Checklist Annex II IVDR - Technical documentation

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES					
1.1.a	Product name	The product or trade name and a general description of the device, including its intended use and intended users.	please select		
1.1.b	Basic UDI-DI	The basic UDI-DI according to Annex VI Part C or another unique identifier that enables traceability.	please select		
1.1.c	Intended purpose	The intended use of the device, including information on detection, function, disease, automation, quantity, sample type, target population and user.	please select		
1.1.d	Test principle	A description of the test principle or the operating principle of the instrument.	please select		
1.1.e	Rationale	The rationale for the qualification of the product as a device.	please select		
1.1.f	Risk class	The risk class of the device and the justification for the classification rule(s) applied.	please select		
1.1.g	Components	A description of the components and, if applicable, the active ingredients of relevant components.	please select		
1.1.h	Specimen collection	A description of the specimen collection and transportation materials supplied with the device or the recommended specifications.	please select		
1.1.i	Automated assays	A description of the appropriate assay characteristics or dedicated assays for automated testing instruments.	please select		

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1.1.j	Instrumentation	A description of the characteristics of appropriate instrumentation or associated instrumentation in automated testing.	please select		
1.1.k	Software	A description of any software to be used with the device.	please select		
1.1.l	Configurations	A description or complete list of the different configurations/variants of the device to be placed on the market.	please select		
1.1.m	Accessories	A description of a device's accessories, other devices and other equipment that are not devices intended to be used in combination with the device.	please select		
1.2 Reference to previous and similar generations of the device					
1.2.a	Previous generations	An overview of the previous generation(s) of the device produced by the manufacturer.	please select		
1.2.b	Similar devices	An overview of identified similar devices available on the market in the EU or on international markets.	please select		
2. INFORMATION TO BE PROVIDED BY THE MANUFACTURER					
2.a	Labeling	The label(s) on the device and its packaging in the accepted languages of the Member States.	please select		
2.b	Instructions for use	The instructions for use in the accepted languages of the Member States.	please select		
3. INFORMATION ON DESIGN AND MANUFACTURE					
3.1 Information on the design					
3.1.a	Critical ingredients	A description of the device's critical ingredients such as antibodies, antigens, enzymes and nucleic acid primers.	please select		
3.1.b	Essential subsystems	For instruments, a description of the main subsystems, the analysis technique and the appropriate computer hardware and software	please select		

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3.1.c	Complete system	For instruments and software, an overview of the entire system	please select		
3.1.d	Methodology for data analysis	For software, a description of the methodology for data evaluation, namely the algorithm.	please select		
3.1.e	Self-application	A description of the design aspects that make devices suitable for self-testing or near-patient testing.	please select		
3.2 Information on production					
3.2.a	Manufacturing processes	Information on the manufacturing processes such as production, assembly, testing of the end device and packaging of the finished device.	please select		
3.2.b	Production sites	Indication of all entities, including suppliers and subcontractors, where manufacturing activities are carried out.	please select		
4. BASIC SAFETY AND PERFORMANCE REQUIREMENTS					
4.a	Safety and performance requirements	The essential safety and performance requirements applicable to the device.	please select		
4.b	Proof of conformity	The method(s) used to demonstrate conformity with each applicable requirement.	please select		
4.c	Harmonized standards	The harmonized standards, GS or other solutions applied.	please select		
4.d	Controlled documents	The precise identity of the controlled documents that prove conformity.	please select		
5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT					
5.a	Risk-benefit analysis	Information on the benefit-risk analysis according to Annex I, Sections 1 and 8.	please select		
5.b	Risk management	Information on the solutions selected and the results of risk management.	please select		
6. PRODUCT VERIFICATION AND VALIDATION					

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6.1 Information on the analytical performance of the device					
6.1.1	Specimen type	Description of the different specimen types suitable for analysis, including conditions for stability.	please select		
6.1.2.1.a	Trueness of the measurement	Information on the trueness of the measurement method.	please select		
6.1.2.1.b	Precision of the measurement	Studies on repeatability and reproducibility.	please select		
6.1.2.2	Analytical sensitivity	Information on the design and results of the test sensitivity study.	please select		
6.1.2.3	Analytical specificity	Interference and cross reactivity studies to determine analytical specificity.	please select		
6.1.2.4	Metrological traceability	Metrological traceability of calibrator and control material values.	please select		
6.1.2.5	Measuring range of the assay	Information on the measuring range and detection limit of the assay.	please select		
6.1.2.6	Assay cut-off	Summary of analytical data to determine the assay cut-off.	please select		
6.1.3	Analysis performance report	The analytical performance report in accordance with Annex XIII.	please select		
6.2 Clinical performance, clinical evidence, Performance Evaluation Report					
6.2	Clinical performance	Information on clinical performance and clinical evidence, Performance Evaluation Report.	please select		
6.3 Stability (except for sample stability)					
6.3.1	Shelf-life	Information on in-use stability studies to substantiate shelf-life.	please select		
6.3.2	In-use stability	Information on studies on shelf life after opening, either real or simulated.	please select		

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6.3.3	Shipping stability	Information on shipping stability studies, either real or simulated.	please select		
6.4 Software verification and validation					
6.4	Software verification and validation	Results of the verifications and validations of the software as used in the finished device.	please select		
6.5 Additional information required in special cases					
6.5.a	Sterile devices	Description of the environmental conditions for the relevant manufacturing steps for sterile devices.	please select		
6.5.b	Tissues, cells and substances	Information on the origin and conditions of collection of tissues, cells and substances of animal, human or microbial origin.	please select		
6.5.c	Measuring function	Description of the methods used to ensure the accuracy of devices with a measuring function.	please select		
6.5.d	Connection to other equipment	Description of the connection and proof of compliance with the basic safety and performance requirements when connected to other equipment.	please select		