The list of documents that must be submitted together with the application for conformity assessment of products according to the procedure given in Annex 6 to the Technical Regulation "Procedure for ensuring the functioning of the quality management system during the production of medical devices"

3. The manufacturer must lodge an application for assessment of his quality system with a notified body.
The application must include:
…
the documentation on the quality system;
…
4. Application of the quality system must ensure that the products conform to the type described in the type-examination certificate.
All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.
5. quality system documentation must include in particular an adequate description of:
1) the manufacturer's quality objectives;
2) the organization of the business and in particular:
- the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,
- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform,
- where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

3) the inspection and quality assurance techniques at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

4) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

For products classified as Class IIa:
1) By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.
2) For devices in Class IIa the notified body shall assess, as part of the assessment in Section 6, the technical documentation as described in Section 3 of Annex 8 for at least one representative sample for each device subcategory for compliance with the provisions of this Technical regulation.
Annex 8 section 3:
3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Technical Regulation. It must include in particular:
- a general description of the product, including any variants planned and its intended use(s),
- design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the above- mentioned drawings and diagrams and the operations of the product,

- the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full,
- in the case of products placed on the market in a sterile condition, description of the methods used and the validation report,
- the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,
- the solutions adopted as referred to in Annex I, Chapter I, Section 2:
  "2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.
  In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:
  — eliminate or reduce risks as far as possible (inherently safe design and construction),
  — where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
  — inform users of the residual risks due to any shortcomings of the protection measures adopted."
- the pre-clinical evaluation,
- the clinical evaluation in accordance with Annex X,
- the label and instructions for use.

For products classified as Class IIb and III, the following documentation shall be submitted with the application in accordance with Annex 4:

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

- a general description of the type, including any variants planned, and its intended use(s),
- design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the above- mentioned drawings and diagrams and the operation of the product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,
- the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,
- a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in Section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,
- a statement indicating whether or not the device is manufactured utilising tissues of animal origin
- the solutions adopted as referred to in Annex I, Chapter I, Section 2:
  "2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.
  In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:
  — eliminate or reduce risks as far as possible (inherently safe design and construction),

— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
— inform users of the residual risks due to any shortcomings of the protection measures adopted."

- the pre-clinical evaluation,
- the clinical evaluation referred to in Annex X
- the draft label and, where appropriate, instructions for use

For your convenience, below is a list of required documents to help you prepare for the application. However, we note that this list is not exhaustive.

List of documents:

☐	1.	Application for the conformity assessment to the requirements of Technical Regulations for medical devices
☐	2.	Application for the assessment of the quality management system that signed by the manufacturer
☐	3.	Quality management system questionnaire
☐	4.	Power of attorney from the manufacturer for the appointment of an authorized representative in Ukraine with a list of products for which it is issued, duly certified in accordance with the laws of the country of origin of the manufacturer (for example apostille).

QMS documentation:

☐	5.	The organizational structures
☐	6.	Quality manual
☐	7.	Quality policy and quality objectives
☐	8.	QMS procedures master-list
☐	9.	List of all subcontractors (outsourcing) performing the functions of development, manufacture, final inspection and testing of medical devices or their components, as well as other critical processes (eg sterilization).
☐	10.	Methods of QMS monitoring of the above subcontractors, types and scope of control applied to them.
☐	11.	Procedures to be used for procurement and verification of purchased products
☐	12.	Procedures to be used during sterilization
☐	13.	Protocol on the concentration of particles in the air and bioburden control protocol in controlled production areas
☐	14.	Procedures for identification of medical devices at each stage of production
☐	15.	The procedures, work instructions etc. relating to the checks, tests and trials before, during and after the manufacture of medical devices that are part of the manufacturer's quality system.
☐	16.	Control of nonconforming medical devices procedure
☐	17.	Control of monitoring and measuring equipment procedure
☐	18.	Information on the institution that performs maintenance of measuring equipment
	19.	The methods of monitoring the efficient operation of the quality system:
☐		Procedure, plan and results of internal audits
☐		Procedure and annual Management review protocol on the effectiveness of the quality management system

Additional documents:

☐	1.	EC Declaration of conformity (93/42/EEC)

☐	2.	EC (93/42/EEC) and QMS (EN ISO 13485) certificates from accredited European CAB
☐	3.	EC and QMS audit reports from accredited European CAB
☐	4.	Catalogue

Technical documentation for products:

☐	1.	Technical Files for all base models (types)
☐	2.	Technical File cover page and index
☐	3.	General description of the product, including any variants planned and its intended use(s)
☐	4.	Technical characteristics, Product Specification
☐	5.	Methods of manufacture, manufacturing flow-chart
☐	6.	Design drawings and diagrams of components, sub-assemblies, circuits, etc.,
☐	7.	List of measures taken to comply with the mandatory requirements of Annex 1 to the Technical Regulation (Essential Requirements Check-list)
☐	8.	List of applicable standards
☐	9.	A statement indicating whether or not the device incorporates, as an integral part medicinal products or derivatives of human origin, or the device is manufactured utilising tissues of animal origin and, if contained, the results of tests performed
☐	10.	Risk Management File
☐	11.	Detailed information on sterilisation validation (initial and overall programme) including bioburden testing, pyrogen testing, testing for sterilant residues, if applicable
☐	12.	Package Qualification and Shelf life (Accelerated Aging and Stability Testing)
☐	13.	Biological Evaluation (EN ISO 10993 biocompatibility test reports)
☐	14.	Clinical Evaluation (according to MEDDEV 2.7.1)
☐	15.	Test reports for compliance with the standards used
☐	16.	Software validation report
☐	17.	Draft declaration of conformity with the requirements of the Technical Regulation
☐	18.	Draft label that meets the requirements of the Technical Regulation
☐	19.	Original label (EC market for example)
☐	20.	Instructions for use that meet the requirements of the Technical Regulations
☐	21.	Original instructions (EC market for example)