Checklist Annex I IVDR - General safety and performance requirements

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
CHAPTER I GENERAL REQUIREMENTS					
1.	Performance and safety	Devices perform as intended and are safe and effective under normal conditions of use.	✓		
2.	Risk reduction	Risks should be reduced as far as possible without negatively affecting the risk-benefit ratio.	please select		
3.	Risk management	Manufacturers establish a risk management system, implement it, document it and maintain it.	please select		
4.	Risk control	Risk control measures comply with the safety principles, taking into account the recognized state of the art.	please select		
5.	Use error	Risks due to use errors must be reduced as far as possible.	please select		
6.	Lifetime	The characteristics and performance of a device must not be impaired during the lifetime of the device in such a way that safety is jeopardized.	please select		
7.	Transport and storage	Products are designed, manufactured and packaged in such a way that their characteristics and performance are not impaired during transport and storage.	please select		

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8.	Risks and benefits	All known and foreseeable risks and undesirable effects must be minimized as far as possible and must be acceptable in comparison to the benefits.	✓		
CHAPTER II PERFORMANCE, DESIGN AND MANUFACTURE REQUIREMENTS					
9. Performance characteristics					
9.1.a	Analytical performance	Products are designed and manufactured to achieve the performance claimed by the manufacturer, including analytical sensitivity and specificity.	please select		
9.1.b	Clinical performance	Products are designed and manufactured to achieve clinical performance, including diagnostic sensitivity and specificity.	please select		
9.2	Lifetime performance	Performance features of the device are retained during its lifetime.	please select		
9.3	Calibrators and control materials	Metrological traceability of the values of calibrators and control materials is guaranteed.	please select		
9.4	Special tests	The characteristics and performance of the device are subject to special testing if they could be impaired if used in accordance with the intended use.	please select		
10. Chemical, physical and biological properties					
10.1	Characteristics and performance	Characteristics and performance requirements from chapter I are	please select		

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	requirements, incompatibilities	fulfilled. Possible impairment of analytical performance due to physical and/or chemical incompatibilities must be taken into account.	✓		
10.2	Contaminants and residues	Risks from contaminants and residues must be kept as low as possible.	please select		
10.3	Release of substances	Risks from released substances or particles must be reduced as far as possible.	please select		
10.4	Ingress of substances	Risks due to the unintentional ingress of substances must be reduced as far as possible.	please select		
11. Infection and microbial contamination					
11.1	Risk of infection	Devices and manufacturing processes are designed to eliminate or minimize the risk of infection.	please select		
11.2	Sterility	Devices labeled as sterile retain their sterility under the intended transport and storage conditions.	please select		
11.3	Sterilization process	Devices marked as sterile are sterilized using suitable validated procedures.	please select		
11.4	Manufacturing conditions	Devices that are to be sterilized are manufactured and packaged under controlled conditions.	please select		
11.5	Packaging systems	Packaging systems for non-sterile products maintain the integrity and purity of the product, for sterile products they	please select		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
		minimize the risk of microbial contamination and are suitable for the selected sterilization process			
11.6	Labeling	Labeling allows differentiation between sterile and non-sterile products.	please select		
12. Devices incorporating materials of biological origin					
12.	Materials of biological origin	The selection, processing and treatment of materials of biological origin provide safety.	please select		
13. Construction of devices and interaction with their environment					
13.1	Combination with other devices	Combinations with other products or equipment are safe and do not affect performance.	please select		
13.2.a	Physical features	Risks in connection with physical features must be reduced.	please select		
13.2.b	External influences	Risks due to external influences or environmental conditions must be reduced.	please select		
13.2.c	Contact with materials	Risks from contact with materials, liquids and substances, including gases, must be reduced.	please select		
13.2.d	Software interaction	Risks due to negative interactions between software and the IT environment must be reduced.	please select		
13.2.e	Ingress of substances	Risks due to unintentional ingress of substances into the device must be reduced.	please select		
13.2.f	Specimen identification	Risks of incorrect sample identification must be reduced.	please select		

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13.2.g	Interference	Risks from foreseeable interference with other devices must be reduced.	✓		
13.3	Risk of fire or explosion	The risk of fire or explosion must be reduced.	✓		
13.4	Maintenance	Devices are designed so that adjustment, calibration and maintenance can be carried out safely and effectively.	✓		
13.5	Compatibility	Devices are designed to ensure reliable and safe interaction and compatibility.	✓		
13.6	Disposal	Devices are designed in such a way that safe disposal, also of related waste substances, is possible.	✓		
13.7	Display devices	Display devices are ergonomically designed.	✓		
14. Devices with measuring function					
14.1	Measuring function	Devices with measuring function ensure appropriate analytical performance according to Annex I section 9.1 a.	✓		
14.2	Legal units	Measurements are expressed in legal units in accordance with Directive 80/181/EEC.	✓		
15. Protection against radiation					
15.1	Exposure	Exposure to radiation must be reduced.	✓		
15.2.a	Radiation control	The characteristics and quantity of the radiation emitted can be controlled.	✓		

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15.2.b	Radiation display	Devices are equipped with displays and/or audible warnings of radiation emissions.	✓		
15.3	Radiation protection	Operating instructions contain information on radiation protection.	✓		
16. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves					
16.1	Programmable electronic systems	Products with programmable electronics systems ensure repeatability, reliability and performance.	✓		
16.2	Software development	Software is developed and produced according to the state of the art.	✓		
16.3	Mobile platforms	Design and manufacture take into account specific characteristics of mobile platforms.	✓		
16.4	IT security measures	Manufacturers define minimum requirements for IT security measures.	✓		
17. Devices connected or equipped with an energy source					
17.1	Energy source	Precautions must be taken in the event of a fault.	✓		
17.2	Internal energy source	Devices with an internal energy source on which patient safety depends are equipped with a warning device or critical charge level indicator.	✓		
17.3	Electromagnetic interference	The risk of electromagnetic interference must be reduced.	✓		
17.4	Immunity to interference	Devices have an adequate intrinsic immunity to electromagnetic interference.	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
17.5	Electric shocks	The risk of unintentional electric shocks must be reduced.	✓		
18. Protection against mechanical and thermal risks					
18.1	Mechanical risks	Users are protected against mechanical risks.	✓		
18.2	Stability	Products are stable under operating conditions.	✓		
18.3	Protective measures	Protective measures against risks from moving parts are provided.	✓		
18.4	Vibrations	Risks from vibrations must be reduced.	✓		
18.5	Noise	Risks from noise must be reduced.	✓		
18.6	Terminals and connectors	Connections to energy sources are safely designed.	✓		
18.7	Assembly error	Errors during fitting or refitting must be prevented by design and construction or by information.	✓		
18.8	Temperature	Accessible parts must not reach dangerous temperatures.	✓		
19. Protection against the risks posed by devices intended for self-testing or near-patient testing					
19.1	Self-testing	Devices for self-testing are designed to fulfill their intended purpose, taking into account the skills of the intended users.	✓		
19.2.a	Safe use	Devices for personal use must be used safely and correctly.	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
19.2.b	Incorrect handling	The risk of incorrect handling and incorrect interpretation of the results must be reduced.	✓		
19.3.a	Function check	Devices for self-application are provided with a function control procedure.	✓		
19.3.b	Warning for invalid result	Devices for self-application warn if the result is invalid.	✓		
CHAPTER III REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE					
20. Requirements for the information supplied with the device					
20.1 General requirements regarding the information supplied by the manufacturer					
20.1.a	Content and format	The medium, format, content, legibility and location of labeling and instructions for use are suitable for the device, its intended purpose and the intended users.	✓		
20.1.b	Labeling	The required information on the label shall be affixed to the device itself or, if not practicable, to the packaging of each unit.	✓		
20.1.c	Readability	Labels in human-readable form can be supplemented by machine-readable information.	✓		
20.1.d	Instructions for use	Instructions for use are provided with the device.	✓		
20.1.e	Multiple devices	Instructions for use can be included for multiple devices.	✓		
20.1.f	Professional use	Instructions for use can be provided electronically.	✓		
20.1.g	Residual risks	Residual risks are included in the supplied information as	✓		

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		restrictions, contraindications, precautions or warnings.	✓		
20.1.h	Symbols	Information can be provided in the form of symbols.	✓		
20.1.i	Hazard pictograms	Hazard pictograms and labeling requirements according to Regulation (EC) No. 1272/2008 are applied.	✓		
20.1.j	Safety data sheet	The provisions of Regulation (EC) No. 1907/2006 on the safety data sheet apply.	✓		
20.2 Information on the label					
20.2.a	Device name	Name or trade name of the device.	✓		
20.2.b	Intended use	Information on the intended use of the device.	✓		
20.2.c	Manufacturer information	Name and address of the manufacturer.	✓		
20.2.d	Authorized representative	Name and address of the authorized representative.	✓		
20.2.e	In vitro diagnostic	Indication that the device is an in-vitro diagnostic, if applicable, reference to "device for performance study".	✓		
20.2.f	Lot number	Lot number or serial number of the product.	✓		
20.2.g	UDI carrier	UDI carriers in accordance with Article 24 and Annex VI, Part C.	✓		
20.2.h	Expiry date	Clear indication of the time limit for using the device safely.	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
20.2.i	Date of manufacture	Date of manufacture if no expiry date is specified.	✓		
20.2.j	Net content quantity	Indication of the net content quantity.	✓		
20.2.k	Storage conditions	Reference to special storage and/or handling conditions.	✓		
20.2.l	Sterile condition	Indication of the sterile state of the product.	✓		
20.2.m	Warnings	Warnings or precautions.	✓		
20.2.n	Instructions for use	Reference to the accessibility of the instructions for use.	✓		
20.2.o	Particular instructions	Particular operating instructions.	✓		
20.2.p	Single use	Reference to single use.	✓		
20.2.q	Self-testing	Note on self-testing or near-patient testing.	✓		
20.2.r	Exclusion of rapid tests	Reference to the exclusion of rapid tests for self-testing or near-patient testing.	✓		
20.2.s	Device kits	Labeling requirements for device kits.	✓		
20.2.t	Identifiability	Devices and their separate components are identifiable.	✓		
20.2.u	Self-testing	Information on the labeling of devices for self-testing: type of	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
		specimen(s), additional materials, contact details.	✓		
20.3 Information on the packaging which maintains the sterile condition of a device ('sterile packaging')					
20.3.a	Sterile packaging	Marking of the sterile packaging.	✓		
20.3.b	Sterile condition	Indication of sterile condition.	✓		
20.3.c	Sterilization method	Indication of the sterilization medhod.	✓		
20.3.d	Manufacturer information	Name and address of the manufacturer.	✓		
20.3.e	Device description	Description of the device.	✓		
20.3.f	Date of manufacture	Month and year of manufacture.	✓		
20.3.g	Expiry date	Clear indication of the time limit for using the device safely.	✓		
20.3.h	Instructions for use	Note on checking the instructions for use if the sterile packaging is damaged.	✓		
20.4 Information in the instructions for use					
20.4.1 The instructions for use shall contain all of the following information:					
20.4.1.a	Device name	Name or trade name of the device.	✓		
20.4.1.b	Device description	Information for clear identification of the device.	✓		
20.4.1.c	Intended use	Intended use of the device: - what is detected - function	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
		- specific information - automatic or not - qualitative, semi-quantitative or quantitative - type of specimen(s) - target population to be tested - for companion diagnostics, the international non-proprietary name of the corresponding medicinal product			
20.4.1.d	In vitro diagnostic	Indication that it is an in-vitro diagnostic medical device, if applicable, indication "device for performance study".	✓		
20.4.1.e	Users	Specification of the intended user.	✓		
20.4.1.f	Test principle	Test principle of the device.	✓		
20.4.1.g	Calibrators and controls	Description of calibrators and controls.	✓		
20.4.1.h	Reagents	Description of the reagents and their composition.	✓		
20.4.1.i	Materials provided	List of materials provided and needed but not provided.	✓		
20.4.1.j	Combination with other devices	Information on combination with other devices and equipment.	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
20.4.1.k	Storage conditions	Reference to special storage and/or handling conditions.	✓		
20.4.1.l	In-use stability	In-use stability and storage conditions.	✓		
20.4.1.m	Sterile condition	Indication of the sterile condition and the sterilization methods.	✓		
20.4.1.n	Warnings	Notes on warnings, precautions and measures.	✓		
20.4.1.o	Infectious material	Warnings in connection with potentially infectious material included in the device.	✓		
20.4.1.p	Special facilities	Information on any special facilities required, e.g. clean room, training, qualifications.	✓		
20.4.1.q	Specimen	Conditions for the collection, treatment and preparation of the specimen.	✓		
20.4.1.r	Pre-treatment	Explanation of any necessary preparatory treatment or handling.	✓		
20.4.1.s	Installation	Information on the correct installation of the device.	✓		
20.4.1.t	Quality control procedures	Recommendations on quality control procedures.	✓		
20.4.1.u	Metrological traceability	Metrological traceability of calibrators and control materials.	✓		
20.4.1.v	Assay procedure	Assay procedures, including calculations and evaluation of results.	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
20.4.1.w	Analytical performance	Characteristics of analytical performance, such as analytical sensitivity and specificity, trueness, precision, accuracy, detection limits, measurement range, linearity, reference measurement methods and materials.	✓		
20.4.1.x	Clinical performance	Characteristics of clinical performance according to Annex I Section 9.1.	✓		
20.4.1.y	Mathematical approach	Mathematical approach for calculating the analytical results.	✓		
20.4.1.z	Clinical performance characteristics	Characteristics of clinical performance such as threshold value, diagnostic sensitivity and specificity, positive and negative predictive value.	✓		
20.4.1.aa	Reference intervals	Reference intervals for unaffected and affected population groups.	✓		
20.4.1.ab	Interfering substances	Information on interfering substances or limitations.	✓		
20.4.1.ac	Safe disposal	Warnings for safe disposal of the device, its accessories and consumables.	✓		
20.4.1.ad	Manufacturer information	Name, address and contact details of the manufacturer.	✓		
20.4.1.ae	Instructions for use	Date of issue of the instructions for use.	✓		
20.4.1.af	Reporting incidents	Note on reporting serious incidents.	✓		

Section	Keyword	Short description	✓= applicable X = not applicable	Comment	Reference
20.4.1.ag	Device kits	Individually available reagents or articles in device kits must comply with the requirements of section 20.4.1 and the IVDR.	✓		
20.4.1.ah	Programmable electronic systems	Minimum requirements regarding hardware and IT security measures.	✓		
20.4.2 In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:					
20.4.2.a	Test procedure	Detailed description of the test procedure.	✓		
20.4.2.b	Specific particulars	Specific particulars are not required if other information is sufficient.	✓		
20.4.2.c	Intended purpose	Intended purpose includes sufficient information to enable the user to interpret the results.	✓		
20.4.2.d	Results	Results are clearly expressed and presented.	✓		
20.4.2.e	Action	Notes and instructions for the user on action to be taken, limitations and influences on the result.	✓		
20.4.2.f	Consultation of a specialist	A clear indication to the user that no medically important decision should be made without prior consultation with a qualified healthcare professional.	✓		
20.4.2.g	Adaptation of the treatment	Advice that if the patient is using a device for self-treatment to control a previously diagnosed pre-existing disease or condition, the patient should only adjust the treatment if he	✓		

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		has received the necessary training.			