Guidance for IVDR Technical Documentation Submissions.

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Introduction

TÜV Rheinland shall ensure the conformity of in vitro diagnostic medical devices being placed on the European market in accordance with the applicable requirements of (EU) 2017/746 In Vitro Diagnostic Medical Devices Regulation (IVDR).

Depending on the classification of the device and the conformity assessment route chosen, one or multiple Technical Documentation(s) need to be assessed by a Notified Body. This Technical Documentation submission guidance is aligned to the requirements of (EU) 2017/246 In Vitro Diagnostic Medical Devices Regulation (IVDR), described in detail in Annexes II and III.

TIPS TO GET STARTED AND COMMON FEEDBACK

TÜV Rheinland and medical device manufacturers are keen to streamline and speed up the review of the Technical Documentation as part of initial applications, during surveillance, substantial change notifications, renewal applications etc. and reducing time to certification. The most common reasons for delays in Technical Documentation reviews are:

- Incomplete Technical Documentation (TD) – not all the information needed for the review was submitted by the manufacturer from the beginning.
- Unsuitable Technical Documentation Structure – the documentation and information is presented in a manner that it is difficult for TÜV Rheinland to verify compliance of the product in question to the regulation, especially with the General Safety and Performance Requirements (GSPRs) of Annex I
- Inaccurate references in the Technical Documentation – References are made to general TD sections (such as “Analytical Performance Data” or “Labelling”) and not precisely to the applicable source of information and the reference is not provided.

TÜV Rheinland has prepared this document in order to help facilitate and streamline the Technical Documentation submission and review process which in the end should allow the Notified Body TÜV Rheinland LGA Products GmbH (TRLP) to issue related certificate(s) under the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR). For the successful processing of IVDR applications, one of the critical factors in the process is the quality and structure of Technical Documentations submitted for review. TÜV Rheinland encourages and highly recommends to follow this guidance when creating and submitting Technical Documentation(s).

Please note: This document does not add or change any requirements defined in the IVDR. It aims to give a guidance on the structure of the documentation expected to be submitted when requesting the Technical Documentation by TÜV Rheinland. Please ensure the Technical Documentation follows the structure as stated in this document. TÜV Rheinland may request further documents and information in line with the requirements of IVDR in the course of the Technical Documentation review.

2 Submission

To begin...

1) Notify your contact person at TÜV Rheinland, that you will have (a) Technical Documentation(s) ready for submission at least 90 days in advance.

2) You will receive a quotation for the TD review(s) if not yet covered by an existing order.

3) Ensure you have the following ready before moving to the next step:

- The Product List and Application [PL&A] (IVDR Annex IX/Annex XI, part A („QMS part")) and where applicable in addition an application for IVDR Annex IX, Chapter II, Section 4 and 5.
- A cover letter accompanying the Technical Documentation submission containing the following information:
  - Certificate # reference(s) (if known)
  - Type of review (new product, surveillance, design change, shelf life extension, etc.)
  - Brief product description, including model numbers involved, B-UDI-DI etc.
  - An explanation of what has been submitted and how it demonstrates compliance and,
  - for changes to existing certification:
    - what is affected (packaging, material change etc.)
    - what is not affected (along with appropriate justification)
- The TÜV Rheinland (Significant) Change Notification (if applicable): TÜV Rheinland | TÜV Rheinland (TÜV.com)
- Ensure compliance of your Technical Documentation with the IVDR, by
  - Following a clear and comprehensive structure as displayed in Annex A
  - Completing the checklist in Annex A and thus ensuring that all required documents are included and references are valid
  - Verify that only approved and controlled documents as per your QMS are included in the technical documentation – no drafts (except for the Declaration of Conformity), containing objective evidence to demonstrate compliance to the IVDR (Annex I (GSPR), Annex II (TD) and Annex III (TD on PMS)).

4) Submit the signed approved purchase order and the application package (as per IVDR Annex IX for initial submissions).

5) Submit the Technical Documentation -following the format and structure listed in Annex A of this document. The suggested format will help us to perform the completeness and technical assessment in the most efficient way. In addition please provide a picture of the device and whenever practical a product sample. A sample is obligatory at least for specific types of devices (self-testing and near-patient testing) referred to in point (b) of Annex IX Sections 5.1 in its final packaging, and without its packaging (to ensure symbols, description is legible).

6) The review process will start after receipt of a signed purchase order accompanied by all required application documentation. TÜV Rheinland will perform a completeness check of the Technical Documentation, in order to verify that all required TD deliverables according to Annex A have been submitted by the manufacturer.
If documentation is missing, the manufacturer will be notified and a letter explaining that the project is on hold until the complete documentation is resubmitted.
Only Technical Documentations that pass TÜV Rheinland´s completeness check will then move to the next phase and technical assessments can be started.

3 Preparing Technical Documentation

IVDR is a new legislation, and for initial certification a complete submission with all relevant parts of the Technical Documentation included is required.

For specific products (class D, self-testing, near-patient testing and companion diagnostic), the IVDR requires a TD review before initial certification. For other types of devices within class B and C, a review of one or multiple TDs per device group (term used synonymously for generic device groups (class C) and product categories (class B)) before certification is required. Additional reviews of other devices from the same group based on a sampling approach over the period of certificate validity will follow. The Technical Documentations to be reviewed for initial certification will be determined by TRLP based on the application documents provided, in line with the requirements and guidelines of the IVDR.

Note: For manufacturers with a high number of products, it is recommended to establish a transfer plan to successively transfer the products from IVDD to IVDR.

Furthermore it is crucial that only those products are listed on the application form(s), for which the TD(s) is (are) established in compliance with IVDR by the manufacturer.

Products being part of the transfer plan but not yet adapted to all IVDR requirements need to be subject to (a) later amendment(s) of the application.

Otherwise it causes delays in the review and certification activities.

The Technical Documentation need to be accompanied by a Declaration of Conformity. For products already in the market under an IVDR certificate, a signed Declaration of Conformity (e.g. for Technical Documentation based on a sampling approach) is required. For new products, a draft of the Declaration of Conformity for the product shall be part of the application.

The Technical Documentation has to contain consistent information throughout all sections, appendices, and attachments.

3.1 Language

In the pre-application phase (i.e. before TÜV Rheinland issues a quotation for the Technical Documentation assessment), we will ask you to provide information regarding the language of the Technical Documentation. It must be an official language of the European Union. We will confirm with you at that stage whether it is feasible for us to perform the assessment in the language in which you would like to submit your Technical Documentation. We strongly recommend that you present the Technical Documentation in English language.

Technical Documentation submissions in other languages of the European Union require a prior approval of TÜV Rheinland.

Original test reports submitted as part of the Technical Documentation need to be translated accordingly. Documents not submitted in the required language are considered not to be part of the submission and must be excluded from the Technical Documentation and subsequently from any review activities.

3.2 Electronic File Format

3.2.1 SUBMISSION ROUTE

TÜV Rheinland can provide access to secure data transfer tools for the submission of your Technical Documentation.

We recommend you prepare ZIP files for the document upload (or you may split your set of documents in more than one file) while keeping your binder and file structure within the ZIP file(s).

Your TÜV Rheinland office serving you for our Technical Documentation assessment will provide further details on the electronic file submission process.

3.2.2 FORMAT

Annex II of the IVDR states "The Technical Documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex." Thus,

- Documents shall be provided as paginated, fully searchable, OCR (Optical Character Recognition) applied and bookmarked PDF files. Main sections as indicated in IVDR Annex II "Technical Documentation" should be bookmarked, as well as any supporting attachments referenced to within the main body (i.e. executive summaries) of the Technical Documentation.
- Clear folder organization and easy navigation will make it easier to find documents and may therefore reduce overall time required for the review.
- An index or detailed table of content has to be part of the Technical Documentation
- File names should be short and self-explanatory, reflecting the information included within the documents. File names should be appropriately cross-referenced in the TD Overview, see the Annex in this document.
- For each main section specified in the IVDR Annex II, one PDF file should be submitted. Each section shall contain an executive summary including the references to the accompanying documents, which contain the documented evidence (e.g. reports). These documents have to be either embedded or filed as separate PDFs along with the section.
- Approvals/signatures are required for any submitted document in the file (signed and dated). No draft versions (except for the Declaration of Conformity and SSCP being part of initial certification submissions) shall be part of the TD submission.

Please note that if the submitted Technical Documentation does not meet the electronic format and language requirements as mentioned in this guidance, this will be considered as a reason to refuse to accept the Technical Documentation. Your submission can be delayed and will be put on hold until it has been submitted per this guidance.

3.2.3 REVIEW PROCESS

After the date of submission is agreed upon, the manufacturer needs to provide the submission according to section 3.2.1 Submission route to TÜV Rheinland on this agreed date. Incomplete TD submissions from manufacturers are one of the most common reasons for questions being raised by our Notified Body reviewers and ultimately can lead to delays in the assessment of TD(s) and the certification process.

A completeness check will be performed within 15 days after the agreed submission date to ensure the TD meets the requirements of the European MDR. We would like to emphasize that the structure of your TD should preferably follow the format outlined in Annex A, which is attached to this document, and will become available soon as a separate document on our web page https://www.tuv.com/landingpage/en/medical-device-testing-and-auditing/meta-navigation/downloads/, as well as upon request from your TÜV Rheinland local contact. Any other format may be less efficient to be assessed by TÜV Rheinland and therefore might cause severe delays in the review process. In any case, we ask you to complete the completeness checklist in Annex A that contains examples of documentation expected in the different sections of the technical documentation. How-ever, please refer to IVDR Annex II and III for the respective requirements to be addressed.

The completeness check of the TD performed by TÜV Rheinland is the first step of the TD assessment process. All missing documents identified during the completeness check need to be provided by the manufacturer before the submission will progress to the next phase. However, failure to provide a complete TD may lead to refusal of the application for the subject device(s) or to rescheduling of the review. Please refer to Annex B describing our Refuse to Accept policy.

Please note that during the review process questions from the reviewers may arise which need to be addressed by additional information to be provided by the manufacturer.

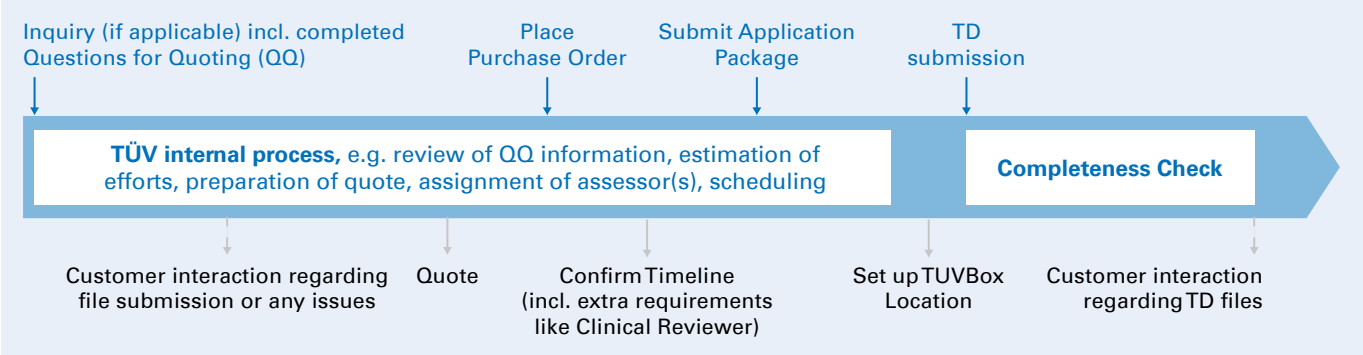

Figure 1: Typically work flow is starting at least 90 days prior to the TD review process. The arrows indicate the deliverables of the client (blue color) and the actions/deliverables of TÜV Rheinland (grey color). TÜV Rheinland confirms the TD submission date after receiving a purchase order and the IVDR application package. After receipt of the Technical Documentation, including the TD Checklist (as shown in Annex A), a completeness check is performed by TUV Rheinland experts to confirm the package is eligible to proceed.

In order to maintain an efficient project management, we would like to ask for your understanding that overall project timelines have to be defined and kept. Therefore, if required documents/evidence are still missing after the 3rd response of the manufacturer to the open questions, TÜV Rheinland reserves the right to cancel the project and/or decide on further measures.

Note: If it is not obvious which parts/documents were revised or updated, the re-review of the complete Technical Documentation will be required and will add review times and by that additional review costs.

After all questions from the reviewers have been satisfactorily addressed and the manufacturer has compiled the final version of the Technical Documentation, the internal documentation needs to be prepared and the complete package delivered to the certification department for the final decision.

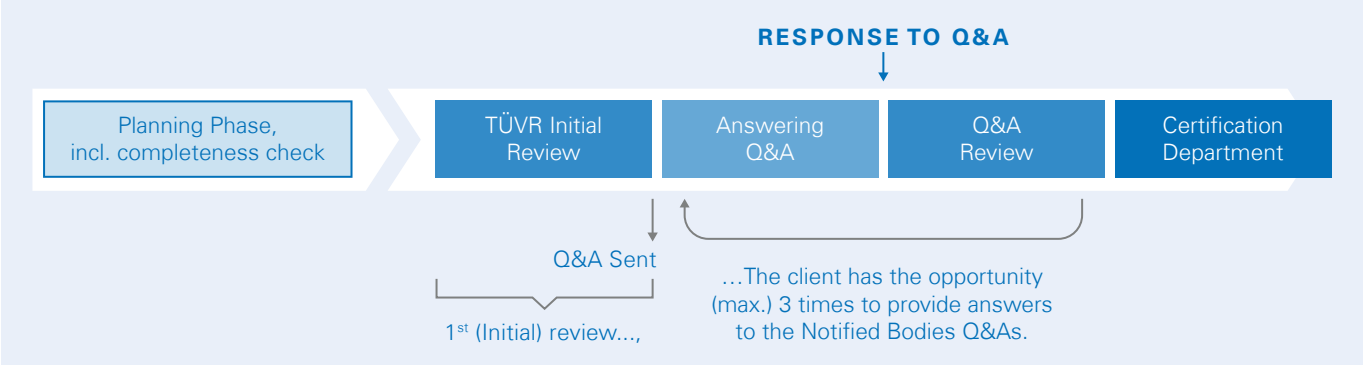

Figure 2: Scheme of the process flow following the planning phase (figure 1). After the initial review there will be a Q&A round, where questions from the initial review need to be answered by the client and time is allocated to check those answers. Depending on the quality of the documentation and responses, a second, third or fourth (last) Notified Body review may be needed, leading to an extension of the review timeline. The review process will be finalized by the decision of the certification department.

The completeness check does NOT count as one of the four maximum (technical) reviews performed by TÜV Rheinland.

Responses to TÜV Rheinland´s questions, must be provided within 20 business days after receipt of the questions documented in the "Technical Documentation Assessment IVDR – Questions and Answers List". In cases, where TÜV Rheinland requires further or more detailed evidence of compliance to the IVDR, the Technical Documentation must be updated accordingly. To support the review workflow, the revised Technical Documentation must be accompanied by a revision history indicating any change in comparison to the initial submission. The Technical Documentation shall only include current and applicable documentation related to the devices under review. New or revised documents have to be highlighted as such. Also documents, which were declared obsolete have to be indicated in the revision history. Obsolete or outdated documentation shall not be part of the submission for Technical Documentation review.

All answers provided by the manufacturer should include a reference to the document number, document name, section and page number that was changed.

To reflect the changes made to the Technical Documentation, a redlined document of the "Annex A: Information on TD Deliverables" should be submitted together with the revised Technical Documentation.

3.2.4 SIGNIFICANT CHANGES

For devices already reviewed and covered by a certificate, it is crucial to describe the reason for the change(s) including its intended effect(s).

The TÜV Rheinland Significant Change Notification (SCN) forms for Product Assessment or QMS Assessment shall be used (e.g. for new products, design changes, shelf life extensions, manufacturing changes etc., depending on the risk class of the products and their conformity assessment).

For submissions in the context of scope extensions or significant changes, as far as is practical, submissions should be stand-alone and not refer to previous submissions for evidence of compliance. A consolidated revised Technical Documentation is expected, highlighting the changes in the "Annex A: Information on TD Deliverables" and indicating new or revised, obsolete or replaced documents as opposed to the previous already reviewed Technical Documentation revision. Any changes or removals of critical suppliers/subcontractors require a revised Product List and Application, along with a Significant Change Notification, if applicable.

If you remove a critical supplier/subcontractor, please also provide justification for their removal.

Note: Before another SCN for a specific Technical Documentation is submitted, the previous SCN review needs to be successfully assessed and closed by the certification department.

Annex A: Information on TD Deliverables

PLEASE USE THIS ANNEX AS FOLLOWS:
Please follow the following format when designing an IVDR Technical Documentation.

In the column "A or N/A", please indicate if the individual requirement is deemed applicable ("A") or non-applicable ("N/A"). In case "N/A" is chosen, please provide a justification. Please add the detailed location of the evidence within the Technical Documentation into the "Add reference to TD Document & Section" column. You may use the "Check off", when you have fully completed the respective section.

Please ensure that the documentation also meets the requirements outlined in section 3.1–3.3.

Please note if the submission does not follow the format listed in this guidance, this can cause delay in our TD review process.

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
0. Application				
	"Product List and Application IVDR (QM part)" (MS-0034326) and/or "Product List and Application IVDR, Technical documentation, Annex IX, chapter II" (MS-0034327)		The following information should be listed on the "Product List and Application" (PLA): Identification of the legal manufacturer who is placing the device on the market. This should be consistent across the device labels, IFU and Declaration of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified. The name and location of the EU Authorized Representative should be identified if required. Only one EU Representative is eligible per device, and this should be consistent across device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorized Representative should be indicated as well. The site(s) responsible for design need to be identified, either external and/or internal. All relevant sterilization facilities, internal/external manufacturing facilities, etc. must be listed on your Product List and Application. **Note:** The design and manufacturing sites indicated on the "Product List and Application" provide an important input into the audit planning. Please complete all lines of the table with the requested information and make sure that this is consistent with the content of the Technical Documentation. Please take into account all relevant MDCG guidance documents, such as 2021-14, 2019-13 and 2018-1. **Note:** For products listed in Annex IX, chapter II (Class D, companion diagnostic, self-testing and near patient testing) both applications are required. Please submit one PLA for each single device (basic UDI-DI) individually. Device extensions or product removals require revised Product List(s) and Application(s), along with the forms for Significant Change Notification.	
	Cover page(s) and table of contents of the Technical Documentation		As part of the application, provide the cover page of the Technical Documentation indicating e.g. document name, TD identifier, revision number and/or date. Please provide the detailed Table of Contents for Technical Documentation.	
	Technical Documentation revision history		Please provide the revision history of the Technical Documentation, including reason for Technical Documentation revision.	
	Presentation of Technical Documentation		Please ensure that the Technical Documentation is provided in a clear, organized, readily electronically searchable and in unambiguous manner.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
1. Device description and specification, including variants and accessories. 1.1 Device description and specification				
1.1. (a)	Product or trade name and a general description of the device including its intended purpose and intended users;		The device description should enable a general understanding of the design, listing of the components incl. controls and calibrators and devices used in combination, packaging (photo might be useful) and other characteristics, e.g. single-use devices, sterile devices. It´s recommended to include the information on all codes IVR, IVS, IVP, IVR, IVD (refer to MDCG 2019-14). If done, it shall be consistent with the application form(s). The intended purpose or intended use should provide enough detail to explain the specific medical purpose as defined by IVDR Article 2. Intended purpose shall be consistent throughout the Technical Documentation (e.g. Instructions for Use, performance evaluation documentation, etc.). The classification rule of Annex VIII need to match with the intended purpose of the device. Identify the intended users of the device (i.e. healthcare professionals or lay persons). Intended users as claimed shall be substantiated by the clinical performance evaluation (lay-users and professional users inside or outside a laboratory (POCT)) and in the risk management and usability file.	
1.1. (b)	Clear identification of device by unambiguous reference allowing traceability Basic UDI-DI *(Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website)* EMDN code *(European Medical Device Nomenclature (EMDN code) shall be identified, refer to guidance published on the EU Commission website)*		Clear identification of device by unambiguous reference, allowing traceability (Basic UDI-DI), together with other traceable reference number (e.g. product code, catalog number, etc.). Information needs to be consistent also with the information on the labeling. The Basic UDI-DI is the main key in the EUDAMED database and relevant documentation (e.g. certificates, declaration of conformity, Technical Documentation and summary of safety and performance). **Note:** Only devices with the same intended purpose, risk class and essential design and manufacturing characteristics are allowed to connect together, e.g. different variants, models or sizes. Please explain the differences among these devices and demonstrate that all of them are in line with the GSPR. For (a) standardized scope(s) on the certificate(s), the 5th level of the EMDN code (letter W + 8-digits) is required. The sampling plan of the Class C devices is calculated on the basis of the 3rd level of the EMDN code (letter W + 4 digits).	
1.1. (c)	Intended purpose of the device which may include information on: (i) what is to be detected and/or measured;		The intended purpose needs to be consistent throughout the Technical Documentation, especially the performance evaluation, risk management, labelling etc. Marker, analyte or measurand	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
	(ii) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;		The given terms need to be provided. Several or additional functions are possible, e.g. confirmation of a reactive result from a first- line assay. **Devices for screening** are used to detect the presence of or the predisposition to a disease, disorder or other physiological state in a specimen not demonstrating clinically evident symptoms. Depending on the nature of the condition and the targeted patient population, screening devices may be used routinely or may be restricted to "at risk" patients. This also includes devices intended to assess the suitability of blood, blood components, cells, tissues or organs, or in any of their derivatives for transfusion, transplantation or cell administration, with respect to transmissible agents. Example: A device intended to screen blood and tissue donations (= first-line device) for syphilis would fall under class D according to rule 1. Alternatively, a device intended to diagnose syphilis, a sexually transmitted agent, in the individual would fall under class C according to rule 3a. **Devices for monitoring** are used for the measurement of the analyte levels for the purpose of adjusting treatments/interventions as required. Examples: Devices which are designed to evaluate an individual's current state, as devices which are used to assess whether an analyte remains within physiological levels or within an established therapeutic drug range or devices which are designed to evaluate changes in an individual's state, as devices which are typically used for the detection/assessment of disease progression/regression, disease recurrence, minimum residual disease, response/resistance to therapy, and/or adverse effects due to therapy. Note: **Aid to diagnosis may not be understood** as a mean to lower the risk classification (e.g. from class C to class B). **Devices for Companion Diagnostic** provide information on the predisposition to a medical condition or a disease to finally predict treatment response or reactions. It is therefore required for the safe and effective use of a therapeutic product to which it is the associated companion diagnostic test.	
	(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate: — a physiological or pathological state; — congenital physical or mental impairments; — the predisposition to a medical condition or a disease; — the determination of the safety and compatibility with potential recipients; — the prediction of treatment response or reactions; — the definition or monitoring of therapeutic measures;		Examples: Urine or blood markers: magnesium, potassium, coagulation rate, white and red blood cells Down syndrome Diabetes mellitus HLA and blood grouping HCV genotyping Medicinal product, or poisonous/toxic products measurement or detection in blood (e.g. lithium, warfarin, valproic acid, drugs of abuse) or in urine (e.g. benzodiazepin)	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
	(iv) whether it is automated or not;		In case of automated and manual devices, both methods shall be described in the instruction for use. Please include all information to identify the validated and safe combination with the analyzer incl. software.	
	(v) whether it is qualitative, semi-quantitative or quantitative;		For quantitative methods the additional performance characteristics should be considered, e.g. limit of detection, measuring range, linearity. Qualitative test results are results of tests not numerically derived (e.g. visual examinations or binary classification tests such as absence/presence, positive/negative, reactive/non-reactive). Semi-quantitative devices are based on a numerical outcome, e.g. based on thresholds and is in line with a quantitative method validation and verification.	
	(vi) the type of specimen(s) required; (vii) where applicable, the testing population; (viii) the intended user;		The suitability of the different sample matrices as stated in the IFU shall be demonstrated. If no specific testing population is stated, it is understood that the device is to be used without limitation. To support this generic claim, this needs to be addressed in the performance evaluation, e.g. as part of the diagnostic sensitivity and specificity or testing of interferences. Professional user (within a laboratory/outside a laboratory (near patient testing)) or lay user.	
	(ix) for companion diagnostics, the relevant target population and the associated medicinal product(s)		Example: Device for the detection of a biomarker in tumor specimens in order to identify patients who may benefit from treatment with the targeted therapy.	
1.1. (d)	Description of the principle of the assay method or the principles of operation of the instrument;		Please provide a detailed description of the principle of the assay method.	
1.1. (e), (f)	Rationale for the qualification of the product as a device; the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;		Please indicate the device classification and the rationale for the classification rule including the sub-rules according to Annex VIII. If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply. Please consider the information given in the Guidance on Classification Rules for in vitro Diagnostic Medical Devices (refer to MDCG 2020-16). The justification for the device classification should be sufficiently robust in particular in borderlines cases, or in combination products. Where there is a foreseeable risk that the tests may be misused a clear limitation of use should be included in the IFU, e.g. “This test device is not intended to be a first-line device to be used for screening for transmissible agents”.	
1.1. (g)	Description of the components and where appropriate, the Description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers;		Please provide a detailed description of the listed components under 1.1 (a) with a focus on the reactive ingredients.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
1.1. (h)	Description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;		Please consider the pre-analytical requirements, e.g. stability of the analyte.	
1.1. (i)	For instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;		Evidence needs to be provided demonstrating the compatibility of the instrument with the appropriate or dedicated assays as part of the performance evaluation. In addition: Provide all relevant evidence of compliance with the appropriate and current standards (applicable parts of the EN 60601 series).	
1.1. (j)	For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;		Please describe the appropriate instrumentation and provide the application sheets for dedicated instrumentation. Evidence needs to be provided demonstrating the compatibility of the automated assay with the appropriate or dedicated instrumentation as part of the performance evaluation.	
1.1. (k)	Description of any software to be used with the device;		Please include the software version which drives the device or influences the use of the device.	
1.1. (l)	Description or complete list of the various configurations/variants of the device that are intended to be made available on the market;		All configurations/variants of the device covered by the Technical Documentation need to be clearly identified. Sufficient information should be provided to distinguish different variants, models or sizes of the device with the same specific intended purpose. It has to be demonstrated that all of them are in line with the relevant requirements.	
1.1. (m)	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		Evidence needs to be provided demonstrating the compatibility of the devices with any applicable accessories/other device or product within the Technical Documentation. Whilst not being an IVD in themselves, accessories are to be used in conjunction with a specific IVD. Examples: buffer, lysing solutions, diluents, library prep reagents and extraction kits.	
1.2. Previous and similar generations of the device				
1.2. (a)	Reference to previous and similar generations of the device. Overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;		Previous or similar generations of the product shall be described outlining the differences with the presented product generation. Information may be important to explain the relevance of data for e.g. the clinical performance evaluation, **p**ost-**m**arket **s**urveillance (PMS) and **p**ost-**m**arket **p**erformance **f**ollow-up (PMPF).	
1.2. (b)	Similar devices available on the Union or International market		Please provide a list and brief description of any similar devices that are available on the Union or International markets. This may also be important in the interest of e.g. the clinical performance, PMS and PMPF.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
2. Labeling *In regard to language requirements, please refer to IVDR, Article 10(10): "Manufacturers shall ensure that the device is accompanied by the information set out in Section 20 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."*				
2. (a)	Complete set of Labels as on the device, on the (e.g. single unit) packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; (see Annex I, #20.1, #20.2 and #20.3)		Please ensure that labels are one-to-one copies. Please ensure that the copy reflects the label as intended. If the device has a sterile barrier, clearly identify the label for the sterile package. If any of the packaging is printed with information for the user (including pictures / schematics of the device) this should also be provided. Please ensure that any specific requirements of relevant standards (EN ISO 18113 series, EN 60601 series, ISO 15223-1) are addressed on the labels.	
2. (b)	Instruction for use (IFU) (see Annex I, #20.1 and #20.4)		Please ensure that the information within the IFUs, especially related to the intended purpose, limitations, and other safety related information such as precautions and warnings are in line with the information within the Technical Documentation such as risk management, performance evaluation, usability etc. Please ensure that any specific requirements of relevant standards or CS are addressed by the instructions for use, for example EN ISO 18113 series, EN 60601 series and ISO 15223-1. Please define the language requirements for the IFUs based on the target markets and provide the IFU including the respective translations as per Art. 10 (10). Some devices incorporate all the information relevant for the user/ patient within the IFU itself. Some devices are accompanied by additional or separate parts, for example application sheets, "kit leaflets" as part of an e-labeling concept or certificates of analysis. Such parts of the labeling need to be provided as well, where applicable. Please note, that any particular performance claims or product benefits stated in the IFU must be supported by adequate performance data. Please provide the IFU in the final print-layout. For class C and D devices the manufacturer shall mention on the label or instruction for use where the summary of safety and performance (SSP) is available as per Art. 29.	
2. (b)	Safety Data Sheet (SDS) (see Annex I, #20.1)		If a safety data sheet (SDS) is provided for the device, the SDS is part of the TD in the respective translations. Please note that the URL of the website where the SDS is available shall mention on the label or instruction for use.	
2. (b)	Electronic Instructions for Use (see Annex I, #20.1 f)		If electronic Instructions for Use (eIFU) are provided for the device, the eIFU should be in compliance with the requirements of the IVD Guideline MEDDEV 2.14/3. Products for near-patient testing and self-testing are excluded from the "e-labeling approach". If applicable, please provide the URL of the website where labelling information as relevant is included in the Technical Documentation.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
3. Design and Manufacturing				
3.1	Information on design stages applied to the device		Please provide information on the design stages (stages like: initial idea, risk analysis, conception, feasibility, design and development, verification and validation activities) applied to the device to be understood. For devices already marketed, please include a history of any major changes to its design, including the reason for design changes. For previously marketed devices certified under the IVDD and applying for IVDR certification, it is crucial to provide the following: • Any changes in the design of the device as CE marked under IVDD vs. the application under IVDR • A comprehensive conclusion / decision for new performance evaluations or assessments to be conducted Where no new performance evaluation has been undertaken, the documentation shall incorporate a rationale for that decision.	
(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;		Please provide the details to identify and trace back the critical ingredients.	
(b)	for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;		Provide all relevant evidence of compliance with the appropriate and current standards (applicable parts of the EN 60601 series). In general, for the test laboratory used for testing of electrical safety, please provide the accreditation/designation of the respective laboratory.	
(c)	for instruments and software, an overview of the entire system;		Please provide all information to understand the safe combination of both parts. In vitro medical device software may be placed on the market or put into service as an integral component/part of a device. For example as a part of a handheld hardware device intended for near-patient testing for the determination of the blood glucose concentration.	
(d)	for software, a description of the data interpretation methodology, namely the algorithm;		Please provide evidence that the software is qualified as a medical device software (MDSW) as per MDCG 2019-11. Full lifecycle management must be demonstrated and provided as appropriate for the risk class of the software. EN ISO/IEC 62304 is the state-of-the-art approach. **Note:** Test report form may not be sufficient by itself.	
(e)	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.		Usability and robustness studies are important processes within the product development process to verify the effectiveness of the design and to evaluate the ease-of-use of a product. Please ensure that any specific requirements of the relevant standard EN 62366 are addressed.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
3.2 (a)	Manufacturing information: information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures;		A general description of the manufacturing processes, including manufacturing technologies used and an indication of special processes need to be part of the Technical Documentation. The detailed overview may be provided as manufacturing flowchart(s), including relevant information on incoming inspection of raw material to final product testing and packaging, etc. The main work instructions and DMR should be identifiable, also to serve as an input for the audit. For class C and D devices please provide selected specifications of the finished device as needed for the batch verification and surveillance activities according to Annex IX 3.4. Please include the following: • Incoming inspection of critical raw materials / active ingredients • Specifications and final concentrations /quantities of critical raw materials / active ingredients in the finished device • Details to in-process controls and final batch release testing incl. acceptance criteria, Please note that the requirements mentioned above equally apply to materials, subcomponents or devices supplied by subcontractors.	
3.2 (b)	identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.		Please ensure that relevant information is provided, e.g. on manufacturing technologies, on location/site (including critical external manufacturing facilities), class of clean room or reference to the existing process validation, e.g. indication of validation master plan (VMP). Internal, external manufacturing sites as well as all subcontractors and critical suppliers need to be identified (including current certificates according to IVDR or EN ISO 13485, if available). This is especially important if a component of the finished device is manufactured by an external facility, and is not altered prior to its addition to the finished device. Level of control of critical supplier need to be evident, e.g. incoming inspection by the legal manufacturer, certificates of the supplier. All sites identified must align with the submitted Product List and Application.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
4. General Safety & Performance Requirements				
4. (a) - (d)	"General safety and performance requirements" document		Please provide a "General safety and performance requirements" document structured according to IVDR, Annex II Section 4: • Containing a "decision column" concerning each individual clause/ sub-clause of IVDR Annex I. If a clause is not deemed applicable, a brief rationale should be indicated • Containing a column to add methods used to demonstrate conformity with each clause/sub-clause of IVDR Annex I • Containing a column to indicate standards applied, Common Specification (CS) or other relevant documents (e.g. CLSI guides) for each clause/ sub-clause • Containing a column to add the precise identity of the controlled documents offering evidence of conformity with each applied standard, CS or other method applied and a cross-reference to the location of such evidence within the full Technical Documentation and, if applicable, the summary Technical Documentation for each clause/sub-clause of IVDR Annex I Please provide an overview of applicable standards/common specification/ etc. and indicate, which of these were (fully or partially) applied, including version (state of the art). Ensure the list of applied standards also considers any normative references. Ensure the list of standards / common specifications contain the appropriate version (State of the Art) of the standard (EN- standard) that has been applied. If an older version or a national standard (e.g. DIN, BS) was applied, gap assessments are requested to demonstrate compliance to state of the art. Refer to additional applicable standards and/or directives applicable for the device in question – e.g. REACH, Regulation (EC) No 1272/2008, scientific opinions, Machinery directive, EMC, guidance as necessary to show state of the art.	
5. Benefit-Risk Analysis & Risk Management				
5. (a) -(f)	Risk Management: Risk management plan *(Refer to Annex. I, #3a)* Risk assessment including risk control *(Refer to Annex. I, # 3b-d, #4)* Information from production phase and PMS on hazards and the frequency of occurrence *(refer to Annex I, #3 e,f)* Overall residual risk evaluation *(refer to Annex I, #8)*		Please refer to the IVDR requirements in Annex I, sections 1 to 8 for specific aspects and life-cycle phases to be covered in the risk management. Please provide the relevant risk management file documents, especially the Risk Management Plan, Risk Assessments / FMEAs and the Risk Management Report. The system used for qualitative or quantitative categorization of probability of occurrence of harm and severity of harm shall be recorded in the risk management file. Please indicate whether the risk management process is based on EN ISO 14971. The risk management file needs to clearly reflect the interface between the risk management process and performance evaluation of the device in question (refer to Annex VII, 4.5.4(c)).	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
Annex I, #5	Usability Evaluation		Please refer to the associated IVDR requirements such as Annex I, section 5 and e.g. clauses #13.2, #19. #19.1, #19.2 or #20.4.2 Please refer to EN 62366-1. For ease of review, please also provide a use flow-chart for the device in question.	
6. Product Verification and Validation 6.1. Information on the Analytical Performance				
6.1	Information on analytical performance of the device		Please demonstrate the analytical performance to all applicable parameters described in point (a) of Section 9.1 of Annex I. All non-applicable characteristics shall be justified, e.g. cut-off in qualitative assays. Please use the terminology of the parameters given in the regulation. The methodology shall be described with the state of the art guidelines, e.g. from CLSI. The analytical performance shall be demonstrated on the basis of analytical performances studies. **Specimen type:** data must be provided to demonstrate performance with all specimen types indicated in the intended purpose. **Accuracy of measurement:** may be demonstrated through trueness and precision separately. **Trueness:** bias using reference standard materials and/or gold standard methods is a priority. **Precision:** reproducibility and repeatability (as defined in state of the art guidelines such as CLSI EP05 A3:2014) shall be demonstrated separately **Analytical specificity:** Requirements in Annex II, 6.1.2.3 shall be addressed, all applicable and non-applicable interferents and cross-reacting substances or agents must be justified. **Calibrator and control:** At least one suitable internal or external example must be stated in the IFU reflecting the performance studies. **Metrological traceability of calibrator and control material values:** If no international reference standard exists, an explanation must be also given about how the assay is standardized (e.g. how internal standards are prepared, what SOTA device is used as reference, etc.). **Measuring range:** Should contain the LoD, Information on Linearity/ Non-Linearity; Hook effect must be demonstrated on the upper limit or, if non-applicable, justified. Please demonstrate and document the analytical performance in a separate analytical performance report with a summary of the results including final claims in the instructions for use.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
6.2. Information on Clinical Performance and Clinical Evidence				
6.2	Information on scientific validity		This section shall be dedicated solely to demonstrate the association of an analyte with a clinical condition or a physiological state. Independent demonstrations may be required if more than one claim is included in the intended purpose. It must not necessarily include data obtained with the particular device being assessed. Please include the search methodology, the literature search protocol and literature search report. A copy of all relevant references must be delivered together with the TD as supplementary information. For scientific (peer-reviewed) literature searches, the literature search methodology and the literature search protocol and literature search report of a literature review must be included in the report scientific validity report, refer to GHTF/SG5/N7:2012 or IMDRF N56 for guidance. Please demonstrate and document the scientific validity of the analyte or marker in a separate analytical performance report.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
6.2	Information on clinical performance		Please consider that the regulation defines clinical performance as: Clinical performance defined as correlation with clinical condition/disease for devices measuring specific analytes that are associated with a clinical condition/disease and have a medical decision point. Or Clinical performance defined as correlation with a physiological or pathophysiological process or state for devices measuring analytes without clear medical decision points or for devices measuring analytes that are not (yet) associated with a clinical condition. Note: The former guidance GHTF SG5N7 addressed clinical performance in correlation with clinical condition only, hence does not cover all devices a clinical performance evaluation is expected for. Concluding, a demonstration of clinical performance (at least for specific performance characteristics) is also required for established and standardized devices. Only in very rare cases clinical performance may not be applicable, e.g. class A urine cups and specimen receptacles. Clinical performance shall demonstrate the characteristics listed in Annex I 9.1.b., although the list is not exhaustive and other characteristics may apply depending on the clinical function (e.g. agreement tables, patient outcome measure and interaction analysis (CDx), hazard ratio, odds ratio). All non-applicable characteristics must be justified. Demonstration shall be based on the sources listed in Annex XIII, 1.2.3. For scientific (peer-reviewed) literature searches, the literature search methodology and the literature search protocol and literature search report of a literature review must be included (refer to GHTF/SG5/N7:2012 or IMDRF N56 for guidance). The level of clinical evidence is not limited to clinical performance data but has a focus on it. Drivers of the level of clinical performance data are: intended purpose, standardization and risk class. Documents expected as part of the clinical performance documentation: • Clinical performance report (CPR), including the attachments based on clinical performance studies In case clinical performance is demonstrated on scientific peer reviewed literature / published experience: • Full text copies of the relevant published literature • Literature search reports • Full list of retrieved articles • Full list of excluded articles, with reasons for exclusion	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
	Clinical performance studies		For clinical performance studies (including post market performance follow up studies) please refer to IVDR; Annex XIII no. 2. Please provide evidence of compliance with the current standard ISO 20916. Ethical considerations shall be always demonstrated. The clinical performance study should be designed to specify the clinical evidence the study intends to create whilst accounting for potential risks, considering appropriate ethical requirements and ensuring compliance with all relevant legal and regulatory requirements. A clinical performance study plan is required. For class D devices, near-patient testing, self-testing and CDx clinical performance studies are required. In case of equivalence studies the suitability of the data shall be described. Independent demonstration of clinical performance may be required if more than one claim is included in the intended purpose. If clinical investigation studies have been conducted, please refer to IVDR, Annex XIV. Please demonstrate and document the clinical performance in a separate clinical performance report.	
	Performance evaluation plan		A performance evaluation plan (PEP) is required to be able to continuously update the performance evaluation. The PEP must be designed in accordance to Annex XIII, 1.1. A description of the state of the art, input target specifications, outline of experimental design and methodology shall be included. A specification of the characteristics of the device as described in Section 9 of Chapter II of Annex I, with a justification of all non-applicable performance (analytical and clinical) characteristics. It must include a reference to PMPF, and every PMPF study shall trigger an update in the PEP. Qualification of external study sites (e.g.for clinical performance studies) needs to be demonstrated. Please provide the performance evaluation plan as a single document.	
	Performance evaluation report		The performance evaluation report (PER) must be designed in accordance to Annex XIII, 1.3.2. Please present within the PER the single reports on the scientific validity, the analytical and the clinical performance together with an assessment of those reports to confirm the performance characteristics as planned in the PEP and the clinical evidence. Please provide the performance evaluation report as a single document.	
Annex I 4. (c)	Common specification (CS)		For all devices Common Specifications (CS) are published for, please clearly identify the specific applicable requirements and provide evidence for compliance, e.g. by means of a correlation table and references to the details study plans and reports within the performance evaluation. For class D devices no CS are published yet but which were classified as Annex II List A products under the IVD Directive 98/79/EC (IVDD) , please take the “Common Technical Specifications” under IVDD into account as an input for the performance evaluation.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
Article 29	Summary of Safety and Performance (for class C and D)		Please provide an SSP keeping in mind the guidance laid down in MDCG 2019-9; Summary of safety and clinical performance and the specific template which is planned to be published as long as there is no IVDR specific guidance available.	
6.3. Stability				
6.3.1 (a)	Study report including the protocol, number of lots, acceptance criteria and testing intervals;		Please ensure that the specific requirements of the relevant standard EN 23640 and the CLSI EP25-A Guidance are addressed.	
(b)	Accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described;		In case accelerated aging data are used initially, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25 °C). Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable.	
(c)	Conclusions and claimed shelf life		Please summarize the results of the stability testing studies and mention the claimed shelf life.	
6.3.2	In-use stability:		The actual routine use must be known, described and considered in the study protocol/plan, e.g. number of open/closed cycles, used time at room temperature/storage time refrigerated. Please be aware that automatic and manual reagent processing shall be addressed separately.	
(a)	Study report (including the protocol, acceptance criteria and testing intervals);		It is good practice to perform the in-use life testing at both the start and end of the product shelf life.	
(b)	Conclusions and claimed in-use stability.		Please summarize the results of the in-use stability testing studies and mention the claimed in-use stability.	
6.3.3 (a)	Shipping stability: Study report (including the protocol, acceptance criteria);		Please consider the respective environmental challenges of the product transport and justify the chosen test conditions (e.g. as required by transportation standards) accordingly.	
(b)	Method used for simulated conditions;		Please provide the transport evaluation/validation for the product in its packaging. The sterile barrier packaging validation related section can be found below, see Section 6.5 a) “Product and packaging stability tests”.	
(c)	Conclusion and recommended shipping conditions		Transportation of the product to the end user must not have an impact on the quality, safety or performance of the device.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
6.4. Software Verification and Validation				
6.4	Summary results of all verification, validation and testing performed		Please demonstrate the full lifecycle management as appropriate for the risk class of the software. EN ISO/IEC 62304 is considered the state-of-the-art approach. Note: Test report form may not be sufficient by itself. Please also refer to the MDCG Guidances 2019-11 and 2020-1 for further information on the qualification and classification as well as the performance evaluation of software.	
	Hardware configurations			
	Where applicable, operating systems identified in the labelling			
6.5. Additional information required in specific cases				
6.5 (a)	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		Environmental conditions for the relevant manufacturing steps need to be identified (e.g. Class of cleanroom). Refer to applicable parts of the EN ISO 14644 series. Bioburden test results (methods/procedures) and evidence of bioburden testing need to be included for the products in question. (see e.g. Annex I, #11.6)	
	Description of sterilization method (including location)		Please note, description and location must align with the information provided in the Product List and Application. Please provide copies of the EN ISO 13485 certificates including the relevant scope for the performed sterilization activities of the sterilization facility/ies.	
	Validation reports addressing bioburden testing, pyrogen testing		Key characteristics of the sterilization process and the related initial validation and all relevant revalidations including all attachments need to be provided (according to the respective sterilization standards). Please ensure that the approach for the sterilization validation is clearly defined. In case the device in question was not part of the sterilization validation, the suitability of the sterilization validation for sterilization of the device needs to be demonstrated. Please provide the documentation according to the applicable standard for respective sterilization method. Information on the biological contamination of the device needs to be provided like: • Evidence of microbiological characterization, which is performed as part of the sterilization validation. • Bioburden and pyrogen test reports, including the information on the recovery rate. • Information on the respective alert and action limits.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
	Testing for sterilant residues, if applicable		Test reports on the sterilization residuals need to be provided. The testing needs to be performed on device samples under consideration of a worst case approach. In case multiple sterilization cycles shall be allowed, the residual test results are to be provided according to the maximum number of sterilization cycle allowed. Refer to applicable standards like EN ISO 10993-7.	
	Description of the sterile packaging Packaging validation including transport simulation		If the device is placed in a primary/secondary package that is intended to be the sterile barrier, please provide the following: • Microbial barrier integrity of materials and seals for packaging • Packaging validation reports reflecting all seals • maintenance of sterility up to the labeled shelf-life (refer to EN ISO 11607-1) • Packaging system performance testing (handling, distribution, storage) In case accelerated aging data are used initially, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25°C). Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable.	
(b)	Devices containing tissues, cells and substances of animal, human of microbial origin Information on the origin of such material Conditions in which the material was collected		As requested in section 12 of Annex I IVDR: Please provide evidence that the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures are carried out so as to provide safety for user or other person. Please identify whether the animals were subject of appropriate veterinary controls, if applicable and the information about the (geographical) origin of the animals. Please provide evidence that the safety with regard to viruses and other transmissible agents is addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the performance of the device. Please detail whether the device is manufactured utilizing tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 and provide compliance to the respective regulation.	
(c)	Devices with a measuring function including evidence of accuracy as specified		This sections applies to IVDR instruments only. Please provide a description of the methods used in order to ensure the accuracy as given in the specifications. Please also refer to related sections in Annex I IVDR, e.g. #14.1 or #13.7.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
(d)	Device is to be connected to other equipment in order to operate as intended 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		Please specify the equipment or accessories that have to be combined with the device for its intended use, such as analyzers / instruments or devices for sample preparation or purification. Evidence needs to be provided that the combination in question is validated and covered by the performance evaluation. Equivalence studies might be provided for further combinations, e.g. same assay on new instrument. Especially in case of "open systems" where the combination is not limited to a specific device, product specifications and characteristics need to be defined. Combination assay with instrument to be validated, performance evaluation, equivalence studies for further combinations with the same assay and further instruments.	
7. Companion diagnostics				
Annex IX 5.2	Consultation process for companion diagnostic		A draft Summary of Safety and Performance (SSP) and draft instructions for use (IFU) need to be part of the application, as a basis for the consultation process between TÜV Rheinland and the designated competent authority for the medicinal product (e.g. EMA). The provided information should enable the determination of the suitability of the device in relation to the medicinal product concerned.	
8. Post market surveillance				
Annex III	Post-market surveillance plan and report (PSUR for class C and D)		Please refer to Annex III section 1 for detailed requirements concerning the PMS plan. Multiple products can be addressed in a combined plan. However it needs to be ensured that the specific regulations / aspects applying to an individual device (Basic UDI-DI) are traceable in the PMS plan. For class B devices, appropriate intervals for PMS activities can be defined and justified by the manufacturer on a risk based approach (e.g. well established device vs. novel device). PMS reports for class B devices are submitted to the Notified Body only upon requests. Details concerning the periodic safety update reports (PSUR) are given in Article 81. PSURs need to be prepared annually for class C and class D devices. For class D devices NBs are obliged to review each PSUR, for class C devices the review is primarily performed for devices subject to the Technical Documentation review as per sampling plan.	

Ref to IVDR	Requirements	A or N/A	Add reference to TD Document & Section, where the information can be found	Check off
Annex XIII Part B	Post-market performance follow-up plan and evaluation report PMPF (update of performance evaluation)		Please refer to IVDR, Annex XIII , Part B Documents expected as part of the PMPF documentation: • PMPF plan • PMPF evaluation report The PMPF plan is typically an integral part of the PMS. If PMPF is not deemed appropriate, this has to be duly justified. For new devices a PMPF report is not required. The plan is mandatory.	
9. Declaration of Conformity				
Annex IV	**EU Declaration of Conformity** according to IVDR, Art. 14 and Annex IV (Draft for new applications, Copy for existing products)		Please ensure that the (draft) declaration of conformity (DoC) contains all information as outlined in IVDR, Annex IV. For initial reviews or new products, a draft DoC is required. For TD reviews of existing products, please provide the related signed copy of the DoC.	

Annex B: Refuse to Accept Policy

The purpose of this section is to explain the process and criteria TUV Rheinland will use in ensuring the Technical Documentation submission meets the requirements to ensure a substantive review.

TUV Rheinland will complete a completeness check to ensure a more efficient approach that safe and effective medical devices reach patients as quickly as possible.

Thus, the Refuse to Accept policy includes an early acceptance review against specific acceptance criteria and to inform the submitter within the first 15 calendar days after receipt of the submission on the agreed submission date if the Technical Documentation has been judged to be complete per Annex II and III of IVD Regulation (EU) 2017/746. TÜV Rheinland is using Annex A of the Technical Documentation IVDR Guidance for this task. This review will identify the missing minimum documents. In order to ensure consistency in Technical Documentation and to help manufacturers better understand the types of information TUV Rheinland needs, this guidance, including the checklist Annex A, has been provided.

It is important to clarify between the completeness check of the Technical Documentation and the quality of the documents and information provided. The completeness check is to ensure the required documents are submitted. The review of the quality of the submitted documentation occurs once provided to a Technical Reviewer.

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