Annex A: Checklist for IVDR Technical Documentation Submissions

This checklist contains the IVDR requirements on the deliverables for IVDR Technical Documentation (TD) Submissions. Please also follow such a structured format when designing an IVDR Technical Documentation. For further information please refer to the "Guidance for IVDR Technical Documentation Submissions".

PLEASE USE THIS CHECKLIST AS FOLLOWS

- Columns with grey header shall be completed by the manufacturer. The right column "Completeness check by TÜV Rheinland" is exclusively for TÜV Rheinland use.
- Column "Page/Section of TD": please include the detailed location in which the relevant IVDR requirement is addressed in the Technical Documentation.
- Column "Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of N/A include justification": The text in black italics on blue background is intended to give guidance and can be deleted when completing this column.
  - Please add the respective information for referenced evidences including the respective document title, document number, applicable chapter, section, page, etc.
  - Please ensure that the references are correct and the referenced evidence is attached.
  - In case the requirement is indicated to be "N/A", please always provide a justification. "N/A" will be not accepted for mandatory requirements.
- Please tick "Check off", when you have fully completed the respective section.
- TÜV Rheinland will perform a completeness check after submission using the right column of the table. The result will be communicated to the manufacturer.
- Please note that if the submission does not follow the IVDR requirements or this checklist is not completed in an acceptable way, the TD Review will be delayed.

Table of Contents

Application

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	"Product List and Application IVDR (QM part)" (MS-0034326)		*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 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.*	☐	☐ available ☐ missing
	and/or "Product List and Application IVDR, Technical documentation, Annex IX, chapter II" (MS-0034327)				☐ available ☐ missing ☐ NA by client Comment
	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.*	☐	☐ available ☐ missing Comment
	Technical Documentation revision history		*Please provide the revision history of the Technical Documentation, including reason for Technical Documentation revision.*	☐	☐ available ☐ missing Comment
	Presentation of Technical Documentation		*Please ensure that the Technical Documentation is provided in a clear, organized, readily electronically searchable and in unambiguous manner.*	☐	☐ acceptable Comment

1 Device Description and Specification

1.1. Device Description and Specification

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
1.1. (a)	Product or trade name and a general description of the device including its intended purpose and intended users		*The device description shall 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 is recommended to include the information on all codes IVR, IVS, IVP, IVD (please refer to MDCG 2021-14). If done, it shall be consistent with the application form(s).* *The intended purpose or intended use shall 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 needs 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.*	☐	☐ available ☐ missing Comment
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 the 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(s) (e.g. product code, catalog number, etc.).* *Information needs to be consistent also with the information on the labelling.* *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).*	☐	☐ available ☐ missing Comment
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.*	☐	☐ available ☐ missing Comment

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1.1. (c)	(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 (e.g. drug monitoring). 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 means 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.*	☐	☐ available ☐ missing ☐ NA by client Comment
	(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate:		*Examples:*	☐	☐ available ☐ missing ☐ NA by client Comment
	▪ a physiological or pathological state;		*Urine or blood markers: magnesium, potassium, coagulation rate, white and red blood cells*		
	▪ congenital physical or mental impairments		*Down syndrome*		
	▪ the predisposition to a medical condition or a disease;		*Diabetes mellitus*		
	▪ the determination of the safety and compatibility with potential recipients;		*HLA and blood grouping*		
	▪ the prediction of treatment response or reactions;		*HCV genotyping*		
	▪ the definition or monitoring of therapeutic measures;		*Medicinal product, or poisonous/toxic products measurement or detection in blood (e.g. lithium, warfarin, valproic acid, drug monitoring) or in urine (e.g. benzodiazepin)*		

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	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.* *The performance data section of the TD should reflect this validation.*	☐	☐ available ☐ missing ☐ NA by client Comment
	(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 are in line with a quantitative method validation and verification.*	☐	☐ available ☐ missing ☐ NA by client Comment
	(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.*	☐	☐ available ☐ missing ☐ NA by client Comment
	(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.*	☐	☐ available ☐ missing ☐ NA by client Comment
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.*	☐	☐ available ☐ missing Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 borderline 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".*	☐	☐ available ☐ missing Comment
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.*	☐	☐ available ☐ missing Comment
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.*	☐	☐ available ☐ missing ☐ NA by client Comment
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).*	☐	☐ available ☐ missing ☐ NA by client Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing ☐ NA by client Comment
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.*	☐	☐ available ☐ missing ☐ NA by client Comment
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.*	☐	☐ available ☐ missing ☐ NA by client Comment
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.*	☐	☐ available ☐ missing ☐ NA by client Comment

1.2. Previous and Similar Generations of the Device

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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, post-market surveillance (PMS) and post-market performance follow-up (PMPF).*	☐	☐ available ☐ missing ☐ NA by client Comment
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.*	☐	☐ available ☐ missing ☐ NA by client Comment

2 Labelling

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."

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing Comment
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-labelling concept or certificates of analysis. Such parts of the labelling 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.*	☐	☐ available ☐ missing Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 be mentioned on the label or instruction for use.*	☐	☐ available ☐ missing ☐ NA by client Comment
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-labelling approach".* *If applicable, please provide the URL of the website where labelling information as relevant is included in the Technical Documentation.*	☐	☐ available ☐ missing ☐ NA by client Comment

3 Design and Manufacturing

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
3.1 (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.*	☐	☐ available ☐ missing ☐ NA by client Comment
3.1 (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.*	☐	☐ available ☐ missing ☐ NA by client Comment
3.1 (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.*	☐	☐ available ☐ missing ☐ NA by client Comment
3.1 (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.*	☐	☐ available ☐ missing ☐ NA by client Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
3.1. (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.*	☐	☐ available ☐ missing ☐ NA by client Comment
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 assess-ment 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 B, 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.*	☐	☐ available ☐ missing Comment
3.2. (b)	identification of all sites, including sup-pliers and sub-con-tractors, where manu-facturing 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.*	☐	☐ available ☐ missing Comment

4 General Safety & Performance Requirements

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing Comment

5 Benefit-Risk Analysis and Risk Management

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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)).*	☐	☐ available ☐ missing Comment
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.*	☐	☐ available ☐ missing Comment

6 Product Verification and Validation

6.1. Information on the Analytical Performance

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 performance 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.*	☐	☐ available ☐ missing ☐ NA by client Comment

6.2. Information on Clinical Performance and Clinical Evidence

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 methodology, the protocol, and report of the literature review must be included in the scientific validity report. Please 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.*	☐	☐ available ☐ missing ☐ NA by client Comment
	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*	☐	☐ available ☐ missing ☐ NA by client Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	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.*	☐	☐ available ☐ missing ☐ NA by client Comment
	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, together with a justification of all non-applicable performance (analytical and clinical) characteristics must be included.* *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.*	☐	☐ available ☐ missing Comment
	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.*	☐	☐ available ☐ missing Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
Annex I 4. (c)	Common specification (CS)		*For all devices, for which Common Specifications (CS) are published, 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 in the study plans and reports within the performance evaluation.*	☐	☐ available ☐ missing ☐ NA by client Comment
Article 29	Summary of Safety and Performance (for class C and D)		*Please provide the SSP based on the MDCG document 2022-9 Summary of safety and performance template.*	☐	☐ available ☐ missing ☐ NA by client Comment

6.3. Stability (Excluding Specimen Stability)

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.3.1. (a)	Claimed shelf-life: 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.*	☐	☐ available ☐ missing Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.3.1. (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 is 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.*	☐	☐ available ☐ missing ☐ NA by client Comment
6.3.1. (c)	Conclusions and claimed shelf life		*Please summarize the results of the stability testing studies and mention the claimed shelf life.*	☐	☐ available ☐ missing Comment
6.3.2. (a)	In-use stability: Study report (including the protocol, acceptance criteria and testing intervals);		*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.* *It is good practice to perform the in-use life testing at both the start and end of the product shelf life.*	☐	☐ available ☐ missing Comment
6.3.2. (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.*	☐	☐ available ☐ missing Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing Comment
6.3.3. (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".*	☐	☐ available ☐ missing ☐ NA by client Comment
6.3.3. (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.*	☐	☐ available ☐ missing Comment

6.4. Software Verification and Validation

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.4.	Summary results of all verification, validation and testing performed Hardware configurations Where applicable, operating systems identified in the labelling		*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.*	☐	☐ available ☐ missing ☐ NA by client Comment

6.5. Specific Cases – Sterile Devices or Devices in Defined Microbiological Condition

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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)*	☐	☐ available ☐ missing ☐ NA by client Comment
	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.*	☐	☐ available ☐ missing ☐ NA by client Comment

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
	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.*	☐	☐ available ☐ missing ☐ NA by client Comment
	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 cycles allowed.* *Refer to applicable standards like EN ISO 10993-7.*	☐	☐ available ☐ missing ☐ NA by client Comment
	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.*	☐	☐ available ☐ missing ☐ NA by client Comment
6.5. (b)	Devices containing tissues, cells and substances of animal, human or 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.*	☐	☐ available ☐ missing ☐ NA by client Comment

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		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
6.5. (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.*	☐	☐ available ☐ missing ☐ NA by client Comment
6.5. (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 connected 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.*	☐	☐ available ☐ missing ☐ NA by client Comment

7. Companion Diagnostics

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing ☐ NA by client Comment

8. Post Market Surveillance

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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 request.* *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.*	☐	☐ available ☐ missing Comment
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.* *For new devices a PMPF report is not required, but a PMPF plan is mandatory.*	☐	☐ available ☐ missing ☐ NA by client Comment

9. Declaration of Conformity

IVDR Reference	Requirements	These columns to be completed by the manufacturers			Completeness check by TÜV Rheinland
		Page / Section / Chapter of TD	Referenced Evidence (Document Title & Number, applicable Chapter, Section etc.) or in case of NA include justification	Check off	
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.*	☐	☐ available ☐ missing Comment

Completeness check of TÜV Rheinland performed by [printed Name and Date]:

Additional remarks/findings during the completeness check to the TD assessor/specialist:

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