1. **Purpose**

This document defines the policies and procedures for creating and compiling the documentation necessary to fulfill the requirements of the EU Medical Device Regulation (MDR). The final compilation of documentation and records is referred to as a Technical File.

1. **Scope**

This procedure applies to the development of all medical devices manufactured that are intended for international distribution.

1. **General** 
   1. **Definitions** 
      * **Technical File** – a structured compilation of technical documentation needed to meet the requirements of the EU Medical Device Regulation
      * **Family of Devices** – A principal device and all of the accessories that are manufactured for use with it. In addition, derivatives of the principal device, with the same intended use, may be included in the Family
   2. **Responsibilities**

**Quality Management** – Quality Management is responsible for ensuring continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** –Quality personnel shall be trained to this document based upon their responsibilities.
  4. **Record Management** – Technical Files are managed and maintained by the Quality Department for a minimum of five (5) years following the last manufacturer of the associated medical device.
  5. **Reference Documents and Materials**

**ISO 13485** Medical Device Quality Management Systems

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**MEDDEV 2 12/1**: Guidelines on a Medical Device Vigilance System

**CP0433 Issue 2**: Documentation Submissions – Best Practices Guideline

**QP-0003** – Design Control Process

1. **Technical File Procedure**
   1. **Availability of the Technical Documentation**

The Technical Documentation is the responsibility of the quality department and shall be maintained for at least five years from the last date of manufacture of the product.

* 1. **Language of Technical Documentation**

All technical file documentation shall be maintained in English. The Technical File Summary may be translated if required by a Competent Authority

* 1. **Changes to the Technical File**

Where the technical documentation or part thereof has been submitted to the Notified Body in connection with conformity assessment involving design - or type - examination, the manufacturer is required to inform the Notified Body of substantial changes and obtain further approval. See MB-MED guidance on “Reporting of design changes and change of the quality systems for additional information.

1. **Technical Documentation Sections – Technical File Summary**

This section consists of a summary of the essential technical data relevant to the conformity assessment procedures, including the following:

* Manufacturer’s and Authorized Representative’s name and address.
* Identification of the device by name, common name, classification and rules.
* Name(s) and address(es) of facilities involved in design and manufacturing.
* Name and address of any Notified Body.
* A statement of conformity assessment procedure.
* A Declaration of Conformity.
* Description of the device, intended purpose, indications for use, and any variants and/or accessories.
* Labeling and instructions for use.
* A statement of relevant regulations.
* Identification of technical standard with which compliance is claimed.
* A statement of the bench testing and clinical data obtained.

1. **Technical Documentation Sections – Product Description**
   1. **Device Description**

This should include the intended range of variants (for example, a group of catheters of a particular type differing only in length), and a description of the packaging where this is relevant to the preservation of the intended characteristics and performances of the device(s). All that is needed, however, is a brief description sufficient to allow an understanding of the design, characteristics, and where appropriate, performances of the device(s) and to distinguish between variants. In many cases, the name of the device(s) will be sufficient. Where the ‘technical documentation’ is to be evaluated by a Notified Body, a general pictorial representation of the device(s), e.g. a schematic diagram, photograph or drawing may be of assistance.

* 1. **Intended Use**

A short description of the intended purpose/ application and/or method of use of the device(s) is needed. This may include, where appropriate, details of the intended patient population(s) and medical condition(s) for which the device is intended. This should also make clear the intended user(s), in particular whether the device is professional use. All of the above may be self-evident from the general description of the device(s). The information may be given by way of reference to the “instructions for use” or operating manual for the device(s). It is not necessary to detail the mechanism by which the device(s) achieves its intended purpose.

* 1. **Description of Incorporated Medicinal Substances**

Where the device(s) incorporates a medicinal substance, the ‘technical documentation’ should make clear the purpose of including the substance and its mode of action in this application. This only applies where the substance is liable to act upon the body with action ancillary to that of the device. The risk analysis should address the additional risks and benefits associated with incorporation of such a substance. The technical documentation should include the data on the tests conducted in this connection.

* 1. **Description of Incorporated Materials of Animal Origin**

Where the device(s) incorporates non-viable materials of animal origin, the risk analysis within the technical documentation should address the additional risks and benefits associated with incorporation of such materials, and the measures taken (for example, in sourcing of animals, veterinary controls and measures taken to eliminate/ inactivate transmissible agents).

* 1. **Device Classification**

The technical documentation should include the rule number(s) applied under the Regulation, together with a brief rationale for this classification, and reasons why particular rules do not apply, if this is not self-evident.

In the case of IVDs, the classification of a particular device is self-evident from the lists given in Annex II of the IVDD or where the device is labeled as for “self-testing”.

* 1. **Special Considerations**

Where aspects of the device(s) are the subject of emerging concern (for example, the use of latex potentially leading to allergic reaction), the risk analysis within the ‘technical documentation’ should address these aspects.

* 1. **Description of Manufacturing**

A summary is required in general terms of the type of manufacturing method (for example, injection/blow molding, extrusion, chemical processing, assembly, packaging/labeling) and the method of sterilization, if relevant. This should make clear the technologies involved and means of assuring the intended characteristics and performances of the devices manufactured. What is not required is an exhaustive description of manufacturing processes.

* 1. **Description of Accessories**

The technical documentation should include the description of other devices or equipment etc. which the device is intended to be used with; for example, where the manufacturer makes specific claims concerning compatibility. It should also include data on the verification and validation of the safety and performance of such combinations.

In describing the requirements for safe and proper operation of the device(s) when used in combination with devices or equipment from other manufacturers, what is needed is a brief description sufficient to understand the important parameters or interfaces (for example, the connectors needed or the voltage, frequency and/or stability of the electricity supply required).

The technical documentation should also address known incompatibilities which may be covered, for example, in the label or the instructions for use.

1. **Technical Documentation Sections – Technical Requirements**
   1. **Safety and Performance Requirements**

The manufacturer should make clear the Regulation(s) which apply to the particular device(s) concerned, including Directives other than the medical devices regulations. Where not self-evident, the manufacturer should document the rationale for classifying as a medical device and deciding what other, if any, requirements apply.

In each case, those Safety and Performance Requirements (SPRs) of the Regulation(s) or Directive(s) and other requirements which apply should be identified. The manufacturer should define the technical requirements/specifications which must be satisfied in order to ensure that each of the applicable Regulation/Directive requirements are met.

Where particular SPRs are deemed not to apply to the device(s) concerned, a brief rationale should be given where this is not self-evident.

* 1. **Safety and Performance Requirement Solutions**

The manufacturer is required to demonstrate how each of the applicable SPR’s and any derived technical requirements/specifications for the particular device(s) concerned has been met. Compliance with published standards is voluntary.

Where “harmonized standards” are used to comply with relevant SPR’s, all that is needed is to demonstrate the device(s) concerned complies with the relevant clauses of the “harmonized standard(s)”.

Where other methods, including compliance with draft and in-house/industry standards, are used to comply with one of a range of relevant SPR’s, the manufacturer should justify that:

* the methods applied adequately address relevant requirement(s) and
* the device(s) concerned comply with the relevant provisions of these.

The evidence of device compliance with standards may take the form of, for example, test reports or records of application of Standard Operating Procedures (SOPs) intended to assure such compliance.

* 1. **List of Standards**

Where the manufacturer demonstrates conformity with particular SPR’s by claiming compliance with available published standards, the Regulations require that these standards should be identified. The manufacturer should make clear where standards which are applied in full or in part are “harmonized standards” (including “common technical specifications” in the case of IVDs). Compliance with all or parts of such “harmonized standards” carries the presumption of conformity with relevant SPR’s of the Regulation(s)/Directive(s).

Where device(s) do not comply with key relevant published standards, a rationale should be given.

1. **Technical Documentation Sections – Design Requirements**
   1. **Risk Management**

The manufacturer is required by the regulations to present the documented results of the risk analysis.

The risk analysis should address all hazards known or reasonably foreseeable for the particular product types and technologies involved, together with the likelihood and consequences of occurrence and measures taken to reduce the resulting risks to acceptable levels. This should address all relevant risks. For example, in the case of devices incorporating e.g. a medicinal substance or materials of animal origin, or natural rubber latex, the risk analysis should include the additional risks and benefits associated with incorporation of such substances.

In the case of devices intended and labeled for “single use”, the risk analysis should address the hazards associated with reuse as an example of foreseeable misuse.

The results must demonstrate that an appropriate risk analysis has been performed and provide a conclusion, with appropriate evidence, that the remaining risks are acceptable when weighed against the intended benefits to the patient. The results of the risk analysis should be reviewed when there are changes to product, changes to standards, or new information with regards to unrecognized hazards, estimated risk, or estimated benefits of the device.

* 1. **Material Specifications and Biocompatibility**

The technical documentation should specify the materials used in the construction of the device, together with the biological safety and biocompatibility of materials intended to come into contact with the body. Particular attention should be paid where materials are invasive with respect to the body and/or will have prolonged contact with the body.

This may include special processes (e.g. molding, sterilization) and environmental conditions to be used for production (e.g. prevention of particulate contamination or electrostatic discharge). In the case of medical devices covered by the IVDD, this should cover characterization of starting materials.

The technical documentation should specify any ‘special processes’, for example sterilization, the results of which may affect the safety and performance of the finished device(s).

* 1. **Product, Sub-Assembly, and Component Specifications**

The manufacturer should determine what specifications, drawings, diagrams etc. are appropriate and sufficient to enable proper manufacture, installation, maintenance and servicing etc. of the product(s) involved in order to assure the intended characteristics and performances are achieved and maintained.

In some cases, the manufacturer will need detailed engineering scale drawings for their product(s). Whereas such drawings may be necessary, for example, for electro-medical devices, it is often sufficient to produce a schematic diagram of, for example, product configuration or kit contents with dimensions and other characteristics indicated as appropriate.

Equally, it may be necessary to have drawings for certain components or sub-assemblies but not for others.

* 1. **Test Specifications**

The procedures, work instructions etc. relating to the conduct of such checks, tests and trials form part of the manufacturer’s quality system.

* 1. **Performance and Compatibilities Intended**

The manufacturer is required to identify the characteristics, performances and compatibilities needed to assure the safe and correct operation of the device. A relevant characteristic might be, for example, sterility assurance of a catheter. A relevant performance might be, for example, the ability of the protective packaging to maintain sterility of that catheter when subject to the stresses associated with transport and storage.

In the case of IVDs, the indication of performances should include those required in connection with analytical performance, for example, to do with sensitivity, specificity, limit of detection, and ratio of false to true results, where relevant.

* 1. **Labeling / Information Supplied by Manufacturer**

The manufacturer is required to include in the technical documentation the label, and where appropriate, the instructions for use, together with any changes to these during the lifetime of the product. This should include the information to be given, both by text and the use of symbols, in the final version of the labeling.

The labeling documentation should make clear where particular information will be provided, for example on the device itself or its component parts, on the packaging for each unit, on the sales packaging, or on the leaflet or user manual supplied with one or more devices.

Information may be provided, for example, by means of electronic display screens or synthesized voice messages.

* 1. **Shelf-Life and Product Lifetime**

In certain cases, such restrictions on use will reflect a time-related deterioration in characteristics that are important to product safety and performance. In other cases, however, the restrictions will be based on other considerations. The ‘lifetime’ of an active device, for example, may be determined by the period for which the manufacturer will support the device by way of availability of spare parts, manuals, training, service/repairs etc.

* 1. **Performance Testing – Bench Data**

Bench testing includes in-vitro/animal studies, simulated use testing and validation of software and the results of special processes (e.g. sterilization validation report(s)).

* 1. **Performance Testing – Clinical Data**

Clinical data includes data from market experience of the same or similar devices (particularly relevant to ‘well established’ devices), prospective clinical investigations and information from the scientific literature.

The scientific literature will often relate to medical devices other than those being assessed. The manufacturer must therefore establish the extent to which the scientific literature is relevant to his device(s). The results from bench testing may be used to establish the extent to which the characteristics of the device(s) being assessed are similar to those of the device(s) covered by the scientific literature, and therefore the relevance of that scientific literature.

The manufacturer should make clear where clinical data is being used to demonstrate conformity with each of the applicable SPR’ for the particular device(s) concerned.

* 1. **Design Changes**

The technical documentation should include records of each design change and the reasons for these, together with any associated verification/ validation data. The documentation should include evidence for believing that the change achieves the desired effect, and that the device continues to comply with the requirements of the regulations.

1. **Technical Documentation Sections – Administrative Requirements**
   1. **Declaration of Conformity**

The Declaration of Conformity is the attestment of the manufacturer that the medical device complies fully with all applicable Essential Principles for Safety and Performance. At a minimum, the declaration shall include the following information:

* An attestation that each device that is subject to the declaration:
  + complies with the applicable Essential Principles for Safety and Performance,
  + has been classified according to the classification rules, and
  + has met all the applicable conformity assessment elements.
* Information sufficient to identify the device/s to which the Declaration of Conformity applies.
* The Global Medical Device Nomenclature (GMDN) code and term for the device7.
* The risk class allocated to the device/s after following the guidance found in Principles of Medical Devices Classification8.
* Which of the conformity assessment elements described in Section 5 have been applied.
* The date from which the Declaration of Conformity is valid.
* The name and address of the device manufacturer.
* The name, position and signature of the responsible person who has been authorized to complete the Declaration of Conformity upon the manufacturer’s behalf.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0027 |  |  | Initial release of the procedure for the creation of a medical device technical file. |