						Technical Documentation	applicable	Evidence
						The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.		
1.						DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES		
	1.1.					Device description and specification		
		a.				product or trade name and a general description of the device including its intended purpose and intended users;		
		b.				the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;		
		c.				the intended purpose of the device which may include information on:		
				i.		what is to be detected and/or measured;		
				ii.		its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;		
				iii.		the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;		
				iv.		whether it is automated or not;		
				v.		whether it is qualitative, semi-quantitative or quantitative;		
				vi.		the type of specimen(s) required;		
				vii.		where applicable, the testing population;		
				viii.		the intended user;		
				ix.		in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s).		
		d.				the description of the principle of the assay method or the principles of operation of the instrument;		
		e.				the rationale for the qualification of the product as a device;		
		f.				the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;		
		g.				the description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers;		
						and where applicable:		
		h.				the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;		
		i.				for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;		
		j.				for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;		
		k.				a description of any software to be used with the device;		
		l.				a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;		
		m.				a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.		
	1.2.					Reference to previous and similar generations of the device		
		a.				an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;		
		b.				an overview of identified similar devices available on the Union or international markets, where such devices exist.		
2.						INFORMATION TO BE SUPPLIED BY THE MANUFACTURER A complete set of:		
		a.				the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;		
		b.				the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.		
						DESIGN AND MANUFACTURING INFORMATION		

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3.	3.1.			Information to allow the design stages applied to the device to be understood shall include:		
		a.		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;		
		b.		for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;		
		c.		for instruments and software, an overview of the entire system;		
		d.		for software, a description of the data interpretation methodology, namely the algorithm;		
		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.		
	3.2.			Manufacturing information		
		a.		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;		
		b.		identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.		
4.	GENERAL SAFETY AND PERFORMANCE REQUIREMENTS					
	The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall also include:					
	a.			the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;		
	b.			the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;		
	c.			the harmonised standards, CS or other solutions applied;		
	d.			the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.		
5.	BENFIT-RISK ANALYSIS AND RISK MANAGEMENT					
	The documentation shall contain information on:					
	a.			the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and		
	b.			the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.		
	PRODUCT VERIFICATION AND VALIDATION					
	The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements. This includes:					
				Information on analytical performance of the device		
		6.1.1.		Specimen type This Section shall describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such as duration, temperature limits and freeze/thaw cycles.		
				Analytical performance characteristics		
		6.1.2.1		Accuracy of measurement		
			a.	Trueness of measurement This Section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow an assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a certified reference material or certified reference method is available.		
			b.	Precision of measurement This Section shall describe repeatability and reproducibility studies.		

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6.	6.1.	6.1.2.	6.1.2.2.		Analytical sensitivity This Section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.		
			6.1.2.3.		This Section shall describe interference and cross reactivity studies performed to determine the analytical specificity in the presence of other substances/agents in the specimen. Information shall be provided on the evaluation of potentially interfering and cross-reacting substances or agents on the assay, on the tested substance or agent type and its concentration, specimen type, analyte test concentration, and results. Interferents and cross-reacting substances or agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:		
				a.	substances used for patient treatment such as medicinal products;		
				b.	substances ingested by the patient such as alcohol, foods;		
				c.	substances added during specimen preparation such as preservatives, stabilisers;		
				d.	substances encountered in specific specimen types such as haemoglobin, lipids, bilirubin, proteins;		
				e.	analytes of similar structure such as precursors, metabolites or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that can mimic the test condition.		
			6.1.2.4.		Metrological traceability of calibrator and control material values		
			6.1.2.5.		Measuring range of the assay This Section shall include information on the measuring range regardless of whether the measuring systems are linear or non-linear, including the limit of detection and describe information on how the range and detection limit were established. This information shall include a description of specimen type, number of specimens, number of replicates, and specimen preparation including information on the matrix, analyte levels and how levels were established. If applicable, a description of any high dose hook effect and the data supporting the mitigation such as dilution steps shall be added.		
			6.1.2.6.		Definition of assay cut-off This Section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, such as:		
				a.	the population(s) studied: demographics, selection, inclusion and exclusion criteria, number of individuals included;		
				b.	method or mode of characterisation of specimens; and		
				c.	statistical methods such as Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.		
		6.1.3.			The analytical performance report referred to in Annex XIII.		
	6.2.				Information on clinical performance and clinical evidence. Performance Evaluation Report The documentation shall contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, as referred to in Annex XIII, together with an assessment of those reports. The clinical performance study documents referred to in Section 2 of Part A of Annex XIII shall be included and/or fully referenced in the technical documentation.		
					Stability (excluding specimen stability) This Section shall describe claimed shelf life, in use stability and shipping stability studies.		
			6.3.1.		This Section shall provide information on stability testing studies to support the shelf life that is claimed for the device. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions. The three lots do not need to be consecutive. Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claims but shall be followed up with real time stability studies. Such detailed information shall include:		
				a.	the study report including the protocol, number of lots, acceptance criteria and testing intervals;		
				b.	where accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies shall be described;		

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	6.3.		c.	the conclusions and claimed shelf life.		
		6.3.2.		In-use stability This Section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device, regardless of whether real or simulated. This may include open vial stability and/or, for automated instruments, on board stability. In the case of automated instrumentation, if calibration stability is claimed, supporting data shall be included. Such detailed information shall include:		
			a.	the study report (including the protocol, acceptance criteria and testing intervals);		
			b.	the conclusions and claimed in-use stability.		
		6.3.3.		Shipping stability This Section shall provide information on shipping stability studies for one lot of devices to evaluate the tolerance of devices to the anticipated shipping conditions. Shipping studies may be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold. Such information shall describe:		
			a.	the study report (including the protocol, acceptance criteria);		
			b.	the method used for simulated conditions;		
			c.	the conclusion and recommended shipping conditions.		
	6.4.			Software verification and validation The documentation shall contain evidence of the validation of the software, as it is used in the finished device. Such information shall typically include the summary results of all verification, validation and testing performed in-house and applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.		
	6.5.			Additional information required in specific cases		
		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. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with regard to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.		
		b.		In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected.		
		c.		In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.		
		d.		If the device is to be connected to other equipment in order to operate as intended, a 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.		

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