Extensive Checklist for IVDR Technical Documentations

This list is based on Regulation (EU) 2017/746 (IVDR) Annex II and Annex III. It helps to identify if all requirements are fulfilled and if you have all relevant documents included in your Technical Documentation.

| **Pos.** | **Requirement** | **Applicable** | **Fulfilled** | **Source** | **Comment or Justification** |
| --- | --- | --- | --- | --- | --- |
| **1** | **Device description and specification, including variants and accessories**Regulation (EU) 2017/746 (IVDR), Annex II Section 1 |
| **1.1** | **Device description and specification** |  |  |  |   |
| **1.1.1** | **Product or trade name and manufacturer** |  |  |  |  |
|  | * The product name shall be consistent with the product displayed on the product’s packaging and marketing brochures as well as the application.
* Name and address of the manufacturer, SRN
* If applicable, name and address of the EU authorised representative, SRN
 |  |  |  |  |
| **1.1.2** |  **Basic unique device identifier** |  |  |  |   |
|  | The Basic UDI device identifier attributed by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability. |  |  |  |  |
| **1.1.3** | **Intended purpose and intended user** |  |  |  | If you need help with the intended purpose of your device, you may use our intended purpose generator AstraPurpose for free: https://astracon.eu/tools/intended-purpose/ |
|  | * what is to be detected and/or measured;
* its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;
* the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
* whether it is automated or not;
* whether it is qualitative, semi-quantitative or quantitative;
* the type of specimen(s) required
* testing population;
* Intended user of the device: what is the intended user group of the device, such as self-testing, near patient and laboratory professional use, healthcare professionals;
* for CDx, the relevant target population with associated medicinal product;
 |  |  |  |  |
| **1.1.4** | **General device description** |  |  |  |  |
|  | * the description of the principle of the assay method or the principles of operation of the instrument;
* the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers; and where applicable:
* the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;
* for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;
* for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;
* a description of any software to be used with the device
 |  |  |  |  |
| **1.1.5** | **Qualification and classification** |  |  |  |  |
|  | * Rationale for the qualification of the product as an In Vitro Diagnostic medical device.
* The rule(s) used for classification including the bullet point of classification rule shall be named, a justification shall be given.
* The risk class of the device
* EMDN classification (if applicable)
 |  |  |  | If you need help with the classification of your device, you may use our classification tool AstraClass for free: https://astracon.eu/tools/classification/ |
| **1.1.6** | **Declaration of Conformity** |  |  |  |  |
|  | Declaration of Conformity according to Annex IV of IVDR (For initial certification (e.g., according to IVDR), the declaration of conformity must be submitted as a draft.) |  |  |  |  |
| **1.1.7** | **Composition of the device** |  |  |  |  |
|  | Specifications Raw materials/parts/components such as technical specifications, materials, properties, dimensions and performance attributes; in particular integrated raw materials as well as substances that come into direct or indirect contact with the human body, specifications packaging materials (primary and secondary packaging, If applicable, meaningful certificates of analysis from suppliers, material certificates, test certificates. |  |  |  |  |
| **1.1.8** | **Sampling and preparation** |  |  |  |  |
|  | Description of the intended sampling procedures, treatments (e.g., storage, anticoagulants) and preparations (filtration, centrifugation, purification, extraction) for all sample materials specified in the intended use. |  |  |  |  |
| **1.1.9** | **Accessories and device combinations** |  |  |  |  |
|  | 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 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. Accessories provided separately need to have their own labelling, instruction for use, packaging and certification.A description of all accessories / equipment that is required for use, but not provided with the device. Must also be mentioned in the IFU. |  |  |  |  |
| **1.1.10** | **Configurations and variants of the device** |  |  |  |  |
|  | If there are any configurations and variants of the device, this shall be laid down in the Technical Documentation, including any model numbers, names, constituents, packing units, sizes etc |  |  |  |  |
| **1.2** | **Reference to previous and similar Generations of the Device** |  |  |  |  |
|  | * An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;
* An overview of identified similar devices available on the Union or international markets, where such devices exist.
 |  |  |  |  |
| **1.3** | **Summary of safety and performance (SSP)****(Only for class C and D devices)**(Regulation (EU) 2017/746 (IVDR), Article 29) |  |  |  |  |
|  | Draft or summary report according to Article 29 IVDR (SSP) safety and performance for class C and D devices, except devices for performance studies.The SSP should:* be written in an understandable language for the intended target group.
* include the identification of the device, including the basic UDI DI and the single registration number.
* include the intended purpose of the device and any indications, contra-indications and target populations.
* include a description of the device, as well as a description of the accessories, other medical devices and combination with other devices, and a reference to previous generation(s) or variants.
* include the summary of the performance evaluation report and relevant information on the post-market production follow up.
* include references to harmonised standards and common (technical) specifications.
* include metrological traceability of assigned values.
* include suggested profile and training for users.
* include information on any residual risks and any undesirable effects, warnings and precautions.
 |  |  |  |  |
| **2.**  | **Information supplied by the manufacturer****(Regulation (EU) 2017/746 (IVDR), Annex II Section 2)** |
|  | * A complete set of the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;
* A complete set of the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.
 |  |  |  |  |
| **3.** | **Design and manufacturing information****(Regulation (EU) 2017/746 (IVDR), Annex II Section 3)** |
| **3.1** | **Design Information** |  |  |  |  |
|  | * Information to allow the design stages applied to the device to be understood:
	+ a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;
	+ for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;
	+ for instruments and software, an overview of the entire system;
	+ for software, a description of the data interpretation methodology, namely the algorithm;
	+ for devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self-testing or near-patient testing.
* Information on the specific design stages, the techniques that are used to control, monitor and verify the design of the device during these stages.
* A summary on the design process with reference to the applied implemented documented procedure(s) and versions date shall be included.
* Information on the sites where the design process was carried out (e.g., outsourced development units, research facilities, etc.).
* For CDx, the design with regards to suitability of the device in relation to the medicinal product concerned.
 |  |  |  |  |
| **3.2** | **Manufacturing Information** |  |  |  |  |
|  | Manufacturing includes production, assembly, final product testing, packaging, sterile packaging, sterilisation, final packaging (as applicable).Flow Chart including 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 chemical required to product the device, including the identification of all sites involved in manufacturing processes (including addresses).In case of sub-contracted (outsourced) processes:* For non-critical component suppliers (e.g., bulk) identification of supplier only.
* For critical component suppliers (e.g., outsourced manufacturing of sterile device) overview of manufacturing processes and corresponding control measures (e.g., references to verification and validation activities, copy of the certificate shall be included).
 |  |  |  |  |
| **4.** | **General Safety and Performance Requirements****(Regulation (EU) 2017/746 (IVDR), Annex II Section 4)** |
| **4.1** | **GSPR Checklist** |  |  |  |  |
|  | Fulfilment of all applicable General Safety and Performance Requirements must be shown. Please make sure: * Non-applicable General Safety and Performance Requirements shall have a justification as to why they are not applicable to the device.
* 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 is provided.
* Assessment of whether the requirements are met
 |  |  |  |  |
| **4.2** | **List of applicable standards** |  |  |  |  |
|  | Current list of applied standards with issue status, as well as indication of which parts of the standards have not been applied, if applicable. This can be integrated into 4.1, if preferred. |  |  |  |  |
| **5.** | **Benefit-Risk Analysis and Risk Management****(Regulation (EU) 2017/746 (IVDR), Annex II Section 5)** |
| **5.1** | **Benefit-Risk Analysis and Risk Management** |  |  |  |  |
|  | * Risk management plan
* Risk analysis including control measures
* Risk management report including evaluation of residual risks and the benefit-risk analysis

If the plan and report are not self-explanatory, a copy of the relevant risk management procedure(s) should be provided. |  |  |  |  |
| **5.2** | **Specific Usability Risks (only for Self-Testing / Near-Patient Testing)** |  |  |  |  |
|  | The risk files should specifically address risks with regards to usability related to self-testing or near-patient testing.All known and foreseeable hazards associated with layman / near-patient use must be identified.All risks associated with these hazards occurring during intended use and during reasonable foreseeably misuse must be estimated and evaluated.Risk control measures related to use error conform to safety principles, taking account of the generally acknowledged state of the art. Risks related to the ergonomic features of the device and the environment in which the device is intended to be used must be reduced as far as possible.The technical knowledge, experience, education, training and use environment must be considered.The medical and physical conditions of intended users must be considered. |  |  |  |  |
| **6.** | **Product Verification and Validation** |
|  | All verification and validation documents in the sections below shall at a minimum comprise a plan, including acceptance criteria and a rationale for sample size, and a report that analyses and summarised the results. For non-applicability a justification shall be submitted. |  |  |  |  |
| **6.1** | **Analytical Performance** |  |  |  |  |
| **6.1.1** | **Specimen Type / Handling** |  |  |  |  |
|  | A description of specimen type and handling, including, where applicable:* Different specimen types that can be analysed
* Determination of appropriate criteria for specimen collection and handling, stability, storage, transport
* Usage of different anticoagulants (EDTA, Citrate, Heparin, etc.)
* The influence of sample pre-treatment
* For 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.
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| **6.1.2** | **Analytical Performance** |  |  |  |  |
|  | The analytical performance shall contain at a minimum, where applicable:* Accuracy and precision of measurement
	+ The intra- and inter-assay-precision. The samples should be representative and cover different levels of reactivity.
* Analytical sensitivity
	+ Specimen type, number of replicates, concentration tested, calculation of determination of sensitivity should be clear.
* Analytical specificity
	+ Interfering endogenous / exogenous substances investigated:
		- Substances used for patient treatment (e.g., medicinal products)
		- Substances ingested by patient (e.g., alcohol, food)
		- Substances added during specimen preparation (e.g., preservatives, stabilisers)
		- Substances encountered in specific specimen types (e.g., hemoglobin, lipids, bilirubin, proteins)
		- Analytes of similar structure (e.g., precursors, metabolites)
		- Typical interfering substances
* Metrological traceability of calibrator and control material values
	+ Measuring range of the assay
	+ Limits of detection and quantitation
	+ Measuring range (including high dose hook effect)
	+ Linearity
* Definition of assay cut-off including description of study design, populations studies, method / mode of specimen characterisation, statistical methods.
 |  |  |  |  |
| **6.1.3** | **Analytical Performance Report** |  |  |  |  |
|  | The results should be summarised in the analytical performance report. It shall contain a conclusion if the Safety and Performance requirements (including Common Technical Specifications / Common Specifications) concerning the sensitivity and specificity are fulfilled. It shall demonstrate the analytical performance, taking into consideration the state of the art (e.g., CE-marked reference test applied). |  |  |  |  |
| **6.2** | **Clinical Performance** |  |  |  |  |
| **6.2.1** | **Clinical Performance** |  |  |  |  |
|  | The clinical performance must be demonstrated based on:* Clinical performance studies and/or
* Scientific (peer-reviewed) literature and/or
* Published experience gained by routine diagnostic testing

If Clinical Performance Studies are performed, a Clinical Performance Study Plan and Report shall be provided. The report shall include, where applicable: * Diagnostic sensitivity
* Diagnostic specificity
* Positive predictive value
* Negative predictive value
* Likelihood ratio
* Expected values in normal and affected populations
 |  |  |  |  |
| **6.2.2** | **Performance of self-testing devices / Near-patient testing devices** |  |  |  |  |
|  | Layperson studies/near-patient studies shall demonstrate the performance for the intended user population, taking into consideration the skills and me |  |  |  |  |
| **6.3** | **Scientific Validity** |  |  |  |  |
|  | Scientific validity shall be demonstrated and documented in the scientific validity reportScientific validity demonstrated based on:* Relevant information of devices measuring the same analyte or marker and/or
* Scientific (peer-reviewed) literature and/or
* Consensus expert opinions / positions from relevant professional associations and/or
* Results from proof-of-concept studies and/or
* Results from clinical performance studies and/or
 |  |  |  |  |
| **6.4** | **Performance Evaluation Report** |  |  |  |  |
|  | An overall Performance Evaluation Report shall summarise all performance evaluation results and shall contain at a minimum, where applicable:* Justification for the approach taken to gather clinical evidence.
* Literature search methodology / protocol / report of literature review (or a reference to it).
* Technology on which the device is based, the intended purpose of the device and any claims made about the device’s performance and/or safety.
* Scientific validity and analytical / clinical performance.
* Clinical evidence demonstrating the state-of-the-art of the device.
* New conclusions derived from Post-Market Performance Follow-Up (PMPF).
 |  |  |  |  |
| **6.5** | **Stability** (Regulation (EU) 2017/746 (IVDR), Annex II Section 6.3) |  |  |  |  |
| **6.5.1** | **Claimed shelf-life** |  |  |  |  |
|  | This Section shall provide information on stability testing studies to support the shelf life that is claimed for the device. 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. Such detailed information shall include: * the study report including the protocol, number of lots, acceptance criteria and testing intervals;
* where accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described;
* the conclusions and claimed shelf life.
 |  |  |  |  |
| **6.5.2** | **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 the case of automated instrumentation, if calibration stability is claimed, supporting data shall be included. Such detailed information shall include: * the study report (including the protocol, acceptance criteria and testing intervals);
* the conclusions and claimed in-use stability.
 |  |  |  |  |
| **6.5.3** | **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. Such information shall describe: * the study report (including the protocol, acceptance criteria);
* the method used for simulated conditions;
* the conclusion and recommended shipping conditions.
 |  |  |  |  |
| **6.6** | **Software Verification and Validation / Functional Safety / Cybersecurity** (Regulation (EU) 2017/746 (IVDR), Annex II Section 6.4) |  |  |  |  |
|  | Documents regarding validation of the software (verification, validation and testing performed in-house and in actual user environment. Documentation should demonstrate the product was developed and manufactured according to state-of-the-art taking into account the principles of development life cycle, risk management, information security, verification and validation. |  |  |  |  |
| **6.7** | **Chemical, Physical and Biological Properties**(Regulation (EU) 2017/746 (IVDR), Annex II Section 6.5) |  |  |  |  |
| **6.7.1** | **Nanoparticle Technology** |  |  |  |  |
|  | The documentation should demonstrate that the nanoparticles were designed and manufactured in such a way as to reduce as far as possible risks linked to the size and the properties of particles used. |  |  |  |  |
| **6.7.2** | **Hazardous Substances** |  |  |  |  |
|  | A documentation of all hazardous substances that are incorporated in the device, and how they are controlled and labelled. Any risks should be addressed in risk management. |  |  |  |  |
| **6.7.3** | **Biological Evaluation** |  |  |  |  |
|  | Assessment of whether there are risks from contaminants and residues of the device or its materials to users, patients or third parties. Where applicable, these substances shall be described and, where appropriate, tests shall be carried out which are adequate in relation to the tissues exposed to these contaminants and residues and the duration and frequency of exposure. |  |  |  |  |
| **6.7.4** | **Substances of Animal / Human / Microbiological Origin** |  |  |  |  |
|  | A documentation of all substance of Animal / Human / Microbiological Origin. What component is affected; what control measures are performed. A validation should be available, if applicable. Any risks should be addressed in risk management. |  |  |  |  |
| **6.7.5** | **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.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. The validation report shall address bioburden testing, and, if applicable, testing for sterilant residues. |  |  |  |  |
| **6.7.6** | **Constructional Safety** |  |  |  |  |
| **6.7.6.1** | **Mechanical Safety** |  |  |  |  |
|  | A documentation that demonstrates that all relevant harmonised (if applicable) or state-of-the-art standards and IVDR provisions were followed, including minimisation of all identified risks. |  |  |  |  |
| **6.7.6.2** | **Electrical safety / electromagnetic compatibility** |  |  |  |  |
|  | A documentation that demonstrates that all relevant harmonised (if applicable) or state-of-the-art standards and IVDR provisions were followed, including minimisation of all identified risks. |  |  |  |  |
| **6.7.6.3** | **Ionising and non-ionising radiation** |  |  |  |  |
|  | A documentation that demonstrates that all relevant harmonised (if applicable) or state-of-the-art standards and IVDR provisions were followed, including minimisation of all identified risks. |  |  |  |  |
| **6.7.6.4** | **Environmental protection and safe disposal** |  |  |  |  |
|  | A documentation that after use, the disposal of product and packaging in accordance with hospital, administrative and/or local government policy is safe. Precautions to be taken against any special, unusual risks related to the disposal of the device should be included in the labelling. |  |  |  |  |
| **6.7.6.5** | **Packaging** |  |  |  |  |
|  | A description of the packaging including a documentation the demonstrates that packaging will not adversely affect the device characteristics and performances during the shelf life of the device. Validation of packaging with regards to integrity, cleanliness, and sterilisation, where applicable. |  |  |  |  |
| **6.7.6.6** | **Devices with connection to other device(s)** |  |  |  |  |
|  | Information how to obtain a validated and safe combination (including key performance characteristics).A demonstration that the whole combination (including the connection system) is safe and does not impair the specified performances. Information given on known restrictions to combinations. If device needs to be connected to other equipment, description of combination given including proof that it conforms to the general safety and performance requirements. |  |  |  |  |
| **6.7.7** | **Devices with a Measuring Function** |  |  |  |  |
|  | Measurements should be expressed in legal units conforming to provisions the respective regulatory requirements. Metrological traceability of values assigned to calibrators and control materials must be shown. |  |  |  |  |
| **7.** | **Post-Market Surveillance****(Regulation (EU) 2017/746 (IVDR), Annex III)** |
| **7.1** | **Post-market surveillance plan** |  |  |  |  |
|  | The post-market surveillance plan shall address the collection and utilisation of available information, in particular:* information concerning serious incidents, including information from PSURs, and field safety corrective actions,
* records referring to non-serious incidents and data on any undesirable side-effects,
* information from trend reporting,
* relevant specialist or technical literature, databases and/or registers,
* information, including feedbacks and complaints, provided by users, distributors and importers, and
* publicly-available information about similar medical devices.
 |  |  |  |  |
|  | The post-market surveillance plan shall cover at least:* a proactive and systematic process to collect any information referred to above. The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;
* effective and appropriate methods and processes to assess the collected data;
* 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;
* effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;
* methods and protocols to manage the events subject to the trend report as provided for in Article 83, 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;
* methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
* reference to procedures to fulfil the manufacturers obligations laid down in Articles 78, 79 and 81;
* systematic procedures to identify and initiate appropriate measures including corrective actions;
* effective tools to trace and identify devices for which corrective actions might be necessary; and
* a PMPF plan as referred to in Part B of Annex XIII, or a justification as to why a PMPF is not applicable.
 |  |  |  |  |
| **7.2** | **Post-Market Surveillance Report (only class A and B devices)** |  |  |  |  |
|  | Summarise the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the notified body and the competent authority upon request. |  |  |  |  |
| **7.2** | **Periodic Safety Update Report (PSUR) (only class C and D devices)** |  |  |  |  |
|  | The results and conclusions of the analyses of the gathered post-market surveillance data according to Annex III together with a rationale and description of any preventive and corrective actions taken shall be gathered in a PSUR, all PSURs are part of the Technical Documentation.Throughout the lifetime of the device concerned this report shall set out:* the conclusion of the benefit risk determination;
* the main findings of the Post Market Performance Follow-up Report and
* the volume of sales of devices and an estimate of the population that use the device
* and, where practicable, the usage frequency of the device.

Manufacturers of class C and D devices shall update the report at least annually and it shall be part of the technical documentation as specified in Annexes II and III. |  |  |  |  |
| **7.3** | **Post Market Performance Follow-Up (PMPF)** |  |  |  |  |
| **7.3.1** | **PMPF Plan** |  |  |  |  |
|  | The PMPF plan shall specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of:* confirming the safety and performance of the device throughout its expected lifetime,
* identifying previously unknown risks or limits to performance and contra-indications,
* identifying and analysing emergent risks on the basis of factual evidence,
* ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio and
* identifying possible systematic misuse.
 |  |  |  |  |
|  | The PMPF plan shall include at least:* the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;
* the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies;
* a rationale for the appropriateness of the methods and procedures mentioned above
* a reference to the relevant parts of the performance evaluation report and to the risk management
* the specific objectives to be addressed by the PMPF
* an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art;
* reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMPF, and;
* a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer.
 |  |  |  |  |
| **7.3.2** | **PMPF Evaluation Report** |  |  |  |  |
|  | PMPF Evaluation reports analysing and concluding results of activities performed according to the PMPF plan shall be part of the Technical Documentation. It should include. at least items according to Annex XIII part B 5.2. Conclusions of the PMPF evaluation reports shall be taken into account for the performance evaluation and in the risk management. Performance evaluation report shall be updated as per the PMPF plan. |  |  |  |  |
| **8.** | **Proposed Perimeters for Products Verification Program (only class D devices)** |
|  | Description of the final Quality Control release testing protocol (specification of samples / panels used, final release criteria). The information must match with the document provided to the Notified Body with the request to release the respective batch of class D product.Documentation of consultation procedures (e.g., with the competent medicinal authority, reference laboratories or other expert bodies). |  |  |  |  |