IVDR Technical Documentation Submission Checklist (Class A sterile, Class B and Class C devices) Minimum Requirements

Technical Documentation (TD) must be submitted electronically to your SGS contact, if possible, with files/ documents smaller than 100 MB. Entire TD must be provided in an indexed, electronic, text-searchable format and must be available in English. If the documents are in PDF format, it is best practice to provide them with bookmarks. PDF files and attachments should not be write-protected or locked. Please ensure that the technical documentation includes a summary of the submitted documentation, and a comprehensive table of contents, containing sufficient information to identify all provided documents.

When submitting the technical documentation for assessment, please consider the Team-NB Best Practice Guidance for the Submission of Technical Documentation: Team-NB PositionPaper-BPG-IVDR-V1-20230225.
This document outlines the consensus of notified body expectations for submission of technical documentation that aligns with the requirements of the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

This SGS NB 1639 submission checklist does not include the minimum requirements for Companion Diagnostic Devices and Class D devices, as those devices are outside of SGS NB 1639's designation scope.

Instructions:

Once requested by SGS, please complete this document, and submit it together with the technical documentation.
For certain types of devices, please additionally complete and attach the relevant Annex documents (available at the end of this document):

- For devices supplied sterile or intended to be sterilised by the user - Annex I (Additional Requirements for Sterile Devices)
- For devices incorporating software or software that are devices in themselves - Annex II (Additional Requirements for Software Devices)

Important information:

1. This checklist is intended to support you in compiling and submitting a complete set of relevant technical documentation, enabling SGS NB 1639 to carry out an efficient conformity assessment. Please acknowledge that this checklist does not guarantee compliance with IVDR requirements. Once our personnel verify the completeness of the submitted TD, a Product Assessor will conduct a detailed assessment of the documentation. Any deficiencies will be recorded in the TD assessment report, which will be provided to you.
2. All identified nonconformities must be closed before the product can be certified under the IVDR.
3. The time quoted for TD assessment is the minimum required. Deficiencies in the TD submission, such as incompleteness, poor structure or insufficient quality may lead to the assessment taking additional time, resulting in extra charges and delays in the certification process.
4. In case we are forced to terminate the assessment due to insufficient quality of the submitted TD, the full assessment time will be invoiced.

COVER LETTER - TO BE COMPLETED BY THE MANUFACTURER FOR EACH TECHNICAL DOCUMENTATION SUBMITTED				
Manufacturer (name, address, and SRN):				
Name and identification of Technical Documentation:				
Name of IVD medical device under assessment:				
Reason for submission:	Select an option		Other (if applicable):	
ID number of Master Service Agreement:				
For devices supplied sterile or intended to be sterilised by the user:	Annex I completed and attached:	Select an option		
For devices incorporating software or software that are devices themselves:	Annex II completed and attached:	Select an option		
I hereby declare and confirm that the submitted technical documentation is: • Complete, and covers all relevant aspects of the checklist below • Provided in English • Presented in a clear, organized, and unambiguous manner • Provided in electronic and text searchable format • Files/documents are smaller than 100 MB • Files/documents are not protected or locked				
Confirmed by: (Legal Manufacturer)	Name: Email address:		Date: (dd.mm.yyyy)	
Verified by: (SGS Delivering Office)	Name: Email address:		Date: (dd.mm.yyyy)	

REQUIREMENTS ADMINISTRATIVE REQUIREMENTS	TO BE COMPLETED BY THE MANUFACTURER Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
1. Table of Contents	
2. For devices previously assessed by Notified Body - TD Change History identifying all changes since the last assessment with the reason for why the change was needed and the benefit. Please include copies of approved SGS Notification of Change forms (or equivalent form from other Notified Body).	

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1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES		
1.1. DEVICE DESCRIPTION AND SPECIFICATION		
1.1.1. Product or trade name and a general description of the device, including its intended purpose and intended users (IVDR Annex II, 1.1 (a))	• All variants, including names, configuration and components • General description of the device sufficient to understand the design, packaging, sterilisation, or other characteristics • Provide pictures or photos of the device and accessories, where appropriate	

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1.1.2. The Basic UDI-DI assigned to the device (IVDR Annex II, 1.1 (b))	• The Basic UDI-DI as referred to in Part C of Annex VI • For devices grouped under one Basic UDI-DI number please describe the differences to demonstrate how these fall under the same group • Ensure the Basic UDI-DI is consistent in the TD, DoC, certificates, SSP, any vigilance or PMS reports etc., where applicable or certificates of free sale	
1.1.3. The intended purpose of the device (IVDR Annex II, 1.1 (c))	• The IVDR refers to intended purpose and intended use, however these terms are considered equivalent • Please refer to detailed requirements listed in Annex II, 1.1 c) (i) to (viii) • If there is a foreseeable risk that the device may be used for purposes other than intended, a clear limitation of use	
1.1.4. The description of the principle of the assay method or the principles of operation of the instrument (IVDR Annex II, 1.1 (d))	• Describe the technology/test platform on which the device is based (e.g., ELISA, CLIA, PCR, Flow Cytometry, etc.), and how the device achieves its function for the specific indications from a technical point of view • Is it established or new technology? • For devices used in combination, discuss interactions between each component and how the overall system works • For instruments, discuss any features/ operating modes that allow the device to be used for its intended purpose • Ensure the principle of the assay is aligned between the device description provided in the TD and the information supplied in the IFU	
1.1.5. The rationale for qualifying the product as an in vitro diagnostic medical device (IVDR Annex II, 1.1 (e))	• Justify qualifying the product as an IVD device according to the IVDR Art. 2(2) definition. MDCG 2024-11 provides guidance on the qualification of IVDs • Pay special attention to software devices qualified as IVD; MDCG 2019-11 provides more detailed information and examples	
1.1.6. The risk class of the device and the justification for the classification rule(s) applied in accordance with IVDR Annex VIII (IVDR Annex II, 1.1 (f))	• The classification should be based on the intended purpose of the device claimed by the manufacturer. Devices for detecting or measuring the same marker or analyte can fall under different risk classes depending on the intended purpose specified by the manufacturer • The justification should address each point of the selected classification rule; if different classification rules apply, the higher classification shall be selected • If the device is intended for multiple markers/ analytes, each one should be classified separately; the overall device shall be classified under the highest classification • MDCG 2020-16 and MDCG 2019-11 provide more detailed information and examples	
1.1.7. The description of the components and, where appropriate, the description of the reactive ingredients of relevant components, such as antibodies, antigens, nucleic acid primers (IVDR Annex II, 1.1 (g))	• Please provide a detailed description of the listed components, identifying the reactive ingredients	

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1.1.8. Where applicable, a description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use (IVDR Annex II, 1.1 (h))	• Record the specimen receptacle and transport materials that are used to collect the specimen and retain the specimen in good condition, even during transport (if applicable) • Include devices that are recommended, when not directly provided by the manufacturer	
1.1.9. For instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays (IVDR Annex II, 1.1 (i))	• Please provide evidence demonstrating the compatibility of the instrument with the appropriate or dedicated assays as part of the performance evaluation	
1.1.10. For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation (IVDR Annex II, 1.1 (j))	• Clarify if the assay is fully automated, semi-automated and if both automated and manual methods are available • Please provide a general description of the instrument characteristics, and if available, specification sheets, manuals and/or operating guides for the appropriate instrumentation • Clearly state if this is a dedicated instrument or a general-use instrument. In case of "open systems" where the instrument is not dedicated, instrument specifications and characteristics need to be clearly defined • If applicable, please provide any instrument-specific application sheets or instructions	
1.1.11. Where applicable, a description of any software to be used with the device (IVDR Annex II, 1.1 (k))	• This applies to any software supplied with the device or software recommended to be used with the device • Please provide the software version supplied/ recommended to be used with the device • Please provide more detailed information on software in Annex II, if appropriate	
1.1.12. Where applicable, a description or complete list of the various configurations/variants of the device that are intended to be made available on the market (IVDR Annex II, 1.1 (l))	• Please list or describe all variants, including names, unambiguous references, configuration, components, sizes, etc. • Families of different devices (if covered within the same assessment) must be adequately justified in terms of similar indications, intended use, design and manufacture, technologies etc.	
1.1.13. Where applicable, 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 the device (IVDR, Annex II, 1.1 (m))	• Describe all accessories, other devices, or generic products necessary to use the device as intended • If any devices or accessories are available separately, they need their own labeling, IFUs, packaging, and certification • If the accessory is an IVD device according to EU 2017/746 (IVDR), provide information on the regulatory status • Provide approval details if the accessory is a medical device according to the Regulation (EU) 2017/745 (MDR) (e.g., a swab)	
1.2. REFERENCE TO PREVIOUS AND SIMILAR GENERATIONS OF THE DEVICE		
1.2.1. An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist (IVDR Annex II, 1.2 (a))	• If this is the first IVDR certification of a device that was previously available on the market under the IVDD, indicate whether it was NB certified or self-declared; describe changes that have been made in comparison to the device marketed under IVDD, if any • Provide market history, including EU and other geographies, to enable understanding of the context of device development; list approvals in other countries, if any • If the device has never been placed on the market previously, please provide a statement confirming this	

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1.2.2. An overview of identified similar devices available on the Union or international markets, where such devices exist (IVDR Annex II, 1.2 (b))	• Similar devices may be identified as part of the description of state of the art or identified during literature review. Similar devices may also be used as a comparator or reference assay during performance evaluation. Provide a comparison of the key specifications if similar devices have been used for performance evaluation purposes • Please provide a justification if there are no similar devices on the market, e.g. if this is a "new" device	
2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER		
2.1.1. A complete set of labels on the device and on its packaging, such as single unit packaging, sales packaging, and 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 (IVDR Annex II, 2 (a))	• Provide labels for all existing and foreseen variants and configurations of the device • Indicate placement of labels on the device and/or their components and provide label specifications (e.g. size) • Ensure all requirements of IVDR GSPR 20.2 and Article 18, as well as any specific requirements of relevant harmonised standards or Common Specifications, are met • Where applicable, clearly identify labels for sterile packages; ensure specific requirements for sterile packaging are met as per IVDR GSPR 20.3 • If the device or its component is classified as dangerous according to Regulation (EC) 1272/2008, use appropriate pictograms and meet relevant requirements • For Class C and Class D devices, if not mentioned in the IFU, the label should contain the information where the SSP is available • If electronic IFUs (e-IFUs) are provided, appropriate information on the device or on a leaflet must be included	
2.1.2. The instructions for use (IFU) (IVDR Annex II, 2 (b))	• Indicate all EU countries in which the device is to be sold and all languages required in these countries • The IFU in English only is acceptable in the initial submission; however, IFUs in all demanded languages are required before the product launch • Please provide a copy of the IFU translation procedure; pay special attention to the validation of translations • Ensure the instructions for use contain all information according to IVDR GSPR 20.4 and Article 18, as well as any specific information required by relevant standards and/or CS • For instruments, provide user manual as well as installation and service manuals if applicable • If applicable and not included on the label, provide instructions for obtaining the safety data sheet (SDS) • If the IFU is not provided in paper form in accordance with IVDR Annex I GSPR 20.1 (f), a reference to their accessibility (or availability), and where applicable, the website address where they can be consulted • Where only electronic IFUs are supplied, provide the procedure that details how eIFU are managed and evidence of appropriate risk assessment	

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2.1.3. Where applicable - Safety Data Sheet (SDS) (IVDR Annex I, 20.1 (j))	• Provide a statement confirming and summarising how conformity to Regulation (EC) No 1272/2008 and Regulation (EC) No 1907/2006 is demonstrated • If the device includes hazardous materials, a SDS may be required • The SDS shall meet requirements according to Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008 • Provide SDS in English only; ensure SDS in languages required on all target markets are available • A separate SDS may not be required if all relevant information is available in the instructions for use	
2.1.4. Declaration of Conformity (DoC) (IVDR Art. 10(5), IVDR Annex IV)	• The DoC shall include the information as per IVDR Annex IV • If the device is also covered by other EU legislation and requires relevant EU DoCs, a single DoC shall be issued and applied to all applicable EU legislation • If no final DoC is available, provide a draft DoC • Submit the DoC in English only; ensure DoC is available in all languages required on all target markets	
2.1.5. Copies of promotional and marketing materials, including websites	• Supply copies of promotional and marketing materials or provide access to locations where these materials can be found • Only promotional material/marketing literature that includes the CE mark or mentions CE marking requirements must be provided	
3. DESIGN AND MANUFACTURING INFORMATION		
3.1. DESIGN INFORMATION		
3.1.1. Design information to allow the design stages applied to the device to be understood (IVDR Annex II, 3.1)	• Provide the top-level design and development/design control procedure and a summary explaining the design stages applied to the device • Provide evidence to show that design outputs meet design inputs e.g. traceability matrix • Provide a history of design changes, including the reason for the changes and their impact on the performance evaluation	
3.1.2. 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 (IVDR Annex II, 3.1 (a))	• Provide formulation/component details highlighting critical ingredients and concentrations of active ingredients • The description should include a reference number for the critical ingredients and be sufficiently specific to allow traceability of components and/or critical materials/processes • Describe how critical ingredients are controlled i.e. specifications, incoming QC or in-process QC • For devices containing ingredients of human, animal, or microbial origin, submit a Certificate of Analysis (CoA), including the information on the origin of such material and on the conditions in which it was collected	
3.1.3. For instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software (IVDR Annex II, 3.1 (b))		

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3.1.4. For instruments and software, an overview of the entire system (IVDR Annex II, 3.1 (c))	• System functional diagrams identifying the key components and functions • Please provide more detailed information on software in Annex II, if appropriate	
3.1.5. For software, a description of the data interpretation methodology (e.g. the algorithm) (IVDR Annex II, 3.1 (d))		

3.1.6. 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 (IVDR Annex II, 3.1 (e))	• Please consider particularly the following aspects (whether they are appropriate for self-testing or near-patient testing):
	  • Assay technology and specimen type
	  • Physical design features
	  • Usability and user interface features
	  • Chemical and biological safety (hazardous and/or potentially infectious ingredients)
	  • Robustness (both physical and performance characteristics)
	  • Information provided to the user (labels and IFUs)	

3.2. MANUFACTURING INFORMATION		
3.2.1. Information to allow the manufacturing processes to be understood (IVDR Annex II, 3.2 (a))	• Provide a detailed overview of the manufacturing processes, preferably as manufacturing flowchart(s), including incoming inspection and key stages of the process (e.g. production, testing, assembly, packaging, sterilisation, final packaging) • Detailed information on incoming inspection of critical raw materials • Specifications and final concentrations or quantities (if applicable) of critical raw materials/components/parts in the final device • In-process QC and final release QC, including a clear description of the test methods and acceptance criteria, as well as sample batch results and a sample CoA for the device • Information to demonstrate that processes are appropriately validated e.g. validation master plan, master validation matrix/file, or other top-level overview of validation status • For outsourced processes – identification of the subcontractor/supplier, and for critical component suppliers – overview of the manufacturing process and corresponding control measures (e.g., verification and validation activities, certificates, etc.)	
3.2.2. Identification of all sites, including suppliers and subcontractors, where manufacturing activities are performed (IVDR Annex II, 3.2 (b))	• Identify the site responsible for design activities • Identify sites performing all stages of production (e.g. assembly, sterilisation, packaging, in-process, and final QC) • For all sites/subcontractors provide name, address, activities/services provided, and certification details, if applicable • Provide top-level supplier control procedure, indicating process for identification/differentiation of relevant suppliers/subcontractors • For relevant suppliers and/or subcontractors, clear evidence that the provided products or service meet the specified requirements (e.g. records of supplier audits, 100% incoming inspection, ISO 13485 or other relevant certificates)	

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3.2.3. Information on packaging materials	• Provide details and specifications for the packaging types/materials used - primary, secondary etc., and summarise how the suitability of the packaging is demonstrated to maintain the integrity of the product	
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)		
4.1.1. Information for the demonstration of conformity with the general safety and performance requirements set out in the IVDR Annex I (IVDR Annex II, 4)	• It is best practice to provide information for the demonstration of conformity with the GSPR as a matrix, checklist or summary table • All clauses/subclauses of GSPR should be addressed independently • Provide a clear statement whether each respective requirement is applicable or not • If not applicable, provide a clear justification • For each applicable requirement, provide the method or methods used to demonstrate conformity, including its justification, validation, and verification • Harmonised standards, Common Specifications, other EU directives/regulations, and/or other relevant documents and guidance along with version no. should be referred to, if applicable • For each applicable requirement, provide precise reference to specific documents within the TD supporting compliance	
4.1.2. List of standards	• Provide a full list of standards, CS and guidelines used, including versions and whether full or partial compliance is claimed	
5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT		
5.1.1. Description of risk management system, including an interface with Performance Evaluation and Post-Market Surveillance (IVDR Annex II, 5. (b), IVDR Annex I, 3)	• Include the information on whether the risk management process is based on EN ISO 14971, and which version of the standard is implemented • Risk management is a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. The documentation should be sufficiently current • The interface between the risk management process and the performance evaluation should be clear and noticeable	
5.1.2. Risk management plan for the device (IVDR Annex II, 5. (b), IVDR Annex I, 3 (a))	• ISO 14971:2019 and ISO/TR 24971:2020 section 4.4 provides guidance for the risk management plan (RMP)	
5.1.3. Risk analysis (IVDR Annex II, 5 (b), Annex I 3(b), 3(c))	• Risk analysis is the systematic use of available information to identify hazards and to estimate the risk • Examples of tools to support risk analysis include FMEA, PHA, FTA/ETA etc. • Ensure known and foreseeable hazards have been identified, including reasonably foreseeable misuse • Ensure hazards are representative/appropriate for the intended end user and intended use environment e.g. laboratory professional, healthcare worker or lay user • Ensure the entire device lifecycle has been considered from design, production/process, user, patient etc. to final disposal • For each hazard identified, estimate the severity and the probability based on defined severity and probability levels, and subsequently evaluate against criteria (as set out in the RMP)	

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5.1.4. Risk Control (Annex II, 5 (b), Annex I, 2, 3(d), 4)	• Risks must be reduced "as far as possible" without adversely affecting the benefit-risk ratio. This has changed from previous risk concept of "as low as reasonably practicable" or taking into account only business/economic factors without considering the benefit-risk ratio aspects, which is now not acceptable • Ensure the most appropriate risk control solutions are used, considering the order of priority • Verify the implementation and effectiveness of all risk control measures • Consider any new risks arising from the risk control measures (where applicable) • Residual risk evaluation for individual hazards is completed during the risk control stage • Ensure users are informed of any residual risks	
5.1.5. Eliminating or reducing risks related to use error (Annex II, 5(b), Annex I, 5)	• IEC 62366, application of usability engineering to medical devices, may be used in addition to ISO 14971 • Ensure to capture the intended user, use errors and the use environment effectively during risk assessment activities • Consider the technical knowledge, experience, education and training of the user	
5.1.6. Evaluation of overall residual risk and benefit-risk determination (Annex II, 5, Annex I, 1, 4, 8)	• Evaluate the acceptability of the overall residual risk i.e. broad perspective, considering the combined contributions from all individual residual risks • The overall residual risk is evaluated in relation to the benefits of the intended use of the device • The overall residual risk must be evaluated by persons with the knowledge, experience and authority to perform such tasks. The criteria for acceptability of the overall residual risk should be defined in the risk management plan • The clinical benefit of the IVD device should always outweigh the overall residual risk • For IVDs, it is most likely that indirect benefit-risk assessments are made. Comparisons may be achieved using information available in the literature, comparison to similar devices, state of the art and data from clinical studies	

5.1.7. Risk management report/review (IVDR Annex II, 5. (b))	• Review the execution of the risk management plan. This review must ensure:
	  • The risk management plan has been appropriately implemented
	  • The overall residual risk is acceptable
	  • Appropriate methods are in place to collect and review information in the production and post-production phases
	• The results of this review shall be recorded and maintained as the risk management report and shall be included in the risk management file
	• Revise or update the risk management report as new information becomes available
	• Clearly indicate that the device, when used as intended, constitutes acceptable risk when weighed against the benefits to the patient and is compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art	

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6. PRODUCT VERIFICATION AND VALIDATION		
6.1. SPECIMEN TYPE		
6.1.1. Specimen type, collection and handling (IVDR Annex II, 6.1.1, Annex I, 9(a))	• Describe specimen types that can be analyzed • Provide information on specimen stability, maximum storage time and methods used for its determination, transport and storage conditions (including duration, temperature limits, freeze/thaw cycles) and, if applicable, any other pre-analytical requirements and limitations • Where applicable, indicate the timeframe between taking the specimen and its analysis • Demonstrate performance of the device with all specimen types indicated in the intended purpose • Where applicable, provide information on specimen collection and transport materials supplied with the device or recommended for use	
6.2. PERFORMANCE EVALUATION AND CLINICAL EVIDENCE		
6.2.1. Performance evaluation plan (PEP) (IVDR Art. 56(1), IVDR Annex XIII, 1.1)	• Include at least the elements listed in the IVDR Annex XIII Section 1.1. Provide a justification in the plan if any of the elements are deemed not applicable • See MDCG 2022-2 for additional guidance • The PEP should provide a defined and methodologically sound procedure for the demonstration of scientific validity, analytical performance and clinical performance • The planned activities should aim to support all aspects of the intended purpose of the device • Ensure state of the art is appropriately considered and described • Performance evaluation of a device is a continuous process. Ensure the PEP provides for a continuous process of performance evaluation • The risk management system should be carefully aligned with and reflected in the performance evaluation process for the device, including the clinical risks to be addressed as part of performance studies, performance evaluation and PMPF. The risk management and performance evaluation processes should be inter-dependent and regularly updated	
6.2.2. Scientific validity report (IVDR Art. 56(3), IVDR Annex XIII, 1.2.1)	• Demonstrate the scientific validity of the device using one or more of the sources outlined in the IVDR Annex XIII Section 1.2.1. • See MDCG 2022-2 for additional guidance • Independent demonstrations may be required if more than one claim is included in the intended purpose	
6.2.3. Analytical performance report, demonstrating the relevant analytical performance characteristics (IVDR Art. 56(3), IVDR Annex I 9.1(a), IVDR Annex II, 6.1.3, IVDR Annex XIII, 1.2.2)	• Demonstrate the analytical performance of the device in relation to all the parameters described in point (a) of Section 9.1 and Section 9.3 of Annex I and in Section 6.1.2 of Annex II, unless any omission can be justified as not applicable • Analytical performance studies are expected • Consider state of the art standards e.g. CLSI • For each parameter, provide details of the methods used, acceptance criteria and results obtained. Where available, provide protocols and reports for individual studies	

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	• Demonstrate and document the final overall analytical performance in the analytical performance report with an overall summary of the results including final claims • Ensure complete and accurate alignment between the performance claims in the IFU and data presented elsewhere in the performance evaluation and technical documentation • If analytical performance studies were conducted using an earlier version of a device and/or using a device prior to any significant design changes, justify how the conclusions of studies are still valid	
6.2.4. If demonstration of clinical performance is based on clinical performance studies: Clinical Performance Study Plan (CPSP) (IVDR Annex XIII, 2.3.2)	• The CPSP shall contain all elements referred to in the second paragraph of Annex XIII 2.3.2 • Consider harmonised standard EN ISO 20916 • Where additional requirements apply for certain performance studies (see Article 58), provide additional evidence to prove that clinical studies are designed, authorized, conducted, recorded and reported in accordance with Article 58 and Articles 59 to 77 and Annex XIV	
6.2.5. If demonstration of clinical performance is based on clinical performance studies: Clinical Performance Study Report (CPSR) (IVDR Annex XIII, 2.3.3)	• The CPSR shall be signed by a medical practitioner or any other authorized person responsible • The CPSR shall contain all elements referred to in Annex XIII 2.3.3	
6.2.6. If demonstration of clinical performance is not supported by clinical performance studies but is based on other sources of clinical performance data: a justification for this is required (IVDR Art. 56(4))	• Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data e.g. scientific literature, experience from routine diagnostic testing. Clinical studies performed outside of the IVDR requirements e.g. prior to the IVDR, are considered as other sources of data • MDCG 2022-2 and GHTF/SG5/N7:2012 provide more detailed information and examples	

6.2.7. Clinical performance report (IVDR Art. 56(3), IVDR Annex XIII, 1.2.3)	• Demonstrate the clinical performance of the device in relation to the parameters described in point (b) of Section 9.1 of Annex I, unless any omission can be justified as not applicable
	• Demonstration of clinical performance should 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
	• If a clinical performance study is used to demonstrate clinical performance, an overview of the study protocol and results, the clinical performance study plan and report should be referenced
	• If clinical performance is demonstrated by scientific peer-reviewed literature/ published experience: full-text copies of the relevant published literature that have been selected for review, literature search protocols and reports, a full list of retrieved articles, and a full list of excluded articles, with reasons for exclusion
	• Demonstrate and document the final overall clinical performance in the clinical performance report with an overall summary of the results including final claims	

REQUIREMENTS	ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER	TO BE COMPLETED BY THE MANUFACTURER Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
6.2.8. Performance Evaluation Report (PER) (IVDR Annex II, 6.2, IVDR Annex XIII, 1.3.2)	• Include at least the elements listed in IVDR Annex XIII Section 1.3.2 • See MDCG 2022-2 for additional guidance • The PER should demonstrate the scientific validity, analytical performance and clinical performance of the device • The clinical evidence must support all aspects of the intended purpose of the device • Ensure state of the art is appropriately considered • Performance evaluation of a device is a continuous process. Include reference to the Post-Market Performance Follow-up (PMPF) plan or provide a justification if PMPF is not deemed appropriate	
6.2.9. For Class C devices – a draft of the Summary of Safety and Performance (SSP) (IVDR Art. 29)	• Submit a draft SSP for validation, including all aspects listed in Article 29 (2) • See MDCG 2022-9 for SSP template • The SSP shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public. Mention on the label or IFU where the SSP is available	
6.3. STABILITY (EXCLUDING SPECIMEN STABILITY)		
6.3.1. Claimed shelf-life (IVDR Annex II, 6.3.1)	• Provide information and supporting evidence for the claimed shelf-life and recommended storage conditions • See IVDR Annex II Section 6.3.1 • Ensure testing is performed on at least three different lots and these are fully representative of the final product manufactured under routine manufacturing conditions • Accelerated studies do not replace the need for real time studies. Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable • Consider state of the art standards e.g. ISO 23640, CLSI EP25	
6.3.2. In-use stability (IVDR Annex II, 6.3.2)	• See IVDR Annex II Section 6.3.2 • Consider state of the art standards e.g. ISO 23640, CLSI EP25	
6.3.3. Shipping stability (IVDR Annex II, 6.3.3)	• See IVDR Annex II Section 6.3.3 • Consider state of the art standards e.g. ISO 23640, ASTM D4169	
6.4. ADDITIONAL INFORMATION REQUIRED IN SPECIFIC CASES		
6.4.1. For devices containing tissues, cells, and substances of animal, human or microbial origin (IVDR Annex II, 6.5 (b))	• Information on the origin of such material and on the conditions in which it was collected • Identification of device components that incorporate such biological material • Biological material related risk assessment • Description of sourcing, processing, preservation, testing, handling, and control procedures • Description of the transmissible agent inactivation performed, if applicable	
6.4.2. For devices placed on the market with a measuring function (IVDR Annex II, 6.5 (c))	• A description of the methods used to ensure the accuracy as given in the specifications • Units of measurements must conform to the provisions of Council Directive 80/181/EEC	
6.4.3. For devices to be connected to other equipment in order to operate as intended (IVDR Annex II, 6.5 (d))	• A description of the resulting combination including proof that it conforms to the general safety and performance requirements set out in the IVDR Annex I when connected to any such equipment having regard to the characteristics specified by the manufacturer	

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7. POST-MARKET SURVEILLANCE		
7.1. Post-Market Surveillance Plan (PMS Plan) (IVDR Annex III, 1)	• The PMS plan shall cover all information outlined in Section 1 of IVDR Annex III • For devices already available on the market, data and post-market experience for the past 5 years should be collected and analyzed • A combination of both reactive and proactive activities is expected • ISO/TR 20416 provides additional guidance on PMS for medical devices	
7.2. Post-Market Performance Follow-up (PMPF) Plan (IVDR Annex III, 1 (b))	• The PMPF plan can be part of the PMS plan, or it can be a standalone plan, but it should be clearly referenced/traceable in the PMS plan • If PMPF is not deemed appropriate for a specific device, then a justification shall be provided and documented within the PMS plan and also within the performance evaluation report • The PMPF plan shall include at least the elements listed in IVDR Annex XIII Section 5.2 • Ensure that appropriate methods (general and specific), procedures and product-specific appropriate triggers for proactively collecting and evaluating safety, performance and scientific data are included in the PMPF plan • Include the frequency and/or timelines for completion of PMPF activities	
7.3. For Class A and Class B devices – Post-Market Surveillance Report (PMS Report) (IVDR Annex III, 2)	• See IVDR Article 80 • The PMS report should summarise the results and conclusions of the analyses of the PMS data gathered in accordance with the PMS plan together with a rationale and description of any preventive and corrective actions taken • Each dataset specified in the PMS plan should be presented and analysed. Assess data in relation to the thresholds defined in the PMS plan • Clearly identify any new or emerging risks, or changes to the existing risks. Ensure that the benefits continue to outweigh the risks • The report shall be updated when necessary	
7.4. Post-Market Performance Follow-up (PMPF) Evaluation Report (may be a part of PMS Report) (IVDR Annex III, 2)	• Analyse the findings of the PMPF and document the results in a PMPF evaluation report • Identify and implement preventive and/or corrective measures if applicable • Ensure conclusions of the PMPF evaluation report are reflected in the performance evaluation and risk management • Both favorable and unfavorable data should be equally considered • PMPF data should support the continued acceptability of the benefit-risk ratio	
7.5. For Class C devices – Periodic Safety Update Report (PSUR) (IVDR Annex III, 2)	• See IVDR Article 81 • The PSUR should be a stand-alone document and updated at least annually • The PSUR should summarise the results and conclusions of the analyses of the PMS data gathered in accordance with the PMS plan together with a rationale and description of any preventive and corrective actions taken • PSUR shall also set out the conclusions of the benefit-risk determination, the main findings of the PMPF, the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device	

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	• Each dataset specified in the PMS plan should be presented and analysed. Assess data in relation to the thresholds defined in the PMS plan • Clearly identify any new or emerging risks, or changes to the existing risks. Ensure that the benefits continue to outweigh the risks	
ADDITIONAL COMMENTS (IF ANY):		

IVDR TECHNICAL DOCUMENTATION SUBMISSION CHECKLIST ANNEX I – ADDITIONAL REQUIREMENTS FOR STERILE DEVICES (Please complete only for devices supplied sterile or intended to be sterilised by the user)		
ADDITIONAL REQUIREMENTS FOR STERILE DEVICES	**ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER**	**TO BE COMPLETED BY THE MANUFACTURER** Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
1. STERILISATION FOR THE PRODUCT SUPPLIED STERILE		
1.1. Confirm the sterilisation method	• E.g., EO, gamma irradiation, steam, hydrogen peroxide, aseptic processing	
1.2. Specify whether sterilisation is carried out in-house or outsourced	• Confirm the number of subcontractors used and the number of sterilisers/chambers used for sterilisation • Provide the name and address of sterilisation facilities, if outsourced • Provide relevant QMS certificate and agreement, if outsourced	
1.3. Relevant standards applied in relation to the sterilisation process(es)	• E.g., EO - EN ISO 11135, irradiation - EN ISO 11137, steam - EN ISO 17665, low temp. H_2O_2 - ISO 22441, aseptic - ISO 13408	
1.4. Claimed Sterility Assurance Level (SAL)	• Confirm the claimed SAL as per applicable sterilisation method	
1.5. Sterilisation procedures	• Sterilisation, bioburden, endotoxin, sterility test, environmental control procedures covering limits, frequency, revalidation, etc.	
1.6. Family name / worst case	• Justification for family and selection of worst case product for sterilisation validation and processing categories as required by individual sterilisation standard requirements, i.e., family name, variants selected, worst case product selection for sterilisation, and justification	
1.7. Bioburden	• Validation of test method as per ISO 11737-1 • Please provide 2 most recent bioburden results • Please provide relevant test facility name, address and relevant QMS certification, if used for the test	
1.8. Endotoxin	• Validation of test method as per ISO 11737-3 and the 2 most recent results • If no testing was performed, provide justification • Please provide relevant test facility name, address and relevant QMS certification, if used for the test	
1.9. Sterility test	• Validation of test method as per ISO 11737-2 or used pharmacopeial method, and the 2 most recent results • Please provide relevant test facility name, address and relevant QMS certification, if used for the test	
1.10. Sterilising agent with concentration, if applicable	• E.g., for EO, H_2O_2	
1.11. Confirm the microbicidal effectiveness of the sterilisation agent used	• As per applied sterilisation methods	
1.12. Material effects of the sterilising agent	• Please provide evidence of effects of the sterilising agent on product composition, material, packaging, etc., including multiple cycles	
1.13. Environmental considerations of the sterilising	• If applicable, please provide evidence, i.e., a risk assessment of the sterilising agent on the environment	

1.14. Evidence for each sterilisation method / subcontractors / sterilisers / chambers used	• Please provide:
	  • Protocols - validation, revalidation
	  • Reports - validation, revalidation
	  • IQ, OQ, PQ, if applicable
	  • PCD-IPCD, EPCD
	  • Cycle data	

ADDITIONAL REQUIREMENTS FOR STERILE DEVICES	ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER	TO BE COMPLETED BY THE MANUFACTURER Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
1.15. Please provide evidence for each of the sterilisation method / subcontractors / sterilisers / chambers used	• For EO: EO residuals report, information on EO gas specification and certificate, biological/ chemical indicators and certificates of analysis, PCD-IPCD, EPCD • For irradiation: protocols and dose mapping report, min-max dose, calibration certificates of the dosimeters used, protocol and dose setting/dose substantiation Method 1, VDmax, Method 2, original validation report, dose audit data (trend and 2 most recent dose audit reports). If the frequency of dose audits is reduced, provide justification for the reduction • For steam: include biological/chemical indicators and certificates of analysis • For aseptic processing: justification for use of this method, media fills initial PQ, media fill periodic Performance Requalification (PRQ) report, media selection and growth support, certificate for the filter used and validation of fluid-specific microbial retention by filters, certificates of the sterilised equipment used • Others: i.e., hydrogen peroxide, dry heat, chemical sterilisation, chlorine dioxide etc.	
2. STERILISATION VALIDATION FOR PRODUCT TO BE STERILISED BY END USER		
2.1. Details of the products supplied non-sterilised and sterilised by end user as per IFU claims	• Worst case justification • Sterilisation validation as per IFU • Cycle parameters, protocols, validation, revalidation as per IFU claim, reports, cycle data, residuals report, if applicable	
3. ASSESSMENT OF CHANGES		
3.1. Assessment of changes which could affect the current sterilisation validation / end user validation	• Product, packaging, raw material, manufacturing process, design, sterilisation, etc., as per relevant sterilisation standard requirement	
4. PACKAGING INTEGRITY AND SHELF LIFE		
4.1. Claimed shelf life and evidence	• I.e., written evidence and justification with an example of the actual batch label • Provide an overview of evidence for the safety and performance of the device at each life cycle stage • Applicable standards related to shelf life for packaging integrity and functional testing	
4.2. Name and address of the testing facility	• Please also provide relevant accreditation certificates for the testing facility	
4.3. Usability evaluation for aseptic presentation for sterile devices. Procedure for final inspection of the device and packaging seal checks	• E.g., EN ISO 11607 - Usability evaluation	
4.4. Protocol for the accelerated aging packaging test	• Please also provide packaging integrity test reports with the actual data • If worst case is used for testing, then please provide worst case rationale	
4.5. Protocol for the real time aging packaging integrity test	• Please also provide packaging integrity test reports and actual data, or real-time aging plan • If worst case is used for testing, then please provide the worst case rationale	
4.6. Protocol for the functionality test covering the life of the device	• Please also provide reports for functionality test covering the life of the device • If worst case is used for testing, then please provide worst case rationale	

ADDITIONAL REQUIREMENTS FOR STERILE DEVICES	ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER	TO BE COMPLETED BY THE MANUFACTURER Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
4.7. Justification for transport conditions and associated test types. Justification for storage conditions	• Please also provide protocol and test report for transit testing covering the standard storage and shipping conditions, product functionality and packaging test, post transit tests etc. • If worst case is used for testing, then please provide worst case rationale	
ADDITIONAL COMMENTS (IF ANY):		

IVDR TECHNICAL DOCUMENTATION SUBMISSION CHECKLIST ANNEX II – ADDITIONAL REQUIREMENTS FOR SOFTWARE DEVICES (Please complete only for devices incorporating software or software that are devices in themselves)		
ADDITIONAL REQUIREMENTS FOR SOFTWARE DEVICES	**ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER**	**TO BE COMPLETED BY THE MANUFACTURER** Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
1. SOFTWARE		
1.1. Software verification and validation (IVDR Annex II, 6.4)	• Documentation detailing the test environment • Information on whether automated testing has been used in verification activities; if yes, please provide test scripts and test log results • System-level test plans/protocols and reports • Evidence that the different hardware and, where applicable, the different operating systems have been verified/validated • If the software is for use with mobile platforms, information demonstrating compliance with GSPR 16.3 • The standards used for the validation of software that are devices in themselves and the required validation documentation • Traceability matrices between software testing and specifications • Evidence of the verification of Software of Unknown Provenance (SOUP) items • An overall verification and validation summary report, including the software version, a summary of test results, details on any errata or unresolved anomalies, including evidence and a risk rationale as to why these are acceptable, conclusion on acceptability, details on the roles and functions approving the summary	
1.2. EN 62304 or other relevant standard compliance checklist	• Based on the standard used for compliance, a standards compliance checklist to the requirements based on the software's risk category is recommended • Direct references to where in the technical documentation the evidence of meeting the requirements of the chosen standard is located should be present in any compliance checklist presented • If a different standard has been used than EN 62304, then a detailed document must be provided that explains how the relevant requirements have been met or exceeded, along with the evidence, considering state of the art	
1.3. Software risk assessment	• Please provide all software risk assessment documentation (e.g., software hazard analysis, software failure mode and effects analysis, fault tree analysis, traceability etc.) • Consider the risk associated with the possible negative interaction between software and the IT environment within which it operates and interacts • Consider the risk associated with cybersecurity issues (see also point 1.11. Cybersecurity)	
1.4. Software development plan	• Please provide relevant procedures/ descriptions which communicate the software development process and the lifecycle requirements • For software in IEC 62304 risk Class B and Class C: describe the development environment used (tools, elements, settings, etc.)	

ADDITIONAL REQUIREMENTS FOR SOFTWARE DEVICES	ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER	TO BE COMPLETED BY THE MANUFACTURER Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
1.5. Software requirements analysis	• Functional and non-functional (timing, stress language scalability, etc.) requirements • Requirements derived from potential software defects and information derived from previous designs • Requirements relating to the use of the device e.g., installation • Evidence that the requirements analysis considered IVDR Annex II 16.4, especially hardware requirements, IT network characteristics, and security requirements in relation to access control and unauthorised access • Evidence in the documentation information relating to the functionalities, capabilities, input data, output data, system interfaces, alarms, security requirements, cybersecurity requirements, user interface requirements, database requirements, installation requirements, requirements related to methods of operation and maintenance, regulatory requirements, etc.	
1.6. Software architectural design	• The architecture design can have graphical representations (UML, class diagrams, blocks etc.) but it should demonstrate how the requirements are allocated to software items that make up the overall software system • Please provide information on the internal and external interfaces of the software, the functional and performance requirements of Software of Unknown Provenance (SOUP) and its additional hardware and software requirements • Depending on the risk class, it may be required to include segregation measures for risk control purposes	
1.7. Software detailed design	• For software with Software System Classification Class B and Class C, subdivide the software until it is represented by software units • A clear identification of the software units that are derived from software items should be provided. This should contain the design data for each software unit and any interfaces between the units and any external components. • Please provide details on the expected inputs and outputs for each software unit	
1.8. Software unit implementation and verification	• Each software unit must be implemented • IEC 62304 provides additional guidance on this issue	
1.9. Software integration and integration testing	• Please check IEC 62304 for more information	
1.10. Software systems testing	• Provide evidence that a set of tests for conducting software system testing, including all software requirements, has been established and performed • Please check IEC 62304 for more information	

ADDITIONAL REQUIREMENTS FOR SOFTWARE DEVICES	ADDITIONAL GUIDANCE AND COMMENTS FOR THE MANUFACTURER	TO BE COMPLETED BY THE MANUFACTURER Identify relevant submitted information or, if the requirement is not applicable, provide a justification. For each document, indicate the title, revision ID, the folder and filename and the relevant section(s) or page number(s)
1.11. Cybersecurity	• Please provide the documentation in relation to the secure design and ongoing maintenance of the medical device in respect to cybersecurity • Clearly state the harmonised or other state of the art standard(s) of compliance used for conformance to the relevant GSPRs • Provide evidence of a security risk management system that supports a secure development lifecycle, including all relevant aspects • Where cloud-based software providers are utilized, evidence of the assigned responsible parties for post-market surveillance and the reporting of security issues • MDCG 2019-16 provides more information on cybersecurity	
1.12. Software release	• The list of known residual anomalies, including a unique identifier, a brief description of the issue, severity/risk level, and justification for why it is acceptable to release the software with the anomaly • Evidence demonstrating how the released software was created (e.g., procedure and environment used) • The final released software version number • Evidence explaining how the released software is archived and how it can be reliably delivered (e.g., to the manufacturing environment or to the software user) • Evidence that all required tasks before release were completed	
2. ARTIFICIAL INTELLIGENCE (AI)		
2.1. Please specify if Artificial Intelligence (AI) or Machine Learning (ML) has been incorporated in the device	• If the software incorporates AI/ ML technologies, please ensure that considerations specific to these techniques are addressed in Section 1 above (SOFTWARE), including AI-specific design inputs, risks, performance metrics, etc.	
2.2. Description of the AI/ML Model	• Please provide information on the intended purpose, intended users, level of autonomy, architecture, etc.	
2.3. Please provide a description of the regulatory status and strategy of the product with regard to the EU AI Act (2024/1689)		
ADDITIONAL COMMENTS (IF ANY):		

When you need to be sure

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