the column “To be audited by”, define the role of the person that shall conduct the audit.

2.14.2 Items for the next regular Audit

In case an item shall be given to the audit team of the next upcoming audit, this item shall be documented in this section. Note, this is not an extra audit but only an assessment item for the regular scheduled audit.

This information has to be transferred into the CBW Database for the related facility as “To Do” for the next audit (see MED_P_09.03). This initial entry is done by the assistant of the project handler.

During the certification process the Senior Technical Certifier (STC) checks these CBW Database entries and, if deemed necessary, adds further follow-up actions, or modifies existing entries. This additional entry or change is done by the assistant of MHS-CRT in the CBW Database.

2.14.3 Follow-up Project

In cases where a follow-up is defined, a follow up project shall be requested from the manufacturer. This section needs to specify the follow-up from the manufacturer. The follow-up must be combined with a date until when the specific -information and/or documentation must be provided.

Additionally the follow-up project is entered in the project database (e.g. PSE, or project handling database like SAP) as follow-up project (by Project Coordinator or PH) and shall be linked with the due date indicated in the FTR. If possible this follow-up project number shall be already mentioned in the FTR.

After response by the manufacturer and assessment of the response the FTR shall be revised or amended (e.g. Technical Short Report IVDR MED_T_09.29) with the result by the PH. A new submission file (e.g. amendment to the original submission file) shall be up-loaded to MHS-CRT by the PH or Project Coordinator. Up-load shall be made with MEDICI (or where MEDICI is not feasible up-load in PSE or other local project handling database). In case that

the follow-up project number is different to the project number of the origin project a clear linkage between these project numbers needs to be described in the follow-up project file.

Details for submission to MHS-CRT are defined in MED_W_10.06.

2.14.4 Recommended Conditions on Certification

A recommendation for a Condition on the Certificate shall apply in cases where a limitation or condition must be stated **on the certificate** (e.g. additional contraindication, limited device distribution, or if within the certification the suspension of certificate has to be announced, certificate validity limitation, etc.).

Final decision regarding conditions is made by the STC according MED_P_10.23. The information in the report is a recommendation and shall identify the source for a recommended condition (e.g. PH, ICR, or other involved parties).

2.15 Summary

The summary section of the FTR (MED_T_09.20 and MED_T_09.22) concludes the assessment. Select the conclusion statement according to the conformity assessment route and classification of device. Delete “not applicable” statements.