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6.0 Device Description including Variants (Configurations) and Accessories					
6.1	**Device Description** **The STED should include the following device descriptive information:**				
a	the intended use of the IVD medical device. This may include:	A	F1 F2 F5	Description of Device Promotional Leaflets Instructions for Use User Manual	
	1. what is detected 2. its function (e.g. screening, monitoring, diagnosis or aid to diagnosis); 3. he specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; 4. whether it is automated or not; 5. whether it is qualitative or quantitative; 6. the type of specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine); 7. testing population;				
b	the intended user (lay person or professional);	A	F5	Instructions for Use User Manual	

c	a general description of the principle of the assay method or instrument principles of operation;	A	Y1	Design Input Device History	
d	the Class of the device and the applicable classification rule according to *Principles of In Vitro Diagnostic Medical Devices Classification*[1]*;*	A	D1	Classification rationale	
e	a description of the components (e.g. reagents, assay controls and calibrators) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers)	N/A			
and where applicable:					
f	a description of the specimen collection and transport materials provided with the IVD medical device or descriptions of specifications recommended for use;	N/A			
g	for instruments of automated assays: a description of the appropriate assay characteristics or dedicated assays;	N/A			

1 SG1/N045:2007 *Principles of In Vitro Diagnostic Medical Devices Classification*

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h	for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;	N/A			
i	a description of any software to be used with the IVD medical device;	A	Y19	Software	
j	a description or complete list of the various configuration/variants of the IVD medical device that will be made availablet	A	F1 F3	Description of Device Data Sheets	
k	a description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device.	A	F4	Description of Accessories	
6.2	**Reference to the Manufacturer's Previous Device Generation(s) and/or Similar Devices or Device History**	A	Y1 F3	Design Input Device History Data Sheets	
	For an IVD medical device not yet available on any market				
	Where relevant to demonstrating conformity to the Essential Principles, and to provide general background information, the STED may provide a summary of:				
a	the manufacturer's previous generation(s) of	A	CE		

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	the IVD medical device, if such exists; and/or		Technical File		
b	the manufacturer's similar IVD medical devices available on the market.	A	F7	Competitors Information and Patients	
	For an IVD medical device already available on the market in any jurisdiction				
	This information may include a summary of the number of adverse event reports related to the safety and performance of this IVD medical device in relation to the number of IVD medical devices placed on the market.	A	H1	Analysis of complaints Post Market Surveillance	
	External certificates and documents which give written evidence of conformity with the Essential Principles may be annexed to the STED.				
7	**Essential Principles (EP) Checklist**				
	The STED should include an EP checklist that identifies:				
a	the Essential Principles;				
b	for each Essential Principle whether it applies to the IVD medical device and if not, why not;				
c	the method used to demonstrate conformity	A	B1	EC Declaration of Conformance	

	with each Essential Principle that applies; and				
d	the reference to the actual technical documentation that offers evidence of conformity with each method used.	A	Z7	Project Progress QC25	
	The method used to demonstrate conformity may include one or more of the following:				
a	conformity with recognized or other standards[2];	A	C2	EN Standards	
b	conformity with a commonly accepted industry test method;				
c	conformity with appropriate in-house test methods that have been validated and verified;	A	Z1	Full inspection and test	
d	comparison to an IVD medical device already available on the market.	A	Z7	Compatibility Trials	
	The EP checklist should include a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the STED (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance). A sample checklist is included in Appendix A.				

2 GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*

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8	**Risk Analysis and Control Summary**				
	The STED should contain a summary of the risks identified during the risk analysis process and a description of how these risks have been controlled to an acceptable level. Preferably, this risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan.	A	E3	Risk analysis reports	
	The summary should address possible hazards for the IVD medical device such as the risk from false positive or false negative results, indirect risks which may result from IVD medical device-associated hazards, such as instability, which could lead to erroneous results, or from user-related hazards, such as reagents containing infectious agents.	A	E4 E5	EN ISO 14971:2001 Annex A EN ISO 14971:2001 Annex D	
	The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. Typically for a Class D IVD medical device a detailed report would be provided.	A	E8 E11	Risk management review Residual Risks	

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9	**Design and Manufacturing Information**				
9.1	**Device Design**				
	The STED should contain information to allow a reviewer to obtain a general understanding of the design applied to the IVD medical device.	A	Y11 Y11.1	Preliminary drawings and images Preliminary Emails and Communications	
	It should include a description of the critical ingredients of an assay such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the IVD medical device.				
	For instruments this would include a description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software.	A	Y16	Design Reviews QC24	
	For standalone software, this would typically include a description of the data interpretation methodology (i.e. algorithms).	N/A			
	For self-testing devices the design should include a description of the design aspects	N/A			

	that make it suitable for lay person use.				
	This section is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. If design takes place at multiple sites, a controlling site must be identified.				
9.2	**Manufacturing Processes**				
	Only for Class D, the STED should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. It is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. This information may take the form of a process flow chart showing, for example, an overview of production including the technologies used, assembly and packaging of the finished IVD medical device. This section should include details of any in-process and final product testing (e.g. the manufacturer's QC release program).	N/A			
9.3	**Manufacturing Sites**				
	For the activities in 9.2, the STED should	A	B5.2	OES (OEM) CE Certificate	

	identify the sites where these activities are performed (this does not include the sites of all suppliers of raw materials but only the sites that are involved in critical manufacturing activities). If QMS certificates, or the equivalent, exist for these sites, they may be annexed to the STED.				
10	**Product Verification and Validation**				
	The information provided in the product verification and validation section of the STED will vary in the level of detail as determined by the classification of the device.				
	Also other characteristics as outlined in section 5.1 will influence the level of detail of the STED.				
	As a general rule, the STED should summarise the results of verification and validation studies undertaken to demonstrate conformity of the IVD medical device with the Essential Principles that apply to it. Where appropriate, such information might come from the literature.	A A A	Z7 H7 Y15	Compatibility Trials Competitors Information and Patients Validation	

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	For the purpose of the STED document, 'summary' and 'detailed information' are defined as:				
	1. Summary Information				
	A summary should provide enough information to allow the RA/CAB to assess the validity of that information. This summary should contain a brief description of:				
a	the study protocol,				
b	the study results,				
c	the study conclusion.				
	This summary may include:				
a	Where a recognized standard exists, a declaration/certificate of conformity to a recognized standard can be provided with a summary of the data if no acceptance criteria are specified in the standard;	A A	C2 B1	EN Standards EC Declaration of Conformance	
b	In the absence of a recognized standard, a declaration/certificate of conformity to a				

	published standard that has not been recognized might be provided if it is supported by a rationale for its use, and summary of the data, and a conclusion, if no acceptance criteria are specified in the standard;				
c	In the absence of a recognized standard and non-recognized published standards, a professional guideline, industry method, or in-house standard may be referred to in the summarized information. However, it should be supported by a rationale for its use, a description of the method used, a summary of the data in sufficient detail and a conclusion to allow assessment of its adequacy;				
d	A review of relevant published literature regarding the device/analyte (measurand) or substantially similar IVD medical devices.				
	2. **Detailed information should include:**				
a	the complete study protocol,				
b	the method of data analysis,				
c	he complete study report,				
d	the study conclusion				

	For detailed information, when a recognized standard exists that contains the protocol and the method of data analysis, this information can be substituted by a declaration/certificate of conformity to the recognized standard. However, a summary of the data and conclusions should be provided.				
	For clinical performance (which is part of the clinical evidence), the detailed information will typically include individual data points (formatted raw data) for a Class D IVD medical device.				
	Where appropriate, actual test result summaries with their acceptance criteria should be provided and not just pass/fail statements.				
10.1	**Analytical Performance**				
	The statements and descriptions in the following sections refer to all IVD medical devices. It must be noted however that there are applicability differences between instrumentation and reagent-based assays, and that the assays themselves may be quantitative, semi-quantitative or qualitative in nature.				

	There may be limited applicability of some of the following subsections for qualitative or semi-quantitative assays. Where possible, comments regarding instrumentation or qualitative assays appear in the subsections.				
	Specimen type				
	This section should describe the different specimen types that can be used. This should include their stability and storage conditions and is typically applicable to all systems and assay types.				
	Stability includes storage and where applicable transport conditions. Storage includes elements such as duration, temperature limits and freeze/thaw cycles.	A			
	This section should include summary information for each matrix and anticoagulant when applicable, including a description of the measurement procedure for comparison or determination of measurement accuracy. This includes information such as specimen type tested, number of samples, sample range (using spiked samples as appropriate) or target concentrations tested, calculations and statistical methods, results and conclusions.	N/A			

	Typically for a Class D IVD medical device, detailed information would be provided.				
	Analytical performance characteristics				
10.1.2.1	**Accuracy of measurement**				
	This section should describe both trueness and precision studies.				
	Note: The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness.				
	While measurement **trueness**, affected by systematic error, is normally expressed in terms of bias, measurement **precision**, affected by random error, is naturally expressed in terms of standard deviation.				
	Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.				

10.1.2.1, 1	**Trueness of measurement**				
	This section should provide information on the trueness of the measurement procedure and summarize the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. Typically for Class C and D IVD medical devices, detailed information would be provided.				
•	**Precision of measurement**			•	
	This section should describe repeatability and reproducibility studies.				
10.1.2.1. 2.1	Repeatability				
	This section should include repeatability estimates and information about the studies used to estimate, as appropriate, within-run variability. Repeatability data is obtained for instrumentation in conjunction with an appropriate assay. Typically for Class C and D IVD medical devices, detailed information would be provided. <u>Note 1:</u> Such studies should include the use of samples that represent the full range of expected analyte (measurand) concentrations that can be measured by the test as claimed by the manufacturer. <u>Note 2:</u> If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions should be provided.				
	Reproducibility				

	This section should include reproducibility estimates and information about the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators and instruments. Such variability is also known as **"Intermediate Precision".** Reproducibility data is obtained for instrumentation in conjunction with an appropriate assay. Typically for Class C and D IVD medical devices, detailed information would be provided. Note 1: Such studies should include the use of samples that represent the full range of expected analyte (measurand) that can be measured by the test as claimed by the manufacturer. Note 2: If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions should be provided.				
10.1.2.2	**Analytical sensitivity**				
	This section should include information about the study design and results. It should provide a description of specimen type and preparation including matrix, analyte (measurand) levels, and how levels were established. The number of replicates tested at each concentration should also be provided as well as a description of the calculation used to determine assay sensitivity. For example:				
a	Number of standard deviations above the mean value of the sample without analyte (measurand), commonly referred to as 'limit of blank' (LoB).				
b	Lowest concentration distinguishable from zero, based on measurements of samples containing analyte (measurand), commonly referred to as 'limit of detection' (LoD).				

c	Lowest concentration at which precision and/or trueness are within specified criteria, commonly referred to as ‘limit of quantitation’ (LoQ).				
	Typically for a Class C and D IVD medical devices, detailed information would be provided.				
10.1.2.1	**Analytical specificity**				
	This section should describe interference and cross reactivity studies to determine the analytical specificity, defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the sample. Provide information on the evaluation of potentially interfering and cross reacting substances/agents on the assay. Information should be provided on the substance/agent type and concentration tested, sample type, analyte (measurand) test concentration, and results. Interferents and cross reacting substances/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 (e.g. therapeutic drugs, anticoagulants, etc.);				
b	substances ingested by the patient (e.g. over the counter medications, alcohol, vitamins,				

	foods, etc.);				
c	substances added during sample preparation (e.g. preservatives, stabilizers);				
d	substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);				
e	analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition (e.g. for a hepatitis A assay: test specimens negative for hepatitis A virus, but positive for hepatitis B virus).				
	Typically, interference studies involve adding the potential interferent to the sample and determining any bias of the test parameter relative to the control sample to which no interferent has been added. Typically for Class C and D IVD medical devices, detailed information would be provided.				
10.1.2.2	**Metrological traceability of calibrator and control material values**				
	Where applicable, summarize the information about metrological traceability of values assigned to calibrators and trueness control materials. Include, for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation.				

	Precision control materials, used when establishing the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method. Typically for a Class D IVD medical device, detailed information would be provided.				
10.1.2.2	**10.1.2.1 Measuring range of the assay**				
	This section should include a summary of studies which define the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This summary should include a description of specimen type, number of samples, number of replicates, and preparation including information on matrix, analyte (measurand) levels and how levels were established. If applicable, add a description of high dose hook effect and the data supporting the mitigation (e.g. dilution) steps. Typically for Class C and D IVD medical devices, detailed information would be provided.				
10.1.2.3	**Definition of assay cut-off**				
	This section should provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:				
a	the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included);				
b	method or mode of characterization of specimens; and				
c	statistical methods e.g. Receiver Operator				

	Characteristic (ROC) to generate results and if applicable, define gray-zone/equivocal zone.				
	Typically for Class C and D IVD medical devices, detailed information would be provided.				
10.2	**Clinical Performance**				
	Where relevant, the STED should contain data on the clinical performance of the IVD medical device.				
	This clinical performance data is one of the elements of clinical evidence that demonstrates the conformity of the IVD medical device to the Essential Principles that apply to it.-				
	Note : Analytical performance and clinical performance are elements of clinical evidence. More detailed recommendations regarding these elements of the STED will be provided in guidance developed in cooperation with SG5.				
10.3	**Stability (excluding specimen stability)**				

	This section should describe claimed shelf life, in use stability and shipping studies.				
	Claimed shelf life				
	This section should provide information on stability testing studies to support the claimed shelf life. Testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Typically for Class C and D IVD medical devices, detailed information would be provided. Such detailed information should describe:				
a	the study report (including the protocol, number of lots, acceptance criteria and testing intervals);				
b	when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;				
c	conclusions and claimed shelf life.	A	G4 G7	Product Life Expected Life of Products	
	Note: Shelf life can be derived from the lot with the longest real time stability data as long as accelerated or extrapolated data from all three lots are comparable.				
	In use stability				

	This section should provide information on in use stability studies for one lot reflecting actual routine use of the device (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 should be included. Such detailed information should describe:				
a	the study report (including the protocol, acceptance criteria and testing intervals);				
b	conclusions and claimed in use stability.				
	Typically for Class C and D IVD medical devices, detailed information would be provided.				
	Shipping stability				
	This section should provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done under real and/or simulated conditions and should include variable shipping conditions such as extreme heat and/or cold. Such information should describe:				
a	the study report (including the protocol, acceptance criteria);	A	M1 M2	Packaging Trials and validation Photographs of Packaging	
b	method used for simulated conditions;				

c	conclusion and recommended shipping conditions.				
	Typically for a Class C and D IVD medical device, detailed information would be provided.				
10.4	**Software Verification and Validation**				
	The STED should contain evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. Typically for a Class D IVD medical device, detailed information would be provided.	A	Y19	Software	
11	**Labelling**				
	The STED should typically contain a complete set of labelling associated with the IVD medical device as described in GHTF guideline *Labelling for Medical Devices*[3]. Information on labelling should include the following:				

3 GHTF/SG1/N43:2005 *Labelling for Medical Devices*

a	Labels on the IVD medical device (immediate and outer container)	A	F7	Labels	
b	Instructions for use	A	F5	Instructions for Use User Manual	
	Where the STED is submitted to a RA/CAB, the labelling set should be in a language required by the reviewing jurisdiction. For inclusion in a STED, the labelling should contain the final content as determined by the manufacturer but does not have to be in the final (printed) format.				
	Format of the STED				
	While this guidance document makes no specific recommendation for the format of the STED, it would be helpful to both manufacturers and reviewers if the STED was organized such that it incorporates the same sections as described in this guidance document e.g. Device Description, Reference to Previous Device Generation(s) and/or Similar Devices or Device History, Essential Principles Checklist, etc.				
13	**Declaration of Conformity**				
	The Declaration of Conformity is not part of the STED. However, it may be annexed to the STED once the conformity assessment process has been completed. The content of the Declaration of Conformity is described in GHTF/SG1/N46:2007 *Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices*.	A	B1	EC Declaration of Conformance	

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Table 1: