The list of documents that must be submitted together with the application for conformity assessment of products according to the procedure given in Annex 3 to the Technical Regulation «Full quality management system assessment procedure»

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 provisions of this Technical Regulation which apply to them at every stage, from design to final inspection. 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 policies and procedures such as quality programmes, quality plans, quality manuals and quality records.
It shall include in particular the corresponding documentation, data and records arising from the procedures referred to subparagraph 3 of paragraph 5 of this Annex.
5. QMS documentation shall 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 quality of design and 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 design and of product, including control of products which fail to conform;
- where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is 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 procedures for monitoring and verifying the design of the products and in particular:
- a general description of the product, including any variants planned, and its intended use(s);
- he techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed, specified in Annex 1 to the Technical Regulation on medical devices, if the national standards included in the list of national standards that comply with European harmonized standards and the voluntary application of which can be perceived as proof of compliance of medical devices with the requirements of the Technical Regulation on Medical Devices are not applied in full;
- the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed;
- 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;
- a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in clause 4 Section II Annex 1 of the Technical Regulation on Medical Devices, 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. Requirements for medical devices manufactured using tissues of animal origin are approved by order of the Ministry of Health;

- the solutions adopted as referred to in Annex I, Chapter I, Section 2 of the Technical Regulation on Medical Devices;
  "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 10 of the Technical Regulation on Medical Devices;
- the draft label and, where appropriate, instructions for use;

4) 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;

5) the appropriate tests and trials which will 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 to trace back the calibration of the test equipment adequately.

Design Examination of the product (for class III devices)

8. In addition to the obligations imposed by "Quality Management System" Section of this Annex цього додатка, the manufacturer or the authorized representative of manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture

9. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this Technical Regulation, as referred to subparagraph 3 of paragraph 5 of this Annex.

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 documents:

☐	5.	The organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned
☐	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.	The techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed
☐	15.	Procedures for identification of medical devices at each stage of production
☐	16.	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.
☐	17.	Control of nonconforming medical devices procedure
☐	18.	Control of monitoring and measuring equipment procedure
☐	19.	Information on the institution that performs maintenance of measuring equipment
	20.	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, 98/79/EC и 90/385/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.	List of measures taken to comply with the mandatory requirements of Annex 1 to the Technical Regulation (Essential Requirements Check-list)
☐	7.	List of applicable standards
☐	8.	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
☐	9.	Risk Management File
☐	10.	Detailed information on sterilisation validation (initial and overall programme) including bioburden testing, pyrogen testing, testing for sterilant residues, if applicable
☐	11.	Package Qualification and Shelf life (Accelerated Aging and Stability Testing)
☐	12.	Biological Evaluation (EN ISO 10993 biocompatibility test reports)
☐	13.	Clinical Evaluation (according to MEDDEV 2.7.1), qualification (dossier) of the group that made the approved clinical file.
☐	14.	Test reports for compliance with the standards used (Validation & Verification reports. For example test reports for the 60601 series from an accredited laboratory)
☐	15.	Software validation report
☐	16.	Draft declaration of conformity with the requirements of the Technical Regulation
☐	17.	Draft label that meets the requirements of the Technical Regulation
☐	18.	Original label (EC market for example)
☐	19.	Instructions for use that meet the requirements of the Technical Regulations
☐	20.	Original instructions (EC market for example)

Additional documents for Design Examination:

☐	21.	Application for Design Examination
☐	22.	Design and development files / Design History File
☐	23.	Device Master Record for latest batch / record for each medical device or batch of medical devices that provides traceability and identifies the amount manufactured and amount approved for distribution
☐	24.	Performances of the product
☐	25.	Materials used. critical materials, components.
☐	26.	Raw material safety data. BSE / TSE certificates for products using materials of animal origin
☐	27.	Classification (with indication of the rule and justification) of a medical device according to Annex 2
☐	28.	List of all materials in direct or indirect contact with the patient or user, including material concentration and particle size
☐	29.	Design drawings and diagrams of components, sub-assemblies, circuits, etc.
☐	30.	The post-marketing surveillance program defined for this product, including details of any post-marketing clinical surveillance (see MEDDEV 2.12 / 2).