Appendix 1 – Internal Audit Checklist for ISO 13485 and in compliance with Article 10 of MDR 2017/745

Commented [AES1]: Delete this part if your organization does

1. Internal Audit Checklist for ISO 13485

Date of audit: [date]

Commented [AES2]: Include the date(s) when you have

ISO 13485 clause	Requirement of the standard	Compliant (Yes/No)	Evidence
4.1.1	Are the processes necessary for the QMS determined, described, managed, and applied in the organization in compliance with ISO 13485:2016 and MDR/2017/745?		
4.1.2	Does the organization implement a risk-based approach to the control of the appropriate processes needed for the Quality Management System, and is there a sequence and interaction of processes?		
4.1.3	Does the organization, for each QMS process, have: • criteria and methods needed to ensure that the control of these processes is effective, • availability of resources and information necessary to support the operation, • monitoring of these processes,		

Commented [AES3]: These are the requirements of the ISO 13485 standard; you should also insert the specific requirements from your own documentation.

Commented [AES5]: To be filled in during the audit – records,

Commented [AES4]: To be filled in during the audit – fill in Yes

Commented [AES6]: Delete this part if your organization does

Commented [AES7]: Delete this part if your organization does

Commented [AES8]: Delete this part if your organization does

4.1.4	How does the organization manage QMS processes in accordance with the requirements of this international standard and applicable regulatory requirements? [illegible]		
4.1.5	How does the organization ensure the control of outsourced processes that could affect product conformity to requirements?		
4.1.6	[illegible]		
4.2.1	Did the organization document the Quality Policy, quality objectives, Quality Manual, and procedures and records required by ISO 13485 and all documents and records defined as necessary by the organization?		
4.2.2	Does the Quality Manual include the scope of the QMS and justification for exclusions, procedures or reference to procedures, and interaction between the QMS processes?		
4.2.3	Does the organization have a medical device file for each medical device type, in line with ISO 13485:2016 and Annex II Technical documentation, Annex III Technical documentation on post-market surveillance, and Annex XIII Procedure for custom made devices from MDR 2017/745? [illegible]		
4.2.4-01	[illegible]		
4.2.4-02	Did the organization ensure that changes, current revision status and relevant versions of applicable documents are legible and readily identifiable and available at point of use?		

Commented [AES9]: You can delete this if your medical device [illegible]

Commented [AES10]: Delete this part if your organization [illegible]

4.2.4-03	[illegible]		
4.2.4-04	[illegible]		
4.2.4-05	Is the period for retention of documents to which medical devices have been manufactured and tested defined for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements?		
4.2.5	[illegible]		
4.2.5-01	Is the period for retention of records related to medical devices manufactured and tested defined for at least the lifetime of the medical device as defined by the organization, but not less than two years from the medical device release by the organization, or as specified by applicable regulatory requirements?		
5.1-01	Did top management demonstrate its commitment to development and implementation of the QMS by emphasizing the importance of meeting customer, statutory and regulatory requirements?		
5.1.-02	[illegible]		
5.2	[illegible]		
5.3	Does top management ensure that the Quality Policy is appropriate to the purpose of the organization and demonstrates a commitment to comply with the requirements and continuous improvement of the QMS, providing a framework for quality objectives communicated within the organization and reviewed?		
5.4.1	[illegible]		

5.4.2-01	[illegible]		
5.4.2-02	[illegible]		
5.5.1	[illegible]		
5.5.2	Did top management appoint a management representative who has the responsibility and authority to ensure processes needed for establishing, implementing and maintaining the QMS, and who reports to top management on QMS performance and need for improvement and promotes awareness of customer requirements throughout the organization?		
5.5.3	[illegible]		
5.6.1	Does top management conduct a QMS review that includes assessing opportunities for improvement and need for changes to the QMS, including Quality Policy and quality objectives, at planned intervals and maintain records about the review in order to ensure its continuous suitability, adequacy and effectiveness?		
5.6.2	Does the management review include information on results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up action from previous management reviews, changes that could affect the QMS and recommendations for improvement?		
5.6.3	[illegible]		
6.1	[illegible]		

6.2.1	[illegible]		
6.2.2-01	[illegible]		
6.2.2-02	[illegible]		
6.3	Did the organization determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements including buildings, workspace, associated utilities, and equipment and supporting services?		
6.4-01	[illegible]		
6.4.2-01	[illegible]		
6.4.2-02	Did the organization document requirements for sterile medical devices for control of contamination and the required cleanliness during assembly or packaging processes?		
7.1-01	Does the organization plan and develop processes needed for product realization, and is its planning compliant with the requirements of the other processes of the QMS in compliance with ISO 13485:2016 and MDR 2017/745?		
7.1-02	While planning product realization, did the organization determine, as appropriate, quality objectives and product requirements and the need to establish process documents and provide resources specific to the product?		
7.1-03	While planning product realization, did the organization determine, as appropriate, required activities of verification, validation, monitoring, measuring, controlling, and testing specific product criteria for product acceptance and records needed in compliance with ISO 13485:2016 and MDR 2017/745?		
7.1-04	[illegible]		

Commented [AES11]: Delete this part if your organization [illegible]

Commented [AES12]: Delete this part if your organization [illegible]

7.1-05	[illegible]		
7.2.1	Did the organization determine requirements specified by the customer, including requirements for delivery and post-delivery activities, requirements not stated by the customer, statutory and regulatory requirements regarding the product and any additional requirements considered necessary?		
7.2.2-01	Did the organization review and approve product requirements and its ability to meet requirements regardless of whether the requirements are documented prior to commitment to supply product to the customer, and maintain a record about the review?		
7.2.2-02	[illegible]		
7.2.2-03	[illegible]		
7.2.3	Did the organization determine and implement effective arrangements for communicating with customers related to product information inquiries, contract or other handling and customer feedback including customer complaints? [illegible]		
7.3.1	[illegible]		
7.3.2-01	Does the organization plan design and development of product by determining design and development stages, review, verification and validation actions that are appropriate to each design and development stage and responsibilities and authorities for design and development?		

Commented [AES13]: Delete this part if your organization [illegible]

Commented [AES14]: Delete this part if your organization [illegible]

7.3.2-02	Does the organization plan design and development of product by determining the methods of traceability of design and development outputs to design and development inputs and the resources needed, including necessary competence of personnel?		
7.3.3	Does the organization determine, maintain records and review inputs adequacy related to product, functional and performance requirements, statutory and regulatory requirements, applicable output(s) of risk management, information derived from previous similar designs and other requirements essential for design and development and record maintenance?		
7.3.4	Are outputs suitable for verification against input product requirements, and do they contain information for purchasing, production and service provision, reference to product acceptance criteria and specified product characteristics essential for its safe and proper use and approved prior to release?		
7.3.4-01	[illegible]		
7.3.5-01	Is a systematic review of design and development conducted in appropriate phases according to planned arrangements in order to evaluate the ability of the results of design and development to meet requirements, and to identify any problems and propose necessary actions?		
7.3.5-02	[illegible]		
7.3.6-01	[illegible]		
7.3.6-02	[illegible]		
7.3.7-01	[illegible]		
7.3.7-02	[illegible]		

7.3.7-03	[illegible]		
7.3.7-04	For medical devices that are connected to, or have interface with, other medical devices, did the validation include confirmation that the requirements for the specified application or intended use have been met when the devices are connected or interfaced?		
7.3.8	[illegible]		
7.3.9-01	[illegible]		
7.3.9-02	[illegible]		
7.3.10	Does the organization maintain a design and development file for each medical device type or medical device family? (This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.)		
7.4.1	Did the organization establish criteria for selection, evaluation and reevaluation of suppliers based on their ability to supply product in accordance with the organization's requirements, and maintain records about results?		
7.4.2	Is purchasing information adequate and contain a description of the purchased product, including, where appropriate, approval of product, procedures, processes and equipment, requirements for qualification of personnel and QMS requirements?		
7.4.3-01	[illegible]		

7.4.3-02	Did the organization state the intended verification arrangements and method of product release in the purchasing information when the organization or its customer intends to perform verification at the supplier's premises?		
7.5.1-01	Does the organization plan and execute production and service provision in managed conditions that include, as applicable, availability of information that describes the product characteristics, work instructions, and, as necessary, use of suitable equipment?		
7.5.1-02	Does the organization provide conditions that include availability and use of monitoring and measuring equipment, implementation of monitoring and measurement and implementation of product release, delivery and post-delivery activities?		
7.5.2-01	[illegible]		
7.5.3-01	[illegible]		
7.5.3-02	[illegible]		
7.5.3-03	[illegible]		
7.5.4-01	Has the organization documented servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met, and maintained records of servicing activities?		
7.5.4-02	Did the organization analyze records of servicing activities carried out by the organization or its supplier to determine if the information is to be handled as a complaint or for input to the improvement process?		
7.5.5-01	[illegible]		
7.5.5-02	[illegible]		

7.5.6	[illegible]		
7.5.7	[illegible]		
7.5.8	[illegible]		
7.5.9-01	[illegible]		
7.5.9-02	Do records for traceability include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements?		
7.5.10	[illegible]		
7.5.11	[illegible]		
7.6-01	Does the organization determine monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements?		
7.6-02	Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?		
7.6-03	Is measuring equipment calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards, and in cases when such standards don't exist, are the bases used for calibration and verification recorded?		
7.6-04	[illegible]		
7.6-05	[illegible]		

7.6-06	[illegible]		
7.6-07	Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements and take appropriate action on the equipment and any product affected?		
7.6-08	[illegible]		
7.6-09	Does the organization confirm the ability of computer software to satisfy the intended application in cases when it is used for monitoring and measurement of specified requirements?		
8.1-01	Does the organization plan and implement the monitoring, measurement, analysis and improvement processes to demonstrate conformity to the product requirements and the QMS, and continual improvement of the effectiveness of the QMS?		
8.1-02	[illegible]		
8.2.1-01	[illegible]		
8.2.1-02	[illegible]		
8.2.1-03	[illegible]		
8.2.2	[illegible]		
8.2.3	Did the organization have a procedure for reporting to regulatory authorities if applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices according to Articles 87 through 90 from the MDR 2017/745?		

Commented [AES15]: Delete this row if your organization does [illegible]

Commented [AES16]: Delete this part if your organization [illegible]

8.2.4-01	Does the organization conduct internal audits at planned intervals to determine whether the Quality Management System conforms to the planned arrangements, to the requirements of the ISO 13485:2016 standard, and to the quality management system requirements established by the organization?		
8.2.4-02	[illegible]		
8.2.4-03	[illegible]		
8.2.4-04	[illegible]		
8.2.4-05	Does the organization select auditors and conduct audits to ensure objectivity and impartiality of the audit process and prevent auditors from auditing their own work?		
8.2.4-06	Does the organization establish documented procedures to define the responsibilities and requirements for planning and conducting audits, establishing and maintaining records and reporting results?		
8.2.4-07	Does the management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes?		
8.2.4-08	[illegible]		
8.2.5-01	[illegible]		
8.2.5-02	[illegible]		
8.2.6-01	Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?		
8.2.6-02	[illegible]		

8.2.6-03	[illegible]		
8.2.6-04	Is the release of product and service to the customer prevented until the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, where applicable, by the customer?		
8.3.1-01	[illegible]		
8.3.1-02	[illegible]		
8.3.2-01	[illegible]		
8.3.2-02	Does the organization, where applicable, deal with nonconforming product by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?		
8.3.2-03	[illegible]		
8.3.2-04	Does the organization, where applicable, deal with nonconforming product by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started?		
8.3.2-05	[illegible]		
8.3.2-06	[illegible]		
8.3.3	Did the organization describe actions and responses for nonconforming product detected after delivery, and does an advisory notice procedure exist in accordance with applicable regulatory requirements?		
8.3.4	[illegible]		

8.4-01	Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made?		
8.4-02	Does the analysis of data provide information relating to: customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, including opportunities for preventive action and suppliers?		
8.5.1	Does the organization continually improve the effectiveness of the QMS through the use of the Quality Policy, Quality objectives, audit results, analysis of data, corrective and preventive actions and management review?		
8.5.2-01	[illegible]		
8.5.2-02	[illegible]		
8.5.2-03	[illegible]		
8.5.2-04	[illegible]		
8.5.2-05	Does the organization establish documented procedure to define requirements for evaluating the need for action to ensure that nonconformities do not recur?		
8.5.2-06	[illegible]		
8.5.2-07	[illegible]		
8.5.2-08	Does the organization establish documented procedures to define requirements for reviewing the effectiveness of the corrective action taken?		
8.5.3-01	Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?		

8.5.3-02	[illegible]		
8.5.3-03	Does the organization ensure that a documented procedure has been established to define requirements for determining potential nonconformities and their causes?		
8.5.3-04	Does the organization ensure that a documented procedure has been established to define requirements for evaluating the need for action to prevent occurrence of nonconformities?		
8.5.3-05	Does the organization ensure that a documented procedure has been established to define requirements for determining and implementing action needed?		
8.5.3-06	[illegible]		
8.5.3-07	Does the organization ensure that a documented procedure has been established to define requirements for reviewing the effectiveness of the preventive action taken?		
MDR article 10 9.3 f)	[illegible]		
MDR article 10 9.3 h)	[illegible]		

Commented [AES17]: Delete this row if your organization does [illegible]

Commented [AES18]: Delete this row if your organization does [illegible]

2. Internal Audit Checklist for technical documentation according to the MDR

Date of audit: [date]

MDR Annex and clause	Requirement from MDR 2017/745	Compliant (Yes/No)	Evidence
1. Device description and specification, including variants and accessories			
Annex II 1.1.a)	Is the device description document prepared with the product or trade name and a general description of the device, including its intended purpose and intended users?		
Annex II 1.1.b)	Is Basic UDI-DI, as referred to in Part C of Annex VI, assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system?		
Annex II 1.1.b)	[illegible]		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	Are the contraindications when using the device defined?		
Annex II 1.1.c) – 1.1.l)	Are the warnings for usage of the device defined?		
Annex II 1.1.c) – 1.1.l)	Are the principles of operation of the device and its mode of action defined?		

Commented [AES19]: You can delete the entire section if your [illegible]

Commented [AES20]: Include the date when you have [illegible]

Commented [AES22]: To be filled in during the audit – records, [illegible]

Commented [AES21]: To be filled in during the audit – fill in [illegible]

Commented [AES23]: Delete this row if your device is [illegible]

Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	Is a description of the accessories for a device, other devices, and other products that are not devices, which are intended to be used in combination with it, defined?		
Annex II 1.1.c) – 1.1.l)	[illegible]		
Annex II 1.1.c) – 1.1.l)	Is a general description of the key functional elements defined, e.g., its parts/components (including software, if appropriate), its formulation, its composition, its functionality, and, where relevant, its qualitative and quantitative composition? [illegible]		
Annex II 1.1.c) – 1.1.l)	Is 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?		
Annex II 1.1.c) – 1.1.l)	Are technical specifications, such as features, dimensions, and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogs, and similar publications?		
Annex II 1.2 a)	Is there a document that gives an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist?		
Annex II 1.2.b)	[illegible]		
2. Information to be supplied by the manufacturer			

Annex II 2.	Is a complete set of the label(s) for the single-unit packaging of the device prepared in the languages accepted in the Member States of the European Union where the device is expected to be sold?		
	Is a complete set of the label(s) for the sales packaging of the device prepared in the languages accepted in the Member States of the European Union where the device is expected to be sold?		
	Is a complete set of the label(s) for the transport packaging in case of specific management conditions of the device prepared in the languages accepted in the Member States of the European Union where the device is expected to be sold?		
	[illegible]		
	[illegible]		
	[illegible]		
3. Design and manufacturing information			
Annex II 3.a)	[illegible]		
Annex II 3.b)	Are purchasing, production, quality control, and warehousing procedure(s) and/or work instructions documented?		
Annex II 3.b)	[illegible]		
Annex II 3.b)	Are validation protocols and reports for all processes that need validation (like sterilization, packaging, clean room, etc.) prepared?		
Annex II 3.b)	[illegible]		
Annex II 3.b)	[illegible]		
Annex II 3.b)	[illegible]		
Annex II 3.b)	Are the identification and traceability processes and the UDI number documented?		

Commented [AES24]: You can delete this if technical drawings [illegible]

Annex II 3.c)	[illegible]		
Annex II 3.c)	[illegible]		
Annex II 3.c)	Is a list of suppliers, with corresponding supplier quality certificates, prepared?		
Annex II 3.c)	Are agreements signed with all suppliers and subcontractors where design and manufacturing activities are performed?		
4. General safety and performance requirements			
Annex II 4.	Are general safety and performance requirements (GSPR) prepared as a document that demonstrates the conformity with Annex I, and are they applicable to the device, taking into account its intended purpose?		
Annex II 4.a)	[illegible]		
Annex II 4.b)	Does the GSPR document define the method or methods used to demonstrate conformity with each applicable general safety and performance requirement?		
Annex II 4.c)	[illegible]		
Annex II 4.d)	Does the GSPR document precisely identify the controlled documents offering evidence of conformity with each harmonized standard, CS, or other method applied to demonstrate conformity with the general safety and performance requirements?		
5. Benefit-risk analysis and risk management (according to the requirements stated in Annex 1 from MDR 2017/745)			
Annex I 5.1.	Is the medical device designed, manufactured, and placed on the market to be safe and effective and not to compromise the clinical condition or the safety of patients, or the safety and health of the users?		
Annex I 5.2.	[illegible]		
Annex I 5.3.	[illegible]		
Annex I 5.3.	[illegible]		

Commented [AES25]: The information referred to under this [illegible]

Annex I 5.3.	[illegible]		
Annex I 5.4.	[illegible]		
Annex I 5.4.	[illegible]		
Annex I 5.4.	[illegible]		
Annex I 5.5.	[illegible]		
Annex I 5.5.	Does the manufacturer give consideration to the technical knowledge, experience, education, training, and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled, or other users)?		
Annex I 5.6.	Does the manufacturer define the characteristics and performance of a device to not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons is compromised during the lifetime of the device?		
Annex I 5.7.	Does the manufacturer design, manufacture, and package the medical device in such a way that its characteristics and performance during its intended use are not adversely affected during transport and storage? (for example, through fluctuations of temperature and humidity)		
Annex I 5.8.	Does the manufacturer minimize all known and foreseeable risks, and any undesirable side effects, to be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use?		
6. Product verification and validation			

Annex II 6.1.a)	Does the technical documentation include all necessary 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?		
Annex II 6.1.b)	Does the technical documentation include detailed information regarding test design, complete test or study protocols, and methods of data analysis, in addition to data summaries and test conclusions?		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	[illegible]		
Annex II 6.1.b)	Are there any tests regarding the performance and safety of the medical device?		
Annex II 6.1.c)	Are the Clinical Evaluation Plan and Clinical Evaluation Report prepared in accordance with Article 61(12) and Part A of Annex XIV?		
Annex II 6.1.d)	Are the PMCF Plan and PMCF Evaluation Report referred to in Part B of Annex XIV, or justification for why a PMCF is not applicable, prepared?		

Commented [AES26]: Where no new testing has been [illegible]

Commented [AES27]: Where no new testing has been [illegible]

Commented [AES28]: Where no new testing has been [illegible]

Commented [AES29]: Where no new testing has been [illegible]

Commented [AES30]: Where no new testing has been [illegible]

Commented [AES31]: Where no new testing has been [illegible]

Commented [AES32]: Where no new testing has been [illegible]

Commented [AES33]: Where no new testing has been [illegible]

Annex II 6.2.a)	Where a device incorporates, as an integral part, a substance that, if used separately, could be considered a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), is a statement prepared indicating this fact? [Documentation shall identify the source of that substance and contain the data from the tests conducted to assess its safety, quality, and usefulness, taking into account the intended purpose of the device.]		
Annex II 6.2. b)	Where a device is manufactured utilizing tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6), and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), is a statement prepared indicating this fact? [Documentation shall identify all tissues or cells of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I.]		
Annex II 6.2.c)	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, has detailed information been prepared, 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 these substances, or of their products of metabolism in the human body, with other devices, medicinal products, or other substances, considering the target population and its associated medical conditions • local tolerance • toxicity, including single dose toxicity, repeat dose toxicity, genotoxicity, carcinogenicity, and reproductive and developmental toxicity, as applicable depending on the kind and nature of exposure to the device In the absence of such studies, justification shall be provided.		

Commented [AES34]: If this is not applicable to your device,

Commented [AES35]: If this is not applicable to your device,

Commented [AES36]: If this is not applicable to your device,

Annex II 6.2.d)	[illegible]		
Annex II 6.2.e)	[illegible]		
Annex II 6.2.e)	[illegible]		
Annex II 6.2.f)	In the case of devices placed on the market with a measuring function, is a description of the methods used in order to ensure the accuracy as given in the specifications prepared?		
Annex II 6.2.g)	If the device is to be connected to other device(s) in order to operate as intended, is 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) with regard to the characteristics specified by the manufacturer, prepared?		
Post-Market Surveillance Plan			
Annex III 1.1.a)	[illegible]		
Annex III 1.1.a)	[illegible]		
Annex III 1.1.a)	Are the records referring to non-serious incidents and data on any undesirable side effects included in the PMSP?		
Annex III 1.1.a)	[illegible]		
Annex III 1.1.a)	Is the information provided by users, distributors, and importers, including feedback and complaints, included in the PMSP?		
Annex III 1.1.a)	[illegible]		
Annex III 1.1.b)	Is a proactive and systematic process to collect any information referred to in point a) covered in the PMSP?		

Commented [AES37]: If this is not applicable to your device, [illegible]

Commented [AES38]: If this is not applicable to your device, [illegible]

Commented [AES39]: If this is not applicable to your device, [illegible]

Commented [AES40]: If this is not applicable to your device, [illegible]

Commented [AES41]: If this is not applicable to your device, [illegible]

Annex III 1.1.b)	[illegible]		
Annex III 1.1.b)	Does the PMSP cover suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I?		
Annex III 1.1.b)	[illegible]		
Annex III 1.1.b)	Does the PMSP cover methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period?		
Annex III 1.1.b)	[illegible]		
Annex III 1.1.b)	[illegible]		
Annex III 1.1.b)	Does the PMSP cover systematic procedures to identify and initiate appropriate measures, including corrective actions?		
Annex III 1.1.b)	Does the PMSP cover effective tools to trace and identify devices for which corrective actions might be necessary?		
Annex III 1.1.b)	Does the PMSP cover a PMCF plan as referred to in Part B of Annex XIV, or justification as to why a PMCF is not applicable?		
Annex III 1.2	[illegible]		
Annex III 1.2	[illegible]		

Commented [AES42]: If you do not have class I medical [illegible]

Commented [AES43]: If you do not have class II or higher [illegible]