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| --- |
| **IVDR 2017/746**  **Application Form: Initial Assessment** |

**Section 1**

**Administration**

|  |  |  |
| --- | --- | --- |
| **General Information** | | |
| PO Number: | |  |
| Manufacturer  (as per definition within the regulation): | |  |
| Address: | |  |
| Device or Device Group Name: | |  |
| Classification: | |  |
| SRN: | |  |
| EU Authorised Representative: | NA | Name:  Address:  Email:  Telephone: |
| Name of Person Responsible for Regulatory Compliance: | |  |
| Company Liaison and Details: | | Name:  Address:  Email:  Telephone: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Please Complete for Impartiality Review** | | | |
| **Critical Suppliers Of Products And Services as defined by your purchasing process for**  **the medical device under review**  ***Note*: A critical supplier is a supplier delivering materials, components, or services that may influence the safety and performance of the device \*NBOG BPG 2010-1.** | | | |
| **Product/Service** | **Supplier Name / Address** | | **Supplier Certified by** |
| e.g., Moulded components | e.g., MouldCo, Inc. California, USA | | e.g., NSAI |
|  |  | |  |
|  |  | | *Add lines as required* |
| List all potential commercial competitor(s) for **the medical device under review** | | | |
| **Client Product to be CE Marked with NSAI** | | **Potential Commercial Competitor Name(s)** | |
| e.g., Pregnancy Test | | CHG, Inc., Pregnancy Laboratories Inc., ACME Testing. | |
|  | |  | |
|  | | *Add lines as required* | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Signatures** | | | | |
| We, the manufacturer, declare the information in this form is correct and has been submitted as instructed. Information not provided, or provided in the wrong format, may result in prolonged review time, delays, or termination of review. | | | | |
| Signed on Behalf of the Manufacturer | | | | |
| Please  Sign  Here | ▶ |  | | |
| Print Name | |  | | |
| Position / Title: | |  | | |
| Contact Person details (if different): NA | | | | |
| Name:  Title: | | | | Email:  Phone: |
| For NSAI Use Only | | | | |
| Reviewer | | | Signed and Dated | |
| Technical | | |  | |
| Sterilisation | | |  | |
| Electrical | | |  | |
| Software | | |  | |
| Clinical Benefit Review | | |  | |
| External Expert | | |  | |
| Trainee | | |  | |
| By signing this, the reviewer confirms that they have no conflict of interest with the above-named company (e.g., training, consultancy, financial, personal, or political) that would affect the integrity of the technical review process and hence the review results and that this activity is not further subcontracted. | | | | |

**Section 2**

**Technical Documentation**

**Instructions**

* All documentation must be in **English**.
* The complete Technical Documentation must be submitted in full. References to files from other products or previous submissions **are not accepted.**
* We do not accept hard copies of Technical Documentation.
* Documents must be provided in the form of **PDF files**, bookmarked, paginated, fully searchable.
* PDF files and attachments should not be file protected or locked.
* File names **must not be long**; they should be succinct and be accurate to the information contained within.
* Data must be of high quality; the duration of the review and the number of queries is dependent on the quality of the data received.

**How to Submit Technical Documentation**

* Manufacturers may submit one PDF file for **all required parts** as listed in Table 1 below

**or**

* Manufacturers may submit one PDF file for **each required part** as listed in Table 1 below.
  + Depending on the size and type of data, it may assist the review to split the data across more than one PDF file.
* All files submitted must be bookmarked, searchable and align to Parts A to M in Table 1 below.

**Table 1: List of required Technical Documentation**

|  |  |
| --- | --- |
| **Technical Documentation** | **IVDR Reference** |
| **Part A** – Device Description And Specification, Including Variants And Accessories | Annex II Section 1 |
| **Part B** – Information To Be Supplied By The Manufacturer | Annex II Section 2 |
| **Part C** – Design and Manufacturing Information | Annex II Section 3 |
| **Part D** – GSPR information | Annex II Section 4 |
| **Part E** – Benefit Risk Analysis and Risk management | Annex II Section 5, Annex I Chapter 1 Sections 1,3 & 8 |
| **Part F** – Product Verification and Validation  Specimen Type | Annex II Section 6.1 |
| **Part G** – Product Verification and Validation  Scientific Validity | Annex XIII Section 1.2.1 |
| **Part G** – Product Verification and Validation  Analytical Performance | Annex II Section 6.1.2 |
| **Part G** – Product Verification and Validation  Clinical Performance | Annex II Section 6.2 and Annex XIII |
| **Part G** – Product Verification and Validation  Performance Evaluation Plan & Report | Annex II Section 6.2 and Annex XIII Sections 1.1 & 1.3.2 |
| **Part H** – Product Verification and Validation  Stability and Packaging | Annex I, II Section 6.3 and XIII |
| **Part I** – Product Verification and Validation  Software Verification and Validation | Annex II Section 6.4 |
| **Part J** – Product Verification and Validation  Additional information required in specific cases | Annex II Section 6.5 |
| **Part K** – Summary of Safety Performance | Article 29 |
| **Part L** – Technical Documentation on PMS | Annex III |
| **Part M** – Declaration of Conformity | Annex IV |

**How to complete this application form**

In each section below please provide a reference to the relevant technical documentation.

The purpose of this form is as a reference to your technical document. **Do not provide data on the form below.**

* Complete each section below by stating:
  + The PDF file name.
  + The reference to where the supporting information can be found with the PDF file.
  + If required, explanatory notes can accompany the reference
  + See example below.

Graphical user interface, text, application, email

Description automatically generated

* Use the NA box in the header for all non-relevant sections. A detailed justification must be provided for all non-relevant sections.

**Part A - Device Description and Specification, Including Variants and Accessories**

This section should include references to information to meet the requirements of Annex II Section 1.

|  |  |
| --- | --- |
| **Product or Trade Name (Annex II, 1.1, a)** | NA |
| Technical documentation reference to the product or trade name and a general description of the device. The product name shall be consistent with the product displayed on the product’s packaging and marketing brochures as well as the application. | |
| **File name:**  **Reference:**  **Note:** | |
| **Basic UDI-DI (Annex II, 1.1, b)** | NA |
| Technical documentation reference to the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question. | |
| **File name:**  **Reference:**  **Note:** | |
| **Intended Purpose of the Device (Annex II, 1.1, c)** | NA |
| Technical documentation reference to details of relevant information as per Annex II section 1.1 c. | |
| The intended purpose of the device which may include information on:   * 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 * where applicable, the testing population * the intended user * in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s). | |
| **File name:**  **Reference:**  **Note:** | |
| **Description of methods and principles of operation (Annex II, 1.1, d)** | NA |
| Technical documentation reference to description of the principle of the assay method or the principles of operation of the instrument. | |
| The technical documentation should include data on   * critical ingredients of the device such as enzymes antibodies, antigens, primers, * specific specimen handling and transport conditions and associated instructions * instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software * relevant information if the device is used by a specific instrument or with an automated assay, if applicable * relevant software information, if applicable * relevant information for | |
| **File name:**  **Reference:**  **Note:** | |
| **Qualification of the product as a device (Annex II, 1.1, e)** | NA |
| Technical documentation reference to the rationale for the qualification of the product as a device. | |
| **File name:**  **Reference:**  **Note:** | |
| **Risk Class / Classification of the device (Annex II, 1.1, f)** | NA |
| Technical documentation reference to identify the rule(s) used for classification as per Annex VIII. The specific bullet point of classification rule shall be identified. Provide a detailed justification for the rule and the specific bullet point. | |
| **File name:**  **Reference:**  **Note:** | |
| **Components of the device (Annex II, 1.1, g)** | NA |
| Technical documentation reference to the description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers. | |
| **File name:**  **Reference:**  **Note:** | |
| **Collection and transport materials (Annex II, 1.1, h)** | NA |
| Technical documentation reference to the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use. | |
| **File name:**  **Reference:**  **Note:** | |
| **Automated assay instruments only (Annex II, 1.1, i)** | NA |
| Technical documentation reference to the description of the appropriate assay characteristics or dedicated assays. | |
| **File name:**  **Reference:**  **Note:** | |
| **Automated assays only (Annex II, 1.1, j)** | NA |
| Technical documentation reference to the description of the appropriate instrumentation characteristics or dedicated instrumentation. | |
| **File name:**  **Reference:**  **Note:** | |
| **Software (Annex II, 1.1, k)** | NA |
| Technical documentation reference to the description of any software to be used with the device. | |
| **File name:**  **Reference:**  **Note:** | |
| **Configurations / Variants of the device (Annex II, 1.1, l)** | NA |
| Technical documentation reference to the description or complete list of the various configurations/variants of the device that are intended to be made available on the market. | |
| **File name:**  **Reference:**  **Note:** | |
| **Accessories (Annex II, 1.1, m)** | NA |
| Technical documentation reference to the description of all accessories for the device, other devices and other products that are not devices, which are intended to be used in combination with the device. Accessories provided separately need to have their own labelling, instruction for use, packaging and certification. Accessories provided separately need to conformity to all relevant GSPRs. | |
| **File name:**  **Reference:**  **Note:** | |

**Reference to Previous and Similar Generations of the Device**

|  |  |
| --- | --- |
| **Previous generations (Annex II, 1.2, a)** | NA |
| Technical documentation reference to an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist. | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Similar Devices (Annex II, 1.2, b)** | NA |
| Technical documentation reference to an overview of identified similar devices available on the Union or international markets, where such devices exist. | |
| **File name:**  **Reference:**  **Note:** | |

**Part B - Information to be Supplied by the Manufacturer**

This section should include information to meet the requirements of Annex II Section 2.

|  |  |
| --- | --- |
| **Labels (Annex II, 2, a)** | NA |
| Technical documentation reference to a complete set of the 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 | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Instructions for Use (Annex II, 2, b)** | NA |
| Technical documentation reference to the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold. | |
| **File name:**  **Reference:**  **Note:** | |

**Part C** - **Design and Manufacturing Information**

This section should include information to meet the requirements of Annex II Section 3.

|  |  |
| --- | --- |
| **Critical Ingredients (Annex II, 3.1, a)** | NA |
| Technical documentation reference to 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. | |
| **File name:**  **Reference:**  **Note:** | |
| **Instruments (Annex II, 3.1, b)** | NA |
| Technical documentation reference for instruments, containing a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software; | |
| **File name:**  **Reference:**  **Note:** | |
| **Instruments and Software (Annex II, 3.1, c)** | NA |
| Technical documentation reference for instruments and software, which contains an overview of the entire system | |
| **File name:**  **Reference:**  **Note:** | |
| **Instruments and Software (Annex II, 3.1, d)** | NA |
| Technical documentation reference for a description of the data interpretation methodology, namely the algorithm | |
| **File name:**  **Reference:**  **Note:** | |
| **Self-Test (Annex II, 3.1, e)** | NA |
| Technical documentation reference for devices intended for self-testing which contains a description of the design aspects that make them suitable for self-testing. | |
| **File name:**  **Reference:**  **Note:** | |

**Manufacturing Information**

|  |  |
| --- | --- |
| **Manufacturing Information (Annex II, 3.2, a)** | NA |
| Technical documentation reference to information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. | |
| Technical documentation should include a summary of manufacturing processes (flow diagrams, manufacturing procedures, process flow charts etc) allowing an understanding of the steps required to produce the device. | |
| **File name:**  **Reference:**  **Note:** | |
| **Sites information - including suppliers and sub-contractors (Annex II, 3.2, b)** | NA |
| Technical documentation reference to identify all sites, including suppliers and sub-contractors, where manufacturing activities are performed. | |
| Technical documentation should clearly identify all critical **and** non-critical sub-contracted processes (supplier of generic parts/components).  For all critical sub-contracted processes (outsourced manufacturing process) Technical documentation should include a summary of manufacturing processes (flow diagrams, manufacturing procedures, process flow charts etc) allowing an understanding of the outsourced process. Include references to verification and validation activities. All relevant certificates should be available. | |
| **File name:**  **Reference:**  **Note:** | |

**Part D - General Safety and Performance Requirements**

This section should include information to meet the requirements of Annex II Section 4.

The documentation provided for Part 4 shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements.

|  |  |
| --- | --- |
| **Applicable and non-applicable GSPRs (Annex II, 4, a)** | NA |
| Technical documentation reference to solutions to the general safety and performance requirements that apply to the device and an explanation as to why others do not apply | |
| **File name:**  **Reference:**  **Note:** | |
| **Methods of conformity (Annex II, 4, b)** | NA |
| Technical documentation reference to the method(s) used to demonstrate conformity with each applicable general safety and performance requirement | |
| **File name:**  **Reference:**  **Note:** | |
| **Common specification, Harmonised Standards and other Standards/Solutions (Annex II, 4, c)** | NA |
| Technical documentation reference to the harmonised standards, CS or other solutions applied | |
| **File name:**  **Reference:**  **Note:** | |
| **Related Documentation (Annex II, 4, d)** | NA |
| Technical documentation reference to the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation. | |
| **File name:**  **Reference:**  **Note:** | |

**Part E - Benefit-Risk Analysis and Risk Management**

This section should include information to meet the requirements of Annex II Section 5.

|  |  |
| --- | --- |
| **Benefit-Risk (Annex II, 5 (a) and (b) and Annex I Chapter 1 Sections1, 3 & 8- GSPRs)** | NA |
| Technical documentation reference to the risk management files which address the specific risk requirements. | |
| Technical documentation should at least include a risk management plan and report. Supporting risk management procedures may be included to aid understanding. State of the art should be considered. | |
| **File name:**  **Reference:**  **Note:** | |

**Part F - Product Verification and Validation – Specimen requirements**

This section should include information to meet the requirements of Annex II Section 6.1.

|  |  |
| --- | --- |
| **Specimen Type / Transport/ Handling (Annex II, 6.1)** | NA |
| Technical documentation reference to specimen type, transport and handling requirements. |  |
| This Section shall describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to 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.  Include information on   * Different specimen types * Determination of appropriate criteria for specimen collection * Specimen handling, stability, storage (including freeze thaw cycle) and transport/shipping * Sample Pre-treatments (e.g. preservatives, anticoagulants, fixatives etc) | |
| **File name:**  **Reference:**  **Note:** | |

**Part G - Product Verification And Validation – Scientific Validity**

This section should include information to meet the requirements of Annex XIII Section 1.2.1.

|  |  |
| --- | --- |
| **Scientific Validity (Annex XIII, 1.2.1)** | NA |
| Technical documentation reference to all relevant scientific validity data. | |
| The manufacturer shall demonstrate the scientific validity **based on** **one or a combination** of the following sources:   * relevant information on the scientific validity of devices measuring the same analyte or marker * scientific (peer-reviewed) literature * consensus expert opinions/positions from relevant professional associations * results from proof of concept studies * results from clinical performance studies.   A summary of all results should be presented in the **Scientific Validity report.** | |
| **File name:**  **Reference:**  **Note:** | |

**Part G - Product Verification and Validation – Analytical Performance**

This section should include information to meet the requirements of Annex II Section 6.1.2.

|  |  |
| --- | --- |
| **Analytical Performance (Annex XIII, 1.2.2, Annex I, 9.1, Annex II, 6.1)** | NA |
| Technical documentation reference to all relevant analytical performance data. | |
| Devices shall achieve the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference and cross-reactions. | |
| Accuracy of Measurement   * Trueness of measurement * Precision of measurement | |
| Analytical Sensitivity   * include information about the study design and results * description of specimen type and preparation including matrix, analyte levels, and how levels were established * number of replicates tested at each concentration * a description of the calculation used to determine assay sensitivity | |
| Analytical Specificity   * describe interference and cross reactivity studies performed * Information on the evaluation of potentially interfering and cross-reacting substances or agents * All or any Interfering endogenous / exogenous substances | |
| Metrological traceability of calibrator and control material values   * Applicable calibrator and control material information | |
| Measuring range of the assay (Annex II 6.1.2.5)   * information on the measuring range * limit of detection * how the range and detection limit were established | |
| Assay Cut Off   * provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off | |
| **Analytical Performance Report**  A summary of all results should be presented in the analytical performance report. This report should have a conclusion statements on device sensitivity, device specificity and analytical performance. Conclusions should be based on (but not limited to) Common specifications (where available) Common technical specifications, safety/performance requirements and the state of the art. | |
| **File name:**  **Reference:**  **Note:** | |

**Part G - Product Verification and Validation – Clinical Performance**

This section should include information to meet the applicable requirements of Annex II Section 6.2 and Annex XIII.

|  |  |
| --- | --- |
| **Clinical Performance (Annex XIII 1.2.3, Annex I 9.1, Annex II 6.2)** | NA |
| Technical documentation references to where the clinical performance has been demonstrated and documented in the clinical performance plan and report.  Evidence of the following, at a minimum is expected:   * + diagnostic sensitivity,   + diagnostic specificity,   + positive predictive value,   + negative predictive value,   + likelihood ratio,   + expected values in normal and affected populations. | |
| The clinical performance shall contain at a minimum, where applicable:  Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:   * clinical performance studies * scientific peer-reviewed literature * published experience gained by routine diagnostic testing.   Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.  A summary of all results should be presented in the **Clinical Performance Report.** | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Self-Test Devices (Annex XIII 1.2.3, Annex I, 19, Annex II 6.2)** | NA |
| Technical documentation references to for all relevant data for self-test devices. | |
| Devices intended for self-testing shall be   * designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. * easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. | |
| Devices intended for self-testing shall be designed and manufactured in such a way as to:   * ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and * reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results | |
| Devices intended for self-testing a shall, where feasible, include a procedure by which the intended user:   * can verify that, at the time of use, the device will perform as intended by the manufacturer; and * be warned if the device has failed to provide a valid result. | |
| The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions. Include performance testing including layperson performance studies (Annex I, 9.4). | |
|  | |

**Part G - Product Verification and Validation – Performance Evaluation Plan & Report**

This section should include information to meet the applicable requirements of Annex II Section 6.2 and Annex XIII.

|  |  |
| --- | --- |
| **Performance Evaluation Pan & Report (Annex II, 6.2 & Annex XIII 1.1 & 1.3.2)** | NA |
| Technical documentation references to the **Performance Evaluation Plan.** | |
| As a general rule the, the performance evaluation plan shall include the contents specified in Annex XIII 1.1. A justification shall be given for any elements that are deemed not appropriate for the plan. | |
| Technical documentation references to the **Performance Evaluation Report.** | |
| The clinical evidence shall be documented in a performance evaluation report. This report shall include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of those reports allowing demonstration of the clinical evidence.  The performance evaluation report shall in particular include:   * the justification for the approach taken to gather the clinical evidence * the literature search methodology and the literature search protocol and literature search report of a literature review * the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety * the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated * the clinical evidence as the acceptable performances against the state of the art in medicine * any new conclusions derived from PMPF reports in accordance with Part B of this Annex * Conclusions on the clinical benefit of the device and how the device will achieve the clinical benefit. | |
| **File name:**  **Reference:**  **Note:** | |

**Part H - Product Verification and Validation – Stability and Packaging**

This section should include information to meet the requirements of Annex I, II Section 6.2 and XIII.

|  |  |
| --- | --- |
| **Stability (Annex II, 6.3) and Packaging (Annex I and II)** | NA |
| Technical documentation references to all relevant Stability and Packaging data. | |
| The performance of the claimed stability shall be supported by appropriate studies, including plan(s) with predefined acceptance criteria and rationale(s) for sample size.  Documentation shall contain the following as appropriate:   * Claimed shelf-life * In-use stability * Real-time stability * Accelerated stability * Open vial stability * Shipping stability * All relevant packaging information | |
| **File name:**  **Reference:**  **Note:** | |

**Part I - Product Verification And Validation – Software**

This section should include information to meet the requirements of Annex II, 6.4.

|  |  |
| --- | --- |
| **Software Verification and Validation (Annex II, 6.4)** | NA |
| Technical documentation references to all relevant Software Verification and Validation data. | |
| Documentation shall contain evidence of the validation of the software, as it is used in the finished device.  Documentation shall contain the following, as appropriate:   * Summary results of all verification validation and testing * Hardware configurations * Operating systems * Justification of State of the Art and appropriate information security solutions | |
| **File name:**  **Reference:**  **Note:** | |

**Part J - Product Verification and Validation – Specific Case Requirements**

This section should include information to meet the requirements of Annex II, 6.5.

|  |  |
| --- | --- |
| **Sterile Devices or in a Defined Microbiological Condition (Annex II, 6.5, a)** | NA |
| Technical documentation references to all relevant data for this section. | |
| Documentation shall contain evidence a description of the methods used, including the validation reports, with regard to packaging, sterilisation and maintenance of sterility.  Documentation shall contain the following, as appropriate:   * Bioburden testing * Pyrogen testing and, if applicable * Testing for sterilant residues | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Devices Containing Tissues, Cells, And Substances Of Animal, Human Or Microbial Origin (Annex II, 6.5, b)** | NA |
| Technical documentation references to all relevant data for this section. | |
| Documentation shall contain evidence and information on the origin of such material and on the conditions in which it was collected. | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Devices with a Measuring Function (Annex II 6.5, c)** | NA |
| Technical documentation references to all relevant data for this section. | |
| Documentation shall contain a description of the methods used in order to ensure the accuracy as given in the specifications. | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Device is to be connected to other equipment** **(Annex II 6.5, d)** | NA |
| Technical documentation references to all relevant data for this section. | |
| Documentation shall contain a description of the resulting combination including proof that it conforms to the general safety and performance requirements set out in Annex I when connected to any such equipment having regard to the characteristics specified by the manufacturer. | |
| **File name:**  **Reference:**  **Note:** | |

**Part K - Summary of Safety and Performance**

This section should include information to meet the requirements laid down by Article 29.

|  |  |
| --- | --- |
| **Summary of Safety and Performance (Article 29)** | NA |
| Technical documentation references to all relevant data for this section. | |
| For Class C and D devices, a Summary of Safety and Performance shall be contained within the technical documentation as per Article 29. | |
| **File name:**  **Reference:**  **Note:** | |

**Part L - Technical Documentation on PMS – Annex III**

This section should include information to meet the requirements of Annex III and as laid down by Article 81.

|  |
| --- |
| **Post Market Surveillance – Annex III** |
| Technical documentation references to all relevant data for this section. |
| The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 78. The PMS plan shall be drawn up in accordance with Article 79.   * The PMS plan shall address the information requirements as per Annex III, Part 1 (a) * The PMS plan shall cover at least the contents of Annex III, Part 1 (b) |
| **File name:**  **Reference:**  **Note:** |

|  |  |
| --- | --- |
| **Post Market Performance Follow-Up (Annex XIII, B)** | NA |
| Technical documentation references to all relevant data for this section. | |
| The PMPF plan and PMPF Evaluation Report shall be reviewed as part of the technical documentation as per Annex XIII part B. | |
| **File name:**  **Reference:**  **Note:** | |

|  |  |
| --- | --- |
| **Periodic Safety Update Report (Article 81)** | NA |
| Technical documentation references to all relevant data for this section. | |
| For Class C and D devices, a Periodic Safety Update Report (PSUR) shall be contained within the technical documentation as per Article 81. | |
| **File name:**  **Reference:**  **Note:** | |

**Part M - Declaration of Conformity**

This section should include information to meet the requirements of Annex IV.

|  |
| --- |
| **Declaration of Conformity – Annex IV** |
| Technical documentation reference to the EU declaration of conformity shall contain the information as per Annex IV |
| **File name:**  **Reference:**  **Note:** |