

Document number: SG 1/N011 & Title: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices

Comment Number	Affiliation (e.g. FDA)	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	SG Decision (reviewed 16 May, 2007)
1	Association of British Healthcare Industries (ABHI)	Throughout the document	Ed/Te	<p>The terms “included” and “contain” need to be used consistently so that it is clear where a document is recommended to be physically included, and where it is sufficient to include its reference/location only.</p> <p>If this comment is accepted, the use of these words needs to be reviewed throughout, with a view to minimizing document duplication between QMS and STED sets.</p>	<p>Add definitions or explanations to section 4.0 as follows, maybe as a Note:</p> <p><i>“Included or contained: where a document should be <u>included</u> or <u>contained</u> in the STED, it must be present in (for real, or physical set of STED documents) or readily visible (in the case of an electronic set).</i></p> <p>“Otherwise it may be adequate to cite a reference to the document’s identity and, if necessary, its location.”</p> <p>(This is similar to the use for the EP Checklist on page 5, para. 3. The EP Checklist can capture much of the required documentation.)</p>	Text modified to clarify requirement and document checked for consistency.
2	ABHI	Throughout the document	Ed/Te	<p>Throughout the document, it is not clear what is meant by a “summary” and what are “details” needed.</p> <p>Failure to get this right could result in unwieldy STEDS containing large amounts of detail and duplicated documents (with the problem of keeping these up-to-date in a continual improvement situation) which alternatively could</p>	<ol style="list-style-type: none"> 1. Provide clarification of what level of documentation is needed in a Summary (eg reference to reports, or overview.). 2. Provide clarification of what level of documentation is needed when details are referred to. 2. Only use “details” where absolutely necessary. 	<p>Text has been added in Section 5.0 to cover this point. .</p> <p>Section 9 focuses on processes/materials where summary</p>

				<p>have been provided on request if the RA/NB needed to examine it. All this information would be available anyhow during on-site inspections.</p> <p>In several places I have suggested that “details” be replaced by “summary”.</p>		information is likely to be insufficient.
3	Swissmedic	General	Ed	Revise page numbers as follows:	“Page X of <u>26</u> ”	Incorporated
4	MEDEC	All	Ed		Change date at bottom of each page to agree with front page	Incorporated
5	JFMDA	General e.g. clause 6.1 Device Description	Ed.	<p>Any paragraph or division should be identified by “a), b), ...” or “1), 2), ...” but not by “• ” or “—”.</p> <p>Rationale: Every part of the document have possibilities to be referred from other document.</p>	<p>e.g. 6.1 Device Description The STED should include the following device descriptive information: a) a general description of the device including its intended use/purpose; b) the intended patient population and medical condition to be diagnosed and/or treated by the device and other considerations such as patient selection criteria; c) the principles of operation of the device; and so on.</p>	Accepted
6	German Designating Authority	General		<p>From my point of view, it would be better to define first the general requirements for records / documentation to be established by the manufacturer. Please compare ISO 13485 : 2003 section 4.2.1, especially the last clause of the following citation:</p> <p>4.2 Documentation requirements</p>		<p>Not agreed.</p> <p>The purpose of the STED is described in the Rationale. Each STED is <u>product specific</u>.</p>

			<p>4.2.1 General</p> <p>The quality management system documentation shall include</p> <ul style="list-style-type: none">a) documented statements of a quality policy and quality objectives,b) a quality manual,c) documented procedures required by this International Standard,d) documents needed by the organization to ensure the effective planning, operation and control of its processes,e) records required by this International Standard (see 4.2.4), andf) any other documentation specified by national or regional regulations. <p>Where this International Standard specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained.</p> <p>For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.</p>		
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				<p>to reflect the obligations of a manufacturer. After that, the “subset” STED could be introduced and described in detail (i.e. Such activities may include the examination and updating of the STED and source documents.</p> <p>I don’t want to question the concept but it should be made clear that there are overall requirements concerning the documentation to be established by the manufacturer.</p>		
7	MEDEC	Page 4, Section 1.0, Introduction, Paragraph 3, sentences 2 &3	Ed	<p>Improve clarity of text :- “Differences in documentation requirements necessitate additional work for the same device in different jurisdictions, increase costs and between countries pose barriers to the timely international access to medical devices. The barriers also have economic impact.”</p>	<p>This should enable a manufacturer to provide, if requested, different Regulatory Authorities or Conformity Assessment Bodies with the same body of evidence that its medical device conforms to regulatory requirements, thus reducing costs for the manufacturer and reviewer, as well as removing barriers to trade.</p>	Agreed
8	MEDEC	Page 4, Section 1.0, Introduction, Paragraph 4, Last line	Ed	Improve text	Delete “similarly”	Agreed
9	Swissmedic	Page 4, Section 1.0, “Introduction” 4 th paragraph, last sentence	Te	<p>Revise the final sentence of the 4th paragraph as follows:</p>	<p>“Such activities may include the examination <i>and updating</i> of the STED and source documents.”</p>	<p>Paragraph cited has been deleted. Text regarding post-market use</p>

						of the STED have been added to the document, e.g. Section 2.2.
10	Swissmedic	Page 5, Section 2.1, "Rationale"	Te	Revise the first sentence of the first paragraph as follows:	"Manufacturers are expected to record and hold documents that show how each medical device was developed, designed and manufactured <i>and how it performs on the market.</i> "	Addressed through modification to section on 'Purpose'
11	FDA	Page 5, Section 2.1, Rationale, Page 5, First and Second Sentence	Ed	... available in a consistent, <u>summarised format</u> while providing sufficient detail to allow the Regulatory The availability of this Summary Technical Documentation (STED) with <u>consistent format and content</u> will available in a consistent, <u>abridged form</u> while providing sufficient detail to allow the The availability of this Summary Technical Documentation (STED) with <u>consistent content</u> will help eliminate	Accepted in part.
12	ABHI	Page 5, Subheading 2.1 Rationale and elsewhere in the document	Ed/Te	<p>The term "subset" is used several times (eg sections 2.1 and 11.0, Figure 1). It is unclear what is acceptable as a subset in these contexts. Does a subset comprise those documents which the STED should <u>contain</u>, as per proposed explanation in #1 above? (<i>see comment on the use of "included" and "contain"</i>)</p> <p>However, selecting a subset from the QMS documentation, for example, may not be easy as this documentation may be inter-linked and not contain suitable "overview" documents.</p> <p>This is one reason why I am</p>	<p>Provide explanation of "subset", such as :</p> <p><i>Subset</i>: documents key to the understanding of the approach used by the manufacturer in demonstrating conformity, and physically contained in the STED.</p>	Comment addressed by adding a "Note" below Fig 1.

				suggesting not including documents, but ideally only referencing them; but where necessary providing an overview document or section of the STED that explains the tests (etc) and summarizes the results so as to support the safety and performance of the device.		
13	MEDEC	Page 5, Subheading 2.1, “Rationale”, Paragraph 1, last sentence	Te	Current text seems confusing. “Some of the <i>documentation will change</i> during the lifecycle of the device.”	Some of the documentation will record any changes made during the lifecycle of the device.	Incorporated with some changes to the wording.
14	MEDEC	Page 5, Subheading 2.1, “Rationale”, paragraph 2	Te	We do not want to be prescriptive about the STED format. Also, include CABs. It is advantageous to both Regulatory Authorities and the regulated industry if a subset of this documentation is available in a consistent, summarised <i>format</i> while providing sufficient detail to allow the Regulatory Authority to fulfil its obligations. The availability of this Summary Technical Documentation (STED) with consistent <i>format and</i> content will help eliminate differences between jurisdictions, thus decreasing the cost of gaining regulatory compliance and allowing patients earlier access to new technologies and treatments.	It is advantageous to both Regulatory (RAs) Authorities / Conformity Assessment Bodies (CABs) and the regulated industry if a subset of this documentation is available in a consistent, summarised form while providing sufficient detail to allow the RA/CAB to fulfil its obligations. The availability of this Summary Technical Documentation (STED) with consistent content will help eliminate differences between jurisdictions, thus decreasing the cost of gaining regulatory compliance and allowing patients earlier access to new technologies and treatments.	Incorporated.

15	MEDEC	Page 5, Section 2.2., “Purpose”, first sentence	Te	We do not want to be prescriptive about the STED format. To provide guidance on the content <i>and format</i> of the STED to be assembled, held and, if required, submitted to a Regulatory Authority or Conformity Assessment Body.	To provide guidance on the content of the STED to be assembled, held and, if required, submitted to a RA/CAB.	Accepted and incorporated
16	FDA	Page 5, Section 2.2., Purpose, First sentence	Ed	To provide guidance on the <i>content and format</i> of the STED to be assembled, held and, if required, submitted to a Regulatory Authority or Conformity Assessment Body.	To provide guidance on the <i>content</i> of the STED to be assembled, held and, if required, submitted to a RA/CAB.	Accepted and incorporated
17	JFMDA	Page 6 Clause 4.0 Recognised Standards Summary Technical Documentation (STED) Technical Documentation	Ed	Term and definition should be identified by a clause number such as in ISO ’s terminological standards to be easy to refer the term in other documents.	<u>4.1</u> Recognised Standards Standards deemed to offer the ... <u>4.2</u> Summary Technical Documentation (STED) a summary of technical ... <u>4.3</u> Technical Documentation The documented evidence, ...	Accepted. And incorporated
18	NB-MED / NBRG (EU Notified Bodies Group)	Page 6, Section 4.0, “Definitions” and other sections in the document	Ed	Recognised and recognized are used throughout the document.	Please use one form only.	Accepted. Uses “recognised” throughout.
19	NB-MED / NBRG	Page 6, Section 4.0,	Te	Addition to definition for “recognized standards”	...safety and performance, <i>where regional law allows.</i>	Not accepted. See SG1

		“Definitions”				guidance document entitled ‘Role of Standards’
20	German Designating Authority	Page 6, Section 4.0, « Definitions », definition for « Technical Documentation »	Ed	A reference to ISO 13485:2003, clause 4.2.1 should be made.		Not accepted
21	TGA	Page 6, Section 5.0, «Intended use of the STED and its preparation» (also sections 8.0 and 9.0)	Te	<p>I have always had difficulty with the concept that the content and depth of the STED could be influenced by the 'novelty' of the device, without an explanation of what we mean by 'novelty'. For example do we mean that it is</p> <ul style="list-style-type: none"> • an entirely new, different and novel treatment or diagnostic modality, and associated new and novel device • used for an accepted treatment or diagnostic procedure, but applied in a different and novel manner • a 'me too' device but of a novel design • a device which uses new and novel manufacturing processes • a device which is not new, but used a new and novel material • a recognised manufacturing process, but a process which is new and novel to the manufacturer of the particular 		<p>Section 5.0 rewritten to describe the circumstances under which more information is required in the STED.</p> <p>Removed the word ‘novelty’ from this section.</p>

				<p>device</p> <p>Unless explained, it has the potential for a manufacturer of a class D device, a pacemaker for example, to take the approach that the new device for which the STED is being prepared is '...just another pacemaker in a long line of pacemakers....', and on that basis abridge or not include in, the STED, documents which we as a Regulatory Agency or CAB consider essential to complete the 'package' the STED is meant to be, because it is not another pacemaker in not a 'novel' device to them.</p>		
22	German Designating Authority	Page 6, Section 5.0, «Intended use of the STED and its preparation»	Te	<p>The first two clauses should be redrafted in order to better reflect the overall documentation requirements (see general comment above, link to ISO 13485). After that, the detailed structure of STED with its different parts could be described. Questionable is also if the STED should be created from the existing documentation or if the documentation should be set up in way to define or recommend the structure of the technical documentation at all with a “subset” STED.</p>		<p>Link made to SG3 documents by inserting the words ‘quality management system’</p> <p>Modify figure to add ‘Typical’ to the heading.</p>

				Second clause, second sentence: necessary? Is the class of a device really a “main argument”?		Text changed to clarify.
23	NB-MED / NBRG	Page 6, Section 5.0, “Intended use of the STED and its preparation”, second paragraph, first sentence	Te	STED at manufacturer may not always be practical, e.g. in case the manufacturing takes place totally different location from the legal manufacturer. Which may be just the corporate head office	The STED will be held by the <i>legal</i> manufacturer, <i>it’s manufacturing site and/or at the representative offices where appropriate</i> , for audit and...	Not accepted as written but text modified to clarify
24	Sanofi-aventis	Page 6, Section 5.0, “Intended Use of the STED and its Preparation”, third paragraph, last sentence	Ed	The text speaks of QMS systems; S already stands for system		Accepted and change made
25	ABHI	Page 6 / section 5.0, last paragraph	Technical	Can a virtual STED held by the manufacturer be a set of hyperlinks to constituent documents. In this case, how is the virtual STED to be sent to the RA if requested?	Maybe this needs to be considered, and some further information provided as to what is acceptable in terms of a virtual STED.	Outside the scope of the existing document but bookmarked for future consideration.
26	ITRI (Industrial Technology Research Institute)	Page 6, Section 5.0, “Intended Use of the STED and its	Ed	The note in the bracket, “see below” has no further indication or description in this section on the controlled documentations that should be included in the STED. If	Change “(see below)” to “(refer to Fig.1)”.	Accepted. Deleted ‘see below’

		Preparation”, third paragraph, third sentence		the note would like to remind the reader to refer to Figure 1, please clarify as such. “While many controlled documents are referenced in the EP checklist, only those controlled documents specifically recommended in this guidance for inclusion (see below) will be incorporated within the STED.”		
27	Sanofi-aventis	Page 7, Section 5.0, “Intended Use of the STED and its Preparation”, figure 1	Ed	Are all the documents mentioned really under QMS-control?		Addressed by a change to first paragraph
28	AdvaMed	Page 7, Section 5.0, “Intended Use of the STED and its Preparation”, figure 1	Te	While I recognize that this diagram is intended to be illustrative and not all-inclusive, I suggest that the illustrated design evaluation section on the left side include "clinical evaluation". Clinical evaluation is a very important part of the EPs, the technical documentation, and the conformity assessment process.		Agreed to be incorporated by Benny after the meeting
29	German Designating Authority	Page 7, Section 5.0, “Intended Use of the STED and its Preparation”, Figure 1	Te	Reference to risk management – in addition to risk analysis – should be made.		Not agreed. The STED is product specific therefore risk analysis rather than management is

						appropriate
30	MEDEC	Page 7, Section 5.0, "Intended use of the STED and its preparation", final paragraph	Te	Clarify what is meant by the term "virtual set of documents"	At the manufacturer's location where responsibility for ensuring the device complies with regulatory requirements resides, the STED may exist as a set of the required documents or as a list that describes the location of all such documents or as a combination of the two.	Addressed through modified text.
31	FDA	Page 7, Section 5.0, Last Sentence	Ed	Clarify what is meant by "real or virtual set of documents"	At the manufacturer's location, the STED may be a real (physical) set of documents or a virtual set of documents (system that allows for retrieval of a set of documents consisting of either electronic or physical copies of documents).	Addressed through modified text.
32	AdvaMed	Page 7, Subheading 6.1, « Device Description », 1st line (« The STED should... »)	Ed	I suggest that "description" be changed to "descriptive" (smoother).		Accepted and incorporated
33	German Designating Authority	Pages 7-8, Section 6.1, « Device Description », and 6.2, « Product Specification »	Ed/Te	The contents and the respective order should be critically reviewed. The separation of "product specifications" into a separate section seems not really reasonable, especially in looking on variants and accessories, which are mentioned in 6.1 as well as in 6.2. Proposal is to combine both sections (which also would better reflect section 3.2 c) in Annex II of the European MDD). What is missing with respect to the MDD		Not accepted. Different information is described Sections 6.1 and 6.2. Furthermore, the purpose of 6.2 is clarified through text change.

				is information concerning design control (see MDD Annex II 3.2.c) second and following indents.		
34	German Designating Authority	Page 7, Section 6.1, « Device Description », 4th bullet point	Te	Due to the fact that classification schemes still differ in the world, at least a Note should be introduced to highlight that classification differences under the various regimes should be mentioned also.		Bookmarked to consider when SG1's guidance on Device Classification is reviewed.
35	ABHI	Page 7, Section 6.3, « Reference to previous generation(s) or similar devices »	Ed	The information included in this section would be better included in the section dealing with clinical data, since it will often have to be repeated there anyhow. See EU Medical Devices Directive Annex X para. 1.1.1.	Delete section 6.3.	Not agreed. The text talks about an 'overview'.
36	COCIR	Page 8, Section 6.3, « Reference to previous generation(s) or similar devices	Te	It is up to the mfr. to decide whether or not to refer to existing products on the market where this is regarded useful for compliance information. This prevents non-value-added proliferation of information and helps all involved focus on the relevant matters: the new information.	Write: “... <i>the STED may refer to ...</i> ” Instead of “... <i>the STED should provide an overview of ...</i> ”	Not agreed. Only recommends that the STED includes detailed information when there is a particular need. Otherwise summaries are sufficient.
37	German Designating Authority	Page 8, Section 7.0, « Essential Principles (EP) Checklist », first clause,	Ed	Reference should be made to document N41.		Not agreed Checked all footnotes and deleted the unnecessary ones.

		first bullet.				
38	MEDEC	Page 8 Section 7.0	Te	The method of demonstrating compliance for an Essential Requirement is often a combination of methods. <i>the <u>method</u> used to demonstrate compliance with each Essential Principle that applies;</i>	<i>the method(s) used to demonstrate compliance with each Essential Principle that applies;</i>	Agreed
39	German Designating Authority	Page 8, Section 7.0, « Essential Principles (EP) Checklist », second clause.	Te	Do we really want to promote the concept of comparison to similar devices (knowing that this also in Europe will normally be part of e.g. clinical evaluation)?		In discussion, SG1 confirmed that it should retain this concept.
40	ABHI	Page 8, section 7.0, “Essential Principles (EP) Checklist, paragraph 2, 4th bullet point.	Ed	The scope of this bullet should be widened to include other data.	Delete 4th bullet point. Replace with: <ul style="list-style-type: none"> “preclinical and comparison tests or clinical data.” 	Added bullet on clinical evaluation – other topics already covered
41	ABHI	Page 9, section 7.0, “Essential Principles (EP) Checklist, end of section <i>and</i> Appendix A.	Te	If the EP Checklist is used exactly as it is, it will be harder for CE Marking manufacturers and their RA/NB assessors to ensure that each of the 14 MDD Essential Requirements has been met, since the two checklists are by no means identical. The Guidance should accept that where the Regulatory	Add new para. 4 to 7.0: “Where the Regulatory Authority has provided an alternative list of essential principles or requirements to be met, an alternative Checklist based on these should be used, instead of the EP proposed in Appendix A.”	Not accepted. GHTF documents all recognise that at this moment, the regulations in different jurisdictions do not align exactly

				Authority has provided an alternative list of principles or requirements to be met, an alternative Checklist should be used, based on those specific regulator's Essential Principles or Essential Requirements.		with GHTF guidance. Convergence is a long-term goal. See 'Introduction'.
42	German Designating Authority	Page 9 Section 8.0, Risk analysis and control summary		There is the overall question in respect to risk management in general, leading to additional requirements / recommendations for a regular update / review of the STED. Has this been discussed in the past? From our point of view, risk management and the consequence of necessary updates should be part of the document.		The STED represents a snapshot in time, normally premarket. During discussion it was agreed the STED has a post-market role (see Section 2.2). The documents it draws upon subsequently change with time, under the control of the QMS, post-market events, risk assessment etc. There is an advantage in having a virtual document with links to source material.
43	NB-MED / NBRG	Page 9, Section 8.0, "Risk	Te	Updates on risk management	The risk analyses should be current at all times.	Not accepted. See comment 42

		analysis and control summary”				
44	ABHI	Page 9, Section 9.0, “Product Verification and Validation”	Te	This section presumably applies to Design Verification and Validation since manufacturing tests are mentioned in section 10.1.1. I find the term “product verification” confusing in this context, as this is more correctly applied to manufacture. The term “Design Validation and Verification would be more clear and moreover be similar to usage in ISO 13485 clauses 7.3.5 and 7.3.6 as a well as 21 CFR 820.30.	Change title of section to read: “9.0 Design Verification and Validation.”	Not accepted
45	German Designating Authority	Page 9, Section 9.0, « Product verification and validation », first clause	Te	Section 9, first clause We are not convinced that the concept “... level of detail will vary, and be determined by” the “class of the device” is helpful (see comment above).		Not accepted
46	Swissmedic	Page 9, Section 9.0, « Product verification and validation », second paragraph	Te	Add as a final bullet :	<ul style="list-style-type: none"> “any experience of it’s use in humans, including clinical trials and results of PMS evaluations.” 	Not accepted. Clinical evidence is covered later in this Section and detailed rather than summary information is called for.
47	AdvaMed	Page 9, second	Ed	I suggest “.... regarding the device or substantially similar devices”		Already

		clause, 5th bullet point (and in the section immediately following)		after "any published literature" (greater clarity).		incorporated
48	German Designating Authority	Page 9, Section 9.0, « Product verification and validation », third clause	Te	Section 9, third clause “Summary information may ...” We would prefer to use plural, e.g. compliance to recognised <i>standards</i> ... instead of a <i>recognized standard</i> ...		Accepted
49	MEDEC	Page 9, Section 9.0, “Product Verification and Validation”, Bullet #11	Te	Current text is confusing when reference is made to an “ <i>in-house standard</i> ”. Refer to alternate section on page 14, Method of Conformity, which refers to “ <i>in-house test methods</i> ” declaration/certificate of compliance to a professional guideline, industry method, or <i>in-house standard</i>	<i>declaration/certificate of compliance to a professional guideline, industry or in-house test method(s).</i>	Agreed
50	ITRI	Page 9, Section 9.0, “Product Verification and Validation”, L15~26 (??)	Te	In some jurisdictions where regulators or conformity assessment bodies lack of regulation bases and adequate experiences of technical review, they could possibly ask for a description of the marketing history, regulatory approval status in different regions, or a summary	Add the following note after L26 of the section: <i>Note: Where appropriate, some jurisdictions may ask the manufacturers for a description of the product’s marketing history, regulatory approval status in different regions, or a summary of compliance in premarket submission.</i>	Not relevant to the scope of the STED. Could be handled by other mechanisms (e.g. mutual recognition for trading purposes)

				of compliance of the product in which they think might help enhance their confidence to it.		
51	NB-MED / NBRG	Page 9, Section 9.0, "Product Verification and Validation"	Te	Add to final bullet under "Summary information may include"...	Similar devices, <i>including where available the manufacturers own clinical data on similar devices and details from manufacturers prospective studies.</i>	Not accepted. Covered in Section 9.1
52	ABHI	Page 9, section 9.0, "Product Verification and Validation"	Te	This section presumably applies to Design Verification and Validation since manufacturing tests are mentioned in section 10.1.1. I find the term "product verification" confusing in this context, as this is more correctly applied to manufacture. The term "Design Validation and Verification would be more clear and moreover be similar to usage in ISO 13485 clauses 7.3.5 and 7.3.6 as a well as 21 CFR 820.30.	Change title of section to read: "9.0 Design Verification and Validation."	Already dealt with in comment 44. Layout and some headings changed within Section 9.0
53	ABHI	Page 8 (???), paras 3 and 4???	Te	Information presented in the STED should be a summary not detailed information. An overview with reference to the applicable reports is sufficient for the purpose.	(a) Amend para 3 first sentence to read: "As a general rule, the STED should include summarized information on:" (b) Amend para 4 to read: "Summarized information will describe the tests performed and their outcomes, and provide reference to the location of applicable protocols and reports of the tests."	Not accepted. The guidance is intended to recommend when detailed rather than summary information should be provided
54	NB-MED /	Page 9,	Te	Add general aspects, EMC and	<ul style="list-style-type: none"> <i>electrical safety</i> 	Not accepted.

	NBRG	Section 9.0, "Product Verification and Validation"		electrical safety to listing of summary information in extra bullet points at the bottom of page 9	<ul style="list-style-type: none"> • <i>EMC</i> • <i>General aspects</i> 	Reference to compliance with standards through a product-specific EP checklist is sufficient
55	ITRI	Pages 9-10, Section 9.0, "Product Verification and Validation", fourth paragraph	Te	We suggest including electrical safety and electromagnetic compatibility in the STED documentation for product verification and validation. This is because there are quite a number of devices which have electrical and mechanical features.	<p>Rewrite the final paragraph of the section as the following: As a general rule, the STED should include detailed information on:</p> <ul style="list-style-type: none"> • sterilisation; • biocompatibility; • clinical evidence. • Electrical safety and electromagnetic compatibility 	<p>Not accepted.</p> <p>See comment above</p>
56	German Designating Authority	Pages 9-10, Section 9.0, "Product Verification and Validation", fourth paragraph	Te	<p>Section 9, 4th clause: As a general rule ...</p> <p>The order / sequence of bullets should be better aligned to the Essential Principles (Document N41, section Design and Manufacturing Requirements, 5.7 Chemical, physical and biological properties ...). What is about e.g. mechanical and electrical safety and the other sections in N41?</p>		Accepted and changes made
57	ABHI	Page 8, Section 9.1, "Sterilization"	Te	Again, too much detail apparently required.	<p>Delete section 9.1 paras 1 and 2 and replace with new paras 1 and 2, as follows: "Where the device is provided sterile, the STED should state:</p> <ul style="list-style-type: none"> • the sterilization method used 	Reviewed text and deleted: "in the form of the most recent validation report."

					<ul style="list-style-type: none"> the sterility assurance level attained sterilization standards applied. <p>The STED should provide a summary of or reference to:</p> <ul style="list-style-type: none"> the initial sterilization validation including procedures and results of bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation, and arrangements for revalidation of the packing and sterilizing processes. 	NOTE: since comment 72 has been accepted, the Section numbers 9.1 through 9.7 have changed in the revised document. This note applies to all comments from 57 to 90.
58	COCIR	Page 10?	Ed	On page 10, reference 8 (SG1 N044) does not match with the reference given in section 3, which contains the existing document. It may be considered useful for the public comment period, to indicate that this document is under review at the moment.		Accepted and already accounted for.
59	JFMDA	Page 10, Section 9.1, Sterilization	Te	<p>The validation report shall be prepared on QMS by Manufacturer. However, submission of them depend on conformity assessment system.</p> <p>In Japan, the regulatory does not request to submit them, although they request the information for validation. And, they was confirmed on the regulatory audit. Therefore, I think that "information" is better than</p>	<p>9.1 Sterilisation: Where the device is supplied sterile, the STED should contain <u>the detailed information</u> of the initial sterilisation validation report including bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. Evidence of the ongoing revalidation of the process shall also be provided in the form of the most recent validation report.</p> <p>Typically, <u>the detailed information</u></p>	Discussed and text modified as agreed.

				"report".	of a validation report should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed against the standards, and a <u>summary report</u> of the results against the protocol.	
60	MHLW	Page 10, Section 9.1, Sterilization	Te	Please add the following sentence as we don't ask companies to submit validation report.	"If the report is submitted in terms of QMS audit, the report may not be submitted as a part of STED. In that case, the declaration written by applicant may be attached with STED." Or Just adding the concept of sentence mentioned-above sounds fine with me.	Discussed and text modified as agreed.
61	NB-MED / NBRG	Page 10, Section 9.1, "Sterilisation", first paragraph, first sentence	Te	Add reference to shelf life	<i>...and packaging validation, including shelf life studies and performance testing at the end of the shelf life.</i>	Not agreed. Already implied by the existing text and within an existing Essential Principle.
62	JFMDA	Page 10 Section 9.1, "Sterilisation", 2 nd paragraph, Line 3	Te	[Rationale] The validation report shall be prepared on QMS by Manufacturer. However, submission of them depend on conformity assessment system. In Japan, the regulatory does not request to submit them, although	[Proposal] Delete the following sentence 9.1 Sterilisation: Where the device is supplied sterile, the STED should contain the detailed information of the initial sterilisation validation report including bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging	Discussed and text modified as agreed.

				they request the information for validation. And, they was confirmed on the regulatory audit.	validation. Evidence of the ongoing revalidation of the process shall also be provided in the form of the most recent validation report.	
63	JFMDA (Hashimoto)	Page 10, Section 9.1, “Sterilization”, 2 nd paragraph, Line 3	Ed	“ <i>against</i> ” should be replaced by “ <i>in accordance with</i> ” for precise understanding.	Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed against <i>in accordance with</i> the standards, and a summary of the results against <i>in accordance with</i> the protocol.	Accepted
64	German Designating Authority	Page 10, Section 9.1, « Sterilisation »	Ed	Reference should be made to applicable / recognized standards		Outside the scope of this document. Many standards are relevant to the STED.
65	ABHI	Page 10, Section 9.2, Biocompatibility	Te	Details again requested but a summary only should be adequate in the STED.	Amend 9.2 first line to read: “An <u>overview</u> should be provided ...”	Not accepted. Details are required in this Section not an overview.
66	German Designating Authority	Page 10, Section 9.2, “Biocompatibility”	Ed	Section should better start with rationals for selection of tests conducted (which, why /why not ..., compare ISO 10993-1). Third sentence “All material that are SIGNIFICANTLY different ...” might be dangerous.		Addressed - Section 9.2 has been rewritten.
67	TGA	Page 10, Section 9.2, “Biocompatibility”	Ed	Our second issue is the use of a number of terms which, while we probably feel we understand what they mean, the less informed		Addressed - Section 9.2 has been rewritten.

				<p>reader of the document may not.</p> <p>For example:</p> <p>What are we meaning by the phrase "All material must be characterized." in section 9.2 on biocompatibility.</p>		
68	ITRI	Page 10, Section 9.2, "Biocompatibility", final two sentences (Lines 3-5)	Te	Characterization and evaluation of the materials used with regard to their physical, chemical, toxicological and biological properties should be done in advance in order to justify the biocompatibility of the these materials. Such evaluation and related biocompatibility tests should be conducted according to related standards. Test protocols developed against the standards should also be included.	<p>Rewrite L3-5 in this section as the following:</p> <p><i>The biocompatibility of all materials should be evaluated with regard to their physical, chemical, toxicological and biological properties. Information describing biocompatibility evaluation, related tests, standards applied, test protocols developed against the standards, the results and the analyses of data should be included.</i></p>	Addressed - Section 9.2 has been rewritten.
69	NB-MED / NBRG	Page 10, Section 9.2, "Biocompatibility", second sentence	Te	"At a minimum, tests should be conducted..." indicates that there always should be tests performed. In some cases rationales only may be sufficient	Remove at a minimum, and start sentence: <i>Where rationales alone are not sufficient, tests.....</i>	Addressed - Section 9.2 has been rewritten.
70	Sanofi-aventis	Page 10, Section 9.2, Biocompatibility	Te	Applicable standards for biocompatibility testing should be mentioned	Last sentence: <i>Information describing the applicable and/or used standards, the tests performed, the results and the analyses of data should be included.</i>	Addressed - Section 9.2 has been rewritten.
71	COCIR	Page 10, Section 9.3, « Software	Ed	Rationale: this paragraph in my opinion is not commensurate with the other topics in this chapter. I	Topic 9.3, page 12, write: <i>"The manufacturer must provide information on the processes he has</i>	Addressed - Section 9.3 has

		Verification and Validation »		believe that the text should be restricted to indicate which process is in place, however covering all the various steps of the process. There is no need to provide all the details of testing, etc.	<p><i>installed to validate the software design and development process. This information should include all steps of verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments."</i></p> <p>In stead of <i>"The manufacturer must provide evidence that validates the software design and development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments."</i></p>	been rewritten.
72	German Designating Authority	Page 10-11, Section 9.3 « Software Verification » Section 9.4 « Biological Safety », and Section 9.5 « Animal Studies »	Ed	<p>Section 9.3 Software Verification ..., Section 4 Biological Safety, and Section 9.5 Animal Studies</p> <p>Sequence? Why is e.g. software between Biocompatibility and Biological safety? Why is 9.5 not related to 9.2?</p>		<p>The order of these sections has been changed as suggested.</p> <p>Biocompatibility and biological safety are different subjects.</p>
73	ITRI	Page 10,	Te	Before conducting software verification and validation, an	Add in the following at the beginning of	Not accepted.-

		Section 9.3, "Software verification and validation"		estimate should be made with regard to the severity of injury that the software could inflict, either directly or indirectly, on a patient or operator as a result of its failures or design flaws. The role of the software in causing, controlling, and/or mitigating hazards that could result in injury to the patient or the operator should be discussed based on a risk management perspective.	S9.3: <i>The intended use of the software and related hazards caused by its failures and design flaws should be described in detail. Risks should be identified and controlled to an acceptable level. (In line with Section 8.0.)</i>	After discussion it was agreed that Section 8 is adequate of itself
74	NB-MED / NBRG	Page 10, Section 9.3, "Software Verification and Validation", third sentence	Te	Sometimes different operating systems have more effect than different hardware	"... for all of the different hardware configurations <i>and operating systems</i> identified..."	Accepted
75	TGA	Page 10, Section 9.4, "Biological Safety"	Ed	Our second issue is the use of a number of terms which, while we probably feel we understand what they mean, the less informed reader of the document may not. For example: The use of the term '.... long term registries' is used in section 9.4 Biological Safety gives no indication of what the registry is about.		Addressed through modification of text
76	ITRI	Pages 10-11, Section 9.4, "Biological	Te	Apart from transmissible agents, the tumorigenicity of the tissue is also a potential hazard for this kind	Rewrite the whole paragraph as the following: In the case of a medical device	Not accepted. Covered under "Biocompatibilit

		Safety”		of devices. It would be beneficial for the manufacturer to describe the source, biosafety level, tumorigenicity, DNA and cytogenetic profile, propagation and preservation of the tissue that serve as a basis of risk evaluation. The aforementioned aspects are critical in process validation of this kind of products as well.	manufactured from or incorporating animal or human tissue or their derivative, detailed information should be provided substantiating the adequacy of the measures taken with regard to the risks associated with transmissible agents <i>as well as tumorigenic features of the the tissue</i> . This will include viral clearance results for known hazards <i>as well as the source, biosafety level, tumorigenicity and DNA and cytogenetic profile</i> . Donor screening concerns should be fully addressed. Methods of harvesting, long-term registries, <i>propagation and tissue preservation</i> should also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.	y”
77	Health Canada	Page 10, Section 9.4, “Biological Safety”, Line 4	Ed	Donor screening usually refers only to donors of human tissue.	Donor screening concerns for human tissues and animal sourcing concerns for animal tissues should be fully addressed.	Text modified in Section 9.4
78	Health Canada	Page 10, Section 9.4, “Biological Safety”, Line 5	Ed	The term “long-term registries” is not clear. Does it refer to the maintenance of records of human donors and animal sourcing in order to allow for traceability? It should be stated more clearly.		Accepted – text modified
79	ABHI	Page 11, Section 9.5, “Animal Studies”	Te	Details again requested but a summary only should be adequate in the STED.	Amend 9.5 first line to read: “An overview of animal studies and their results should be included ...”	Not accepted. Section 9 is required because summaries are not adequate in

						the cited situations.
80	TGA	Page 11, Section 9.5, “Animal Studies”	Te	<p>Our second issue is the use of a number of terms which, while we probably feel we understand what they mean, the less informed reader of the document may not.</p> <p>For example:</p> <p>Section 9.5 on animal studies seems to be mixing, and possibly confusing the reader, in referring to two types of animal studies. There is referral to '...interaction with animal fluids and tissues</p> <p>which, I think is more appropriately referenced in the section on biocompatibility and then there is '.... functional effectiveness of the device in the experimental animal model.' which is what I would normally consider to be called an animal study.</p>		Text modified to accommodate comment
81	German Designating Authority	Page 11, Section 9.5, « Animal Studies »	Te	<p>What is the reason to include animal studies only, when they were conducted to support the probability of effectiveness in humans. See also comment above from German Authority.</p>		Text modified to clarify purpose of Section.
82	Swissmedic	Page 11, Section 9.5, “Animal Studies”, first sentence	Te	<p>Revise the first sentence as follows:</p>	<p>Reports of animal studies should be included, when these studies are conducted to support the probability of effectiveness <i>and safety</i> in humans.</p>	Accepted.

83	NB-MED / NBRG	Page 11, Section 9.5, "Animal Studies"	Ed	Replace "effectiveness" by "safety and performance" to be in line with MDD	... when these studies are conducted to support the probability of <i>safety and performance</i> in humans.	Accepted
84	ITRI	Page 11, Section 9.5, "Animal Studies"	Te	The GLP mentioned here is a universal practice for all biomedical related companies or laboratories. The major concern of animal testing lies in the practice on care and handling of the laboratory animals in biomedical research. This is to optimize the performance of animal experiments, to reduce the number of laboratory animals and to maintain the quality of animal testing.	Rewrite L2~3 of the section as the following: <i>These studies should be undertaken using standardized practice on care and handling of the laboratory animals in biomedical research.</i>	Text modified to clarify purpose.
85	German Designating Authority	Page 11, Section 9.6, « Medicinal Substances »		Why is no reference made to documents / processes usual in the pharmaceutical sector?		Not accepted. The paragraph explains why.
86	NB-MED / NBRG	Page 10, Section 9.7, "Clinical evidence"	Ed	The reference to section 4 is not understood	Remove reference	Accepted.
87	German Designating Authority	Page 10, Section 9.7, « Clinical Evidence »	Ed/Te	It might be better to include the "result of the clinical evaluation" instead of ... results of clinical evaluation studies undertaken... (perhaps SG 5 should be consulted directly – if they haven't commented already on this clause).		Accepted and 'studies' deleted
88	Swissmedic	Page 11, new section	Te	Add the following new section:	9.8 Post market follow up: Any ongoing PMS evaluations	Addressed

89	ABHI	Page 11, Section 9.7, "Clinical Evidence", first sentence	Ed	The reference to Section 4.0 does not seem correct. There is no information in 4.0 relevant to sentence, <u>unless this reference section is amended to incorporate the explanations mentioned under point #1 above.</u> Were there originally some such explanations in 4.0 that have been subsequently omitted?	Either: (a) remove reference to Section 4.0 in first sentence, or (b) incorporate explanations/definitions in 4.0	Accepted – reference deleted
90	NB-MED / NBRG	Page 11, following Section 9.7	Te	Following Section 9.7, add Sections 9.8, 9.9 and 9.10 on general aspects, EMC and electrical safety		Not accepted see Section 5, 3 rd paragraph, for the reason
91	COCIR	Page 11, Section 10.0, "Design and Manufacturing Information"	Te	The request is awkward for those situations where key-parts of the device are produced by other companies (this is the case with OEM-products), that may not be willing to share information that can be considered confidential and competition sensitive. The relation with the supplier and the management of the quality level is to be covered in the audited QMS, for which a valid certificate then should to be presented	Insert after the header: <i>"Where no valid quality management system certificate issued by a recognized body can be produced, covering the steps of manufacturing and, where appropriate, design & development, the following information must be included in the STED."</i>	After changes to 10.1 and 10.2, this comment was withdrawn.
92	ABHI	Page 11, section 10.1.1, Manufacturing Process	Ed	Incorrect level of numbering for this section	Replace 10.1.1 with 10.1.	Accepted. Numbering corrected
93	ABHI	Page 11	Ed	Incorrect level of numbering for	Replace 10.1.2 with 10.2.	Accepted.

		Section 10.1.2, “Design and Manufacturing Sites”		this section		Numbering corrected
94	German Designating Authority	Page 11, Section 10, « Design and Manufacturing Information », Subheadings 10.1.1 « Manufacturing Processes » and 10.1.2 « Design and Manufacturing Sites »		Section 10 Design and Manufacturing Information Section 10.1.1 (not 10.1, please renumber or delete subheadlines in this section at all) Manufacturing Processes and 10.1.2 Design and Manufacturing Sites From our point of view, these sections should be combined and aligned with the spirit in ISO 13485 (process approach, sequence and interaction of processes; please compare also sections 4.1 and 7 (product realization) of the standard). What the documentation should contain is detailed information about special processes and any outsourced processes as well as the information, which processes are done at which site of the manufacturer. The easiest would be to include the information “done where” in the process map. Especially Section 10 is directly related to the work of SG4. Therefore I would like to suggest that SG4 should comment on it.		Accepted. Numbering corrected Location requirement dealt with in 10.3
95	ITRI	Page 11, Section 10.0, “Design and	Te	Please clarify the definition of “design” mentioned in this section. In previous sections of this	N/A	New section added to clarify the design

		manufacturing information”		guidance, some major concerns related to product design such as EP compliance, product verification and validation, specification as well as design control have been covered in depth.		requirement
96	JFMDA	Page 11, Clause 10.1.1, “Manufacturing processes” Line 3	Te	“design” shall be deleted. Rationale: Designing of the device is not included in manufacturing process.	10.1.1 Manufacturing Processes The manufacturing processes for the finished device should be provided in the form of an overview of the activities and quality management system associated with the fabrication of the device. This would include design , production, assembly, final product testing and packaging of the finished medical device.	New section added to clarify the design requirement
97	NB-MED / NBRG	Page 11, Section 10.1.1, “Manufacturing Processes”	Te	Add software and add interim inspections. The current wording assumes full final product testing which is very often not performed, but rather samples are taken during steps in production	Change wording to:assembly, <i>incoming goods inspection, interim quality testing and/or</i> final product testing and packaging of the finished medical device, <i>including its software where applicable.</i>	Not accepted. The text makes it clear that the list is one of examples rather than complete.
98	ABHI	Page 10 Section 10.1.2 (proposed 10.2), “Design and Manufacturing Site, first sentence	Te	Not clear what is meant by “overview of activities”. May appear to require too much information.	Replace first sentence with: “If multiple facilities are involved in the design and manufacture of a device, the STED should state which type of activity relevant to the device is conducted at each.”	Addressed through changes to the text.
99	NB-MED / NBRG	Page 11, Section 10.1.2,	Te	What if parts are devices themselves?	Incorporated into the device, <i>but does apply to subcontractors to whom the design is fully outsourced by the manufacturer.</i>	Addressed through changes to the text.

		“Design and manufacturing sites”			<i>Critical subcontractors are to be described.</i>	
100	NB-MED / NBRG	Page 11-12, Section 11.0, “Labelling”	Te	All labelling, IFU and others may be a lot when a lot of marketing and translations is done	Add: <i>When extensive material is available in many languages, this may be done on a sampling basis, e.g. material in one language for one country.</i>	Text modified to clarify requirement.
101	ABHI	Page 11, Section 11.0, “Labelling”	Te	Large amounts of labelling can be associated with a device or device family, and it may be updated for various reasons such as change of distributor details, improved instructions for use, new warnings and precautions, improved drawings, format, style etc. It is unnecessary to include these documents as physical copies if they are controlled as quality system documents.	Amend first sentence of 11.0 to read: “ The STED should list all labelling associated with the device as described ...”	Text modified to clarify requirement.
102	Swedish Medical Products Agency	Page 11, Section 11.0, “Labelling”, first sentence	Te	It is written in section 11.0 that the STED should contain all labelling associated with the device. In our opinion it should be stressed that this includes all linguistic versions of labelling associated with the device and in accordance with rules and regulations applicable in different countries within the European community, as this would make market surveillance easier for competent authorities.		Not accepted. Text modified to clarify requirement.
103	Sanofi-aventis	Pages 11-12, Section 11.0, “Labelling”	Te	If the labeling is performed according to recognized standards, this fact and the standards should		Not accepted. Not relevant to

				be mentioned		the STED. Covered in a separate SG1 guidance document on labelling.
104	ITRI	Page 12, Section 11.0, "Labelling", final bullet	Te	In some jurisdictions, the regulators do not include promotional materials as part of the labeling. Additionally, in SG1/N043:2005, "promotional materials" is conditional and serves as a note in the guidance. We suggest relating this element consistently with SG1/N043:2005.	N/A	Not accepted
105	JFMDA	Page 12, Clause 11.0, "Labelling", final bullet	Te	"promotional material " shall be deleted. Rationale: Promotional materials are not the medical device but the information released to expected-users.	11.0 Labelling The STED should contain all labelling associated with the device as described in GHTF guideline SG1/N043:2005 <i>Labelling for Medical Devices (revised)</i> . Information on labelling will include the following subsets: a) labels on the device and its packaging; b) instructions for use, including an overview of any end-user training materials offered by the manufacturer and not included within them. • promotional material.	Not accepted
106	NB-MED / NBRG	Page 12, Section 12.0, "Declaration of Conformity"	Te	For MDD other statements may be necessary, e.g. statement on animal tissue and human blood derivatives	<i>In the annex, statements in relation to animal tissue, human blood derived material and/or medicinal products not being integrated into the device may be added to this annex when appropriate.</i>	Not accepted. This subject is dealt with in a separate SG1 document. Bookmarked for consideration

						when SG1's guidance on Conformity Assessment is next reviewed
107	ITRI	Page 12, Section 12.0, "Declaration of Conformity"	T	If the declaration of conformity is not a part of the STED, please reconsider the necessity of including it in this section. We suggest writing a separate note for this relating to the aspects on conformity assessment or just delete this section.	Delete the section or make a note using the original text, like the following: <i>Note: 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/N40:2006 <u>Principles of Conformity Assessment for Medical Devices</u>.</i>	Not accepted.
108	NB-MED / NBRG	No specific reference	Te	In line with ISO 14971:2007, a section on post market surveillance planning may be added. Will this fit the scope of the document? If not, then reference to the standard might be in place in a section where post market surveillance is mentioned.		Post-market surveillance is a topic dealt with by SGs 2 & 4 and outside the scope of this document.
109	JFMDA	Page 14, Appendix A, "Essential Principle (EP) Checklist" a) title b) 2 nd para.	Ed.	a) the title should be replaced by "Essential Principle (EP) Checklist" Rationale: Harmonize with the term used in the main document. b) "a few pages" should be	Essential Principle (EP) Checklist a) The EP checklist can be used by b) The contents of the checklist will vary	Accepted. Spelling corrected.

		Line 2		<p>replaced by “ less numbers of pages”</p> <p>Rationale:</p> <p>In the experience in Japan for 2 years, all EP Checklist have their pages more than that of the template provided in Japanese language of 17 pages, because of the regulatory requirement of full re-writing of the Essential Principles.</p>	<p>from device to device. Very simple devices will have EP checklists of <u>a few less numbers of</u> pages ...</p> <p><u>c)</u> The following is a recommended ...</p>	
110	NB-MED / NBRG	Appendix A, page 14, first and second paragraphs	Ed	Replace “principals” by “principles”	<i>principles</i>	Accepted
111	JFMDA	Page 14, Appendix A, “Applicable to device?” and “Method of Conformity”, And them	Ed	<p>The brief explanation where the answer is “No” (not applicable to the device) in “Method of Conformity:</p> <p>[Rationale:]</p> <p>Regulatory Authorities and CABs need to know</p> <p>a) whether the standard(s), industry or in-house test method(s), comparison study(ies) or other method is(are) selected to demonstrate compliance, and</p> <p>b) the Brief explanation of “No” in the column of applicability of the EP.</p>	<p><u>A2.2</u> Applicable to device?</p> <p>Here the answer is either ‘Yes’ or ‘No’.</p> <p>Example <i>of ‘No’</i>:</p> <p>For a device that does not incorporate biological substances, the answer to Essential Principal 5.8.2 would be ‘No’.</p> <p><u>A2.3</u> Method of Conformity</p> <p><u><Replace the following sentence;></u></p> <p><u>a) The manufacturer should explain briefly the type(s) of the method selected to demonstrate compliance;</u></p> <p><u>b) if the answer is ‘No’ in the column of applicability of the EP, this should be briefly explained</u></p> <p><u>Examples:</u></p>	<p>Accepted.</p> <p>Appendix A modified.</p>

				<p>We think that it is better to identify the selected method to demonstrate compliance and the actual information for the applied standards or the method.</p>	<p><u><i>a) Compliance to this EP is demonstrated by conformity to a Recognised standard.</i></u></p> <p><u><i>b) For a device that does not incorporate biological substances, the brief explanation to Essential Principal 5.8.2 would be ‘The device does not incorporate biological substances.’</i></u></p> <p><<Deleted>>The manufacturer should name the title ...</p> <p><u>A2.4 Identify of Specific Documents</u></p> <p><<Move same of current sentence of “Method of Conformity” into this clause>></p> <p><u><i>The manufacturer should name the title and reference of the standard(s),</i></u></p> <p><<Deleted>>This column should contain the reference to the actual technical</p> <p><u>A2.5 Reviewed result</u></p> <p><<Move same of current sentence of “Identify of Specific Documents” into this clause>></p> <p><u><i>This column should contain the reference to the actual technical</i></u></p>	
112	NB-MED / NBRG	Appendix A, page 14, “Method of Conformity”, first sentence	Ed	In section on method of conformity add (recognized)	The manufacturer should name the title and reference of the <i>recognized</i> standard(s), industry or in-house test method(s)...	Accepted. Appendix A modified.
113	ABHI	Annex A	Te	See point #7 above:	Delete para 3 last sentence (“The consistent use of this template ..”) and replace with:	Not accepted.

			<p><i>If the EP Checklist is used exactly as it is, it will be harder for CE Marking manufacturers and their RA/NB assessors to ensure that each of the 14 MDD Essential Requirements has been met, since the two checklists are by no means identical. The Guidance should accept that where the Regulatory Authority has provided an alternative list of principles or requirements to be met, an alternative Checklist should be used, based on those specific regulator's Essential Principles or Essential Requirements.</i></p> <p>Need to provide for EP checklists more in line with specific regulator's requirements, such as EU MDD.</p> <p>The last sentence is true in an ideal world, but in practice very many manufacturers have to provide a MDD Essential Requirements Checklist which is of identical function but different in a lot of detail. It should be stated that an EP Checklist based on specific regulator's requirements is equally acceptable.</p> <p>It may be argued that making the change I have suggested would undermine harmonization. But all the main body of the Guidance will still be useful and valid. The extent</p>	<p>“In cases where a regulatory authority requires additional or different information, or information in a different format/order, an equivalent EP Checklist may be used based on these requirements.</p>	<p>GHTF guidance documents represent a target for <u>eventual</u> harmonisation (see Introduction).</p>
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		Checklist”, second heading and table header				problem.
118	MEDEC	Page 19, Appendix A, Essential Principles Checklist, Sect. 5.8.9	Te	<p>Confusing text > <i>Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated</i></p> <p>I don’t believe that manufacturers stipulate a “level of cleanliness” for non-sterile devices)</p> <p>Also confusing text:</p> <p><i>the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.</i></p> <p>the packaging system used for the transport of the unsterile device would not be the same package used by the end customer for sterilization</p>		<p>Not accepted since the EPs have been extracted from a separate document.</p> <p>Bookmarked for next review of <i>Essential Principles of Safety and Performance of Medical Devices.</i></p>
119	JFMDA (Morooka)	Page 14 to 25, Appendix A, Essential Principles Checklist the columns	Ed	A new column may named	Essential Principl <u>e</u>	Accepted.
					General Requirements	Appendix A modified.
					<ul style="list-style-type: none"> Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, 	

