Document: Consolidated comments on SG1(PD) /N015 Document Title: Principles of Medical Device Classification

ISSUE 2 of 22/03/2006 with outcome of discussion added on 28-30 March 2006

Comment Number	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	SG Decision (28 to 30 March 2006)
1.	Whole document	Technical	Rewrite document such that it is not based on generic rules but assigns risk classes to specific devices and then allow for adjustment after evidence has been collected on safety (see letter of 2 February 2006 for rationale).	None offered	Not accepted. It is not considered practical to establish and maintain a list-based system Also, there is experience that a rules-based system is flexible to the acceptance of new devices/technology. Also, even a list-based approach is underpinned by informal "rules".
2.	Throughout Document	Ed	Instead of using the term "rule(s)", which implies/(y) legal regulatory requirement(s) of public notice and comment prior to implementation of a regulatory requirement, consider using the term principle(s).	Replace throughout the document the term "Classification Rules" to "Classification Principles" or something along those lines to avoid using "rule(s)" language in a guidance document suggest using "principle(s)".	Not accepted. The Preface to this document makes it clear this document is non-binding guidance.
3.	Page 4 / Section 1.0	Editorial	**Comment:** Recommend the addition of a statement for industry to consult with their local RA regarding their requirements. **Rationale:** The current text only alludes to the need to consult with local RA. This should be made explicit for efficiencies and post-market surveillance requirements.	"Industry is reminded to consult with local regulatory authority (RA) for local regulatory requirements and the application of this guidance document to their regions."	Not accepted. Already covered in Section 6.1 bullets #5 and #7.
4.	5	Technical	While the content of the paragraph is correct, it leaves an unanswered question – what about		Accepted:

	Scope		IVD's Suggest there should be a short reference to separately developed documents to cover IVD's, and possible they IVD documents should be cited as references in Section 3.0		Add: ……for which a separate document is being developed.
5.	Page 5 Section4.0 / Line 4	Technical	"for more than 30 days" should be added to the end of the sentence. In order to specify that the device must remain in place for greater than 30 days since this is part of the definition of an implantable device.	""….., and which is intended to remain after the procedure for more than 30 days."	Decision: Delete definition of "Active Implantable Medical Device"
6.	5 Section 4.0 Definition of Active medical device	Editorial	Insert comma after Any	Any medical device, …….	Accepted.
7.	Page 5 / Section 4.0 / Line 6	Editorial	A comma should be added after the word "device" and the word "the" should be added before the word "operation". Proper grammar requires a change to the sentence structure as it is written currently.	"Active medical device: Any medical device, the operation of which depends…."	Accepted.
8.	6 Section 4.0 Definition of Active therapeutic device	Editorial	Replace therapeutical with therapeutic	Therapeutic	Accepted. Word search to find all examples and correct.
9.	Page 6 / Section 4.0	Technical		**Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary	Modify definition by adding after "aorta":- " (includes all segments of the aorta)"

				arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aortic arch and the thoracic and abdominal aorta, inferior and superior vena cava.	Also deleted:- "renal arteries and common iliac arteries"
10.	Page 6 / Section 4.0	Technical		**Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, the thoracic and abdominal aorta, inferior and superior vena cava, renal arteries and common iliac arteries." [Ed: For completeness, we might want to state that the definition is exclusive of vessels in the limbs.]	Not accepted. Proposed additional statement is not required.
11.	Page 6 / Section 4.0	Technical		**Central circulatory system:** For the purposes of this Directive, `central circulatory system' means the following vessels: arteriae pulmonales, aorta ascendens, arteria coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteria cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.	This is not a comment as such and may be ignored. Definition extracted from the existing EU regulations.

12.	Page 6 / Section 4.0	Technical		**Central Cardiovascular System:** Means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachycephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries.	This is not a comment as such and may be ignored. Definition extracted from the existing Canadian regulations.
13.	Page 6 / Section 4.0	Technical	"Common carotid arteries" does NOT include the "internal carotid artery" which is badly missing! So we propose to delete the word "common", so it remains "carotid arteries" which include the "internal carotid artery".	**Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, celiac trunc, jugular vene, renal arteries and common iliac arteries.	Accepted but add: (Common, internal and external) after carotoid artery. Final definition becomes:- **Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.
14.	Page 6 / Section 4.0	Technical	Definition of central circulatory system greatly exceeds current definition in EU MDD (does not include ileac arteries or renal arteries) and Australia TGA (does not include renal arteries). Health Canada Regulations do not define “central circulatory system”, but “central cardiovascular system” (definition consistent with text of this document). This lack of harmonization in definition creates significant	**Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries,	Accepted. Final definition agreed as in comment 13.

			classification differences for many medical devices, since contact duration with the central circulatory system is a key determinant to risk classification. Expansion of this definition will cause many stapling, clip and other devices to be reclassified from risk category 3 to 4.	cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava and common iliac arteries.	
15.	Page 6 Definition of "Central circulatory system"	Technical	Remove renal arteries from definition of the Central Circulatory System		Accepted. Final definition agreed as in comment 13.
16.	Page 6 Definition of "Central circulatory system"	Technical	The listing of the carotid arteries is expanded from the common carotid arteries (as in the current SG1 version) to the external and internal carotid arteries which originate at the bifurcation of the common carotid arteries (as in the current definition of Directive 93/42/EEC). This makes sense because also the cerebral arteries are listed in all definitions. Also, the current SG1 definition only mentions "aorta". In order to avoid any misunderstanding, the different sections of the aorta should be named: ascending aorta, aortic arch, descending aorta to the aortic bifurcation (which comprises the thorassic and the abdominal aorta).	**Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, ascending aorta, aortic arch, descending aorta to the aortic bifurcation, external and internal carotid arteries, inferior and superior vena cava.	Addressed (see comment 13 above)
17.	6 Section 4, Definition of Duration of Use - long term	Technical	Amend **Note** to indicate duration of continuous use considers the accumulation of discrete uses of a medical device to be continuous, and not each discrete use in isolation. There is some confusion whether a number of discrete uses of the same device are considered multiple 'continuous' uses of the device, or whether they multiple discrete uses of the device	In calculating duration of continuous use, it is the both discrete use and accumulation of discrete uses of the same device for its intended purpose which must be considered. Where the reason for any interruption is to replace a failed or failing device with one that has the same intended purpose	Replace existing NOTE with: NOTE: For the purpose of this document, continuous use means: a) the entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.

			accumulate to reflect 'continuous', e.g. multiple uses of a scalpel, or multiple uses of a suction catheter during a procedure …..	(e.g. replacement of a urinary catheter), this should be regarded as an extension of continuous use	b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type. Also remove contact lenses as an example in the table as Class B device under Rule 5. **Bookmark** in the minutes that when this document is first revised, the classification of contact lenses should be reviewed.
18.	Page 7 /Section 4.0 / Line 25 Reusable surgical instrument	Technical	The word "similar" should be removed and the words "other surgical" should be added in its place. Remove the word similar which is not specific enough. As well, this allows for the acceptance of any non-active, reusable surgical tool that is not specifically mentioned in the list of actions (e.g. cutting, drilling, sawing, etc)	"Reusable surgical instrument: Instrument intended … retracting, clipping or other surgical procedures, without connection to…."	Accepted – replace 'similar' with 'other surgical' in definition
19.	Page 8 Section 5, General Principles Final paragraph	Technical	'degree of innovation' does not necessarily reflect in risk presented by a medical device	Remove '…degree of innovation….' From the sentence	Modify paragraph to start: The risk presented by a device also depends, in part, on its intended user(s), its mode of operation, and/or technologies. In general, the classification rules are intended to accommodate new technologies.
20.	Page 9 / Section 6.1 / 4th, 6th, and 8th bullets	Technical	• The initial determination of class should be based on a set of rules derived from those features of devices that create risk. In most cases the initial rules based classification will also be the final classification. • The rules should be capable of	It appears that a method of reclassification should be sought and developed for future revisions as an action item.	No decision at this time. **Bookmark** for consideration at the first revision of this document, a procedure to change modify classification (either up or down) of a device when new evidence emerges.

			accommodating future technological developments. • Decisions on final classifications, which deviate from the initial rules-based classification, should be weighed against the disadvantages of disharmonized international classification.		
21.	Page 9 Section 6.2	Technical	There is confusion with regard to classification of software when supplied alone as a medical device (not the software inherent in the operating system of most electromedical devices) Suggest adding statement clarifying that, for the purposes of classification, software is considered an active medical device – because is needs a computing platform which depends on a source of energy and acts by converting that energy …..	For the purposes of classification, standalone software, when supplied as a medical device is considered to be an active medical device.	Accepted Add after paragraph starting "While most software etc.:" Standalone software (to the extent it falls within the definition of a medical device) is deemed to be an active medical device.
22.	Page 9 Section 6.2, last bullet point on the page	Technical	Procedure packs do need to be classified, for the purposes of preparing a DOC, and where necessary for entering on to National Registers of Medical Devices	Do not have any draft words, but underlying principle for classifying procedure packs is to ♦ 'exclude' any medicines from the pack ♦ Consider all devices in the pack and their intended purpose in the pack (not necessarily the intended purpose attributed by the OEM) (e.g. a hypodermic needle (Class B) may only be a Class A if used as a mixing cannula) ♦ Pack takes on the class of the highest classified	Substitute at end of bullet 2: …… the 'classification allocated to the assemblage for the purpose of a Declaration of Conformity is at the level of the highest classified device included within it'.

				device in the pack	
23.	Pages 9-10 / Section 6.2	Editorial	**Comments:** As proposed, a device may be classified differently by different regions despite using a harmonized classification model. This is based on the intended use, what post-market surveillance information a RA chooses to act upon and a RA's health system (e.g. reimbursement schemes, demographics and inclination for off-label use). It is therefore recommended that a statement, specific to industry is provided to inform them that despite harmonization, devices may be classified differently. **Rationale:** Industry members may expect devices to be classified the same in every region, which may compromise the quality or quantity of information required to support any required pre-market review in a given region.	See "Comment and rationale".	Not accepted. It is generally understood that national regulations may differ from some aspects of any GHTF document. It is unnecessary to repeat this point again.
24.	Page 9 / Section 6.2	Ed	Factors Influencing Device Classification -	Suggest revising the third full paragraph to say that this may involve combination products and some regulatory authorities may have different regulatory approaches for such products.	Not accepted. Existing document deals adequately with this subject. See Section 8.1 and change to the rationale for Rule 13 (Page 20)
25.	Page 10 Section 6.2	Editorial	Para at top of page needs a bullet point because it is a further sub-part of the preceding para	♦	Accepted
26.	Page 10 Section 6.2 second para on page – addresses	Technical	Accessories should be treated as medical devices for the purpose of classification and assessment, but should not be considered medical devices in their own right. This one is easier to explain than document, but	Accessories to medical devices are not medical devices, but are treated as medical devices for the purposes of classification and conformity assessment.	No change at this time. **Bookmark** for consideration at the first revision of the Medical Devices Definition document.

	accessories		without this qualification, accessories to accessories to accessories ……. means the chain never ends and all are considered medical devices !!! E.g. –x-ray film > processor > water filter in plumbing > tap in plumbing, etc, etc. This principle breaks the chain, for the example above, at the film processor, and means the plumbing fixtures are not captured.	I know it sounds obtuse, but …. We can talk about it on the day !!!	
27.	Page 9 / Section 6.2 / Para 6	Technical	The two sentences in this paragraph do not appear to be consistent with one another. The first sentence says that the accessory associated with another device is classified with that device. The second sentence says that the accessory may be classified on its own. This implies that the accessory might not be given the same classification as the parent device. Accessories that are sold only with a parent device should be classified with the parent device. Accessories that are sold separately, but are used with another device should be classified on their own. The second sentence should be changed to add the words “”that is sold separately” after the words “…an accessory”	“For classification purposes, an accessory that is sold separately is classified as though it is a medical device in its own right.”	Addressed by modifying the paragraph in question. The first sentence now reads:- Accessories intended specifically by manufacturers to be used together with a ‘parent’ medical device to enable that medical device to achieve its intended purpose, should be subject to all the GHTF guidance documents as apply to the medical device itself (e.g. Essential principles for Safety and Performance, post-market surveillance etc.).
28.	Page 10 / Section 6.2 / Line 10	Tech	1. There is no rule that addresses stand alone software, which would appear to mean that it falls under rule number 12, and is a Class A device. As a Class A device, it would not require design and development. 2. Also, we are concerned that devices which contain software but are Classified as Class A or B would not be subject to design and development.	Suggest that language be added to the classification document which states that stand-alone software will be handled according to its intended use – e.g. software intended to map the face in order to make a patient fitted CPAP device would be classified as a Class B device under Rule 2.	Issue 1 addressed on a previous comment (see comment 21). Issue 2 - not accepted.

				We also recommend the addition of an asterix to the conformity assessment tables which states that all devices containing software are subject to design and development.	
29.	10 of 28 Section 6.2 3rd para on page, first bullet point	Technical	Refer to my comment No 7 This may be a more appropriate place to put clarification on classification of software		Comment withdrawn.
30.	Page 9 Section 6.2 3rd para on page, first bullet point	Technical	Disagree – By default, any medical device is a class A unless raised to a higher class by another rule. Thus a PC for example would be a class A. However when loaded with software that takes on a diagnostic function, it becomes an active medical device for diagnosis and Class B at least – Rule 10	Where software which is a medical device is used to drive or influence the use of a separate medical device, the classification of either the software, or the combination of the two devices, will take on the highest classification afforded to each of the devices individually.	Addressed by modifying bullet 1 to read: • Where it drives or influences the use of a separate medical device, it should be classified according to the intended use of the combination.
31.	Page 10 Section 6.2 4th para	Technical	The para should be removed – encourages local classifications	Delete	Accept - delete
32.	Page 10 Section 6.2 final para	Editorial	Addition of the word 'are'	…. regulatory controls applied to a medical device are proportionate to risk.	Accepted.
33.	Page 10 / Section 6.2 / Line 25	Tech	Experience gained from the clinical use of a particular type of medical device may suggest that the rules appearing in Section 8.0 of this document are inappropriate. Current GHTF procedures require that all GHTF documents be reviewed at regular intervals. Such a review of this document will provide any participant with an opportunity to suggest a change of text that,	It appears that a method of reclassification should be sought and developed for future revisions as an action item.	**Bookmark** for consideration of a procedure to reclassify a device at the first revision of this document.

			in their opinion, will address any shortcoming.		
34.	Page 10 /Section 6.2 / para 3	Technical	The last sentence is too broad and suggests that the issue is prior regulation not prior use. As written it doesn't speak to the risk but to the market in which the product is used.	The first introduction of complex novel device technology to a country may require a higher level of oversight but the risk classification should not be based on the market in which the product is introduced.	Addressed by deleting the paragraph (see comment 31).
35.	Page 10 / Section 6.2 / Line 15	Technical	This paragraph is not in line with the intention of harmonization. By allowing regions and countries to individually evaluate the risk classification, rather than following the general GHTF classification rules implies that for any new technology, there may be different classification decisions made in different constituencies. This should be removed from the guidance document and regions and countries encouraged to conform to the global classification rules. If this principle is not encouraged, there will be no global harmonization of classification rules.	Remove the 4th paragraph on this page completely.	Accepted (see comment 31).
36.	Page 11 / Fig 1	Technical	Not all implants for a given use like orthopaedic implants are of equal risk – there needs to be flexibility.	Recommend changing examples that do not overlap classifications.	Accept - Delete orthopaedic implant and substitute bone fixation plate
37.	Page 11 / Fig 2	Editorial	The order in which the regulatory controls are listed should be meaningful	Suggest reordering: 1,3,4,2,5,6	Accept
38.	Page 12 Section 7.0, item 2	Editorial	Additional words '.. and document..'	'Determine and document the intended use of the medical device	Accept also delete "determine and" Becomes: Document the intended use of the medical device
39.	Page 12 / Section 7.0 / Line 25	Tech	NOTES: Once a rules-based system has been adopted, modifications may occasionally be required. For example, where through post-market experience, a level of risk for a type of	It appears that a method of reclassification should be sought and developed for future revisions as an action item.	Accept. **Bookmark** for consideration of a procedure to reclassify a device at the

			medical device, classified using the criteria found in this guidance document is no longer appropriate, consideration should be given to re-classification by a change to the rules. Similarly, the historical knowledge of a device may necessitate a different class than the one assigned by the initial classification. Unlike the principle of reclassification after post-market experience with a device, this principle of historical knowledge should be applied immediately by RA/CAB when the initial classification yields an inappropriate result.		first revision of this document.
40.	Page 13 / Section 7 /NOTE	Technical	Not all reclassifications change the rules.	Recommend changing the end of the sentence to read: "consideration should be given to change to the class of a product."	Addition of recommended text not accepted.
41.	Page 13 / Section 7.0 / Line 13	Technical	In the case of products that are composed of a medical device and a non-medical device component (drug /or tissue), the classification of the product should be done based on the separate consideration of the two components. That is, the device component should be classified as if it is a stand alone device and the drug or the tissue component should be required to meet their separate regulatory requirements. (See also comments on section 20/8.0/22)	Add another paragraph to this section that conveys this interpretation.	This is a multi-faceted problem. **Bookmark** to consider combination products at a later date (possible new work item).
42.	Page 13 Section 7, item 4	Editorial	Reword to make more positive in meaning	Determine if the device is subject to special national rules …..	Accepted.
43.	Page 13 Section 7, Note to Item 4	Editorial	Additonal words '…of the device type..' in last sentence	'…. Consideration should be given to re-classification of the device type by a change to the rules.	Accepted

44.	Page 13 Section 8, 1st para	Editorial	Remove the word 'precise' from the first sentence.	Delete 'precise'	Accepted
45.	Page 13 Section 8, 2nd para	Editorial	Relocate to section 6.2 – Factors affecting classification, and reword. 6.2 is more appropriate for this sort of overarching statement.	If, based on the manufacturer's intended purpose, two or more rules apply to the device, the device is allocated the highest level of classification applying under those classification rules.	Accepted Modify Section 6.2 second paragraph to read:- If, based on the manufacturer's intended purpose, two or more classification rules apply to the device, the device is allocated the highest level of classification indicated. Delete paragraph in Section 8.0
46.	Clause 8.0	Technical	This guidance document is intended to describe principal of medical devices classification, and it is not intended to specify the classification for each product. Therefore, we think that "Example" in the table is a sample for understanding the classification rule, and it does not specify the class. In actual, the classification will be introduced and specified into each jurisdiction according to this guidance document. We think that "Example" should be deleted or might be remove into appendix as Final Document. In the other guidance documents, such example or national deviation is described in the appendix.	We suggest deleting "Example" in the table, or remove them into the appendix.	Not accepted at this time. There was general agreement that the examples were helpful to understanding the rules. However, the devices selected as examples should be uncontroversial. Also, the first paragraph in Section 8.0 describes the role of the examples provided in the table. **Bookmark** to consider moving away from a tabular layout at the first revision of this document..
47.	Page13 / Section 8.0 Rules 1 & 2	Tech	Both discuss devices for storage of blood with different categorizations. One says these devices are outside the scope of the rule, the other says they are either class A or B. The table says certain blood bags are class C. This needs clarification with regard to blood bags used in transfusion before we can make informative comments.	Blood bags that are used to freeze blood and blood components should be regulated as Class C, because cryopreservatives may be used and may affect the bag and the component. Blood bags/containers used to store	Accepted (see comment 48).

				blood for transfusion or further manufacturing should be regulated as Class C. Blood bags/containers that have a medicinal product (e.g. anticoagulant) used to store blood for transfusion or further manufacturing should be Class D or regulated under other authorities.	
48.	Page 13 Section 8 Rule 1, Note to rule 1 and Rule 2	Technical	These two rules and the associated note leave much confusion in relation to blood bags. They made a lot more sense when the rule made blood bags, by derogation, Class C. That rule, however, was removed. Blood bags containing anti-coagulant, etc are special cases and we need to be explicit that rule 13 applies to these products	Re-instate the special rule – A medical device which is a blood bag is Class C Add blood bags with a medicinal component to the examples for rule 13	Accept. Add an additional "unless" to Rule 2 that says:- "Unless they are blood bags, in which case they are Class C." Also clean up other references to blood bags from the Notes to clarify. Also, in order to improve interpretation, exchange existing Rules 1 and 4. Delete the NOTE to new Rule 4. Modify the charts to suit.
49.	Page 13 Section 8 Rule 1, Note to rule 1	Technical	Can somebody shed some light on the last part of the note which describes '…… generating energy that is delivered to the body' What types of devices are we trying to exclude here. Devices which deliver energy to the body are class B by rule 9		New Rule 4 (see comment 48) Accept – delete as suggested.
50.	Page 13 / Section 8.0 Rule 2	Tech	Blood bags intended to store blood for transfusion with anticoagulants or other chemicals may need to be regulated differently.	Identify that Rule 13 applies – Class D	Blood bags addressed through a special sub-set of the Rule (comment 48). Blood bags of this type are added to the examples in Rule 13.

51.	Page 13 / Section 8.0 / Rule 2	Tech	Rule 2 classifies syringes as Class A devices, not subject to design and development. Syringes can have sophisticated design features and probably should be subject to design and development.	Modify to be Class C devices or identify Class B but subject to design and development.	Not accepted. After discussion, SG1 confirmed that existing rules are adequate for this device.
52.	Page 14 / Section 8.0 / Rule 3	Tech	Rule 3 states if treatment involves heating, etc. the device should be Class B (not Class C). CBER regulates blood warmers and similar devices. Based on risk, these devices have been regulated at more stringent criteria - i.e., needs design & development and review; i.e., Class C. Also blood warmers include "thawing" devices and they should be class C	…treatment consists of filtration, …or exchanges of gas or of heat, in which case they are in Class C. Blood warmers involving microwave devices should be class C. blood warmers include "thawing" devices and they should be class C	Not accepted. Most blood warmers also covered by existing Rule 9 since they are active devices. Most Regulatory Authorities regulate warmers as Class B. Remove example from Rule 3.
53.	Page 14 Rule 4, para commencing with **unless …**	Technical	Experience suggests we need a definition for 'secondary intent'.	Healing by secondary intent occurs when there is no direct apposition of the wound edges. To close the wound, new tissue (granulation tissue) must be formed in the base of the wound. Once this tissue has been formed, epithelial cells proliferate and migrate across the surface of the granulation tissue to cover the wound and repair the surface defect."	New Rule 1 (comment 48) Add to the notes column: To close the wound, new tissue must be formed within the wound prior to external closure. Also add "primary intent" to rule.
54.	Page 15 / Section 8.0 / Rule 5	Tech	Rule 5 classifies dental restorative materials as Class B even though these devices characteristically have multiple effectiveness claims, and there raise safety issues with respect to certain materials, e.g. mercury.	We suggest that rule 5 be changed that dental restorative materials are classified into Class C.	Note that Rule 8 applies <u>not</u> Rule 5. Not accepted: Concerns about mercury addressed through *Essential Principles of Safety & Performance* document and through the manufacturer's risk assessment.

55.	Page 15 / Rule 5	Technical	The proposed classification places continuous wear contact lenses into Class C (moderate-high Risk). This is contrary to current classification schemes such as the EU MDD. This classification contradicts the definition for long term use (pg 6), which is normally intended for continuous use for more than 30 days.	Contact lens device classification should be made according to the risk associated with the intended use. Contact lenses worn for less than 30 days without removal for cleaning and disinfection should be considered Class B devices and Contact Lenses worn for greater than 30 days without removal for cleaning and disinfection should be considered Class C devices. The comment "(for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use)" should be removed. Replace with "(long-term continuous use is defined as being worn on the eye for greater than 7 days without removal for cleaning or maintenance)"	Not accepted as proposed. Dealt with by modifying the NOTE to the definition of Duration of Use (see comment 17).
56.	16 of 28 Rule 6	Technical	It was proposed by Japan, and agreed by SG 1, in Morges in 2005 I believe, that all transient use devices intended specifically intended for direct contact with the central nervous system were to be class D	Add a further **unless** …. Unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D	Accepted. Add: Unless they are intended specifically for use in direct contact with the central nervous system, in which case they are Class D. Modify flow chart for Rule 6 to suit.
57.	Page 16 / Section 8.0 / Rule 6	Tech	-- unless they are reusable surgical instruments, in which case they are in Class A; This is an exception that may not be acceptable depending upon whether it is intended to address Re-use of multiple use device used in neurological applications or Re-use of single use devices.	Clarify limitations and make Re-use of multiple use device used in neurological applications or Re-use of single use devices to be Class C.	Not accepted. SG1 does not believe this document is appropriate to address the topic of reuse of single use devices.

58.	Page 16 / Section 8.0 / Line 28 / Rule 6 third "unless"	Technical	The words "material or" should be added in front of the words "…resulting degradation products…" In some cases, (ophthalmic intraocular gases for instance), the material itself (the gas) is gradually absorbed into the bloodstream and then eliminated by the body virtually unchanged (not metabolized or broken down by degradation. These gases are very inert and non-reactive and are simply eliminated via the lungs and kidneys).	"…The term "absorption" refers to the elimination of a material or of the material's resultant degradation products from the body."	Addressed by adding an additional NOTE.
59.	Page 16 / Section 8.0 / Rule 6 Page 17 / Section 8.0 / Rule 7 Page 18 / Section 8.0 / Rule 8	Ed	the third "unless" – "devices" are not products "intended to have a biological effect or be wholly or mainly absorbed," these appear to be more drug-like than device-like	Suggest revising the box to say ""in which case, they are in Class C, if regulated as through the device authorities (see Note); we also suggest an accompanying note to say: "In some jurisdictions, such products are regulated as medicinal products." (or something like this). Please note there is similar language in other places in the document. Suggest similar revisions there (e.g., page 17, rule 7, the 4th "unless"; page 18, rule 8, the 5th "unless").	Not accepted.
60.	Page 18 Rule 9	Editorial	Replace the word therapeutical with therapeutic	All active therapeutic devices …..	Accepted - also scan document for other occurrences.
61.	Page19 Clause 8.0 Rule10	Technical	For X-ray Diagnostic devices, if it is complied with ICRP (International Commission on Radiological Protection) Pub 60 or 33 or IEC Standards (e.g. IEC60601-1-3), their risk level is controlled, and they are considered as Low-moderate Risk. Therefore, we propose to add the note for such	We suggest adding the following note; Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or	Not accepted. This was not seen as an acceptable method of addressing the wish to down-classify these devices. Views have not changed since this subject was discussed at length previously and

			exemption.	those which directly influence their performance, are in Class C. Note: X-ray Diagnostic devices that comply with ICRP (International Commission on Radiological Protection) Publication 60 or 33 or with IEC Standards (i.e. IEC 60601-1-3:1994 Medical Electrical Equipment - Collateral Standard – Part 3 Collateral Standard: General Requirements for radiation protection in diagnostic X-ray equipment) are in Class B.	disagreement remains on the classification of this device type. **Bookmark** for consideration again at first revision of this document.
62.	Page 20 / Section 8.0 / Rule 11	Tech	The rules are very cumbersome and in some instances are highly subject to interpretation, e.g., Rule 11: unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, or the part of the body concerned and of the mode of application, in which case they are in Class C.	To simplify and remove chance for interpretation, we suggest that rule 11 be changed to all to be classified into Class C.	Addressed by changing examples such as:- Examples of Class B devices: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous. Also modify second part of rule to read: **unless** this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.
63.	Page 20 / Section 8.0	Tech	Needle disposal and needle destruction devices are not addressed by the rules, and so would likely be classified under rule 12 as Class A	We would recommend that Needle disposal devices be Class C and needle destruction devices be Class	Not accepted. These products are not medical devices

	/ Rule 12		devices. These devices play an important role in preventing disease among health care workers. Needle destruction devices, in particular, can generate toxic substances and aerosolized micro-organisms and can generate sparks.	D devices.	when the definition of a medical device is applied to them.
64.	20 of 28 Rule 13	Technical	Add note to table	**Note:** The medicinal component of these types of combination devices may be required to comply with the regulatory framework for medicines, applicable to the jurisdiction(s) in which the manufacturer intends market the device.	Addressed by adding a note (see comment 65 below)
65.	Page 20 / Section 8.0 / Rule 13	Ed	13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D. These devices cover combination devices that incorporate medicinal substances in a secondary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound. – Currently some are Class II others are Class III for FDA but could consider higher classification into Class D.	Suggest revising the last phrase in the rule box by replacing "are in Class D" with "are in Class D, if regulated as through the device authorities" (see Note); Also suggest an accompanying note to say: "In some jurisdictions, such products are regulated as medicinal products or through other regulatory controls." (or something like this).	Add: NOTE: Such medical devices may be subject to additional conformity assessment according to the regional or national requirements of medicinal product Regulatory Authorities.
66.	Page 21 / Section 8.1 / Rule13 Rationale	Technical	Rule 13 states that risk classification could be based upon the public perception of risk. Risk classification principles should be based on sound science and not perception.	Recommend that the third bullet under rule 13 be deleted.	Accept. Also delete or modify any similar statements in Rules 14, 15 and 16.

67.	Page 20 / Section 8.0 / Line 22 / Rule 13	Technical	This section needs to be modified. By classifying all drug containing devices into Class D, many existing simple devices would be changed to Class D when this is not justified. For instance, a simple sodium fluorescein impregnated paper strip for staining the cornea would be classified as a Class D product under this proposed guidance. Currently, such products are classified as Class B. As mentioned above, the device component of any "combination product" should be evaluated as a device in its own right. In the case of the sodium fluorescein impregnated paper strip, the device is in contact with the surface of the eye and is a transient use device. Therefore, the proper (and current in Canada) classification should be Class B.	A new paragraph should replace the current one.	Not accepted.
68.	Page 20 Rule 14	Technical	There is much confusion regarding animal material rendered non-viable, and its appropriate classification. We believe the intent of the rule is to capture animal origin material which has to be rendered non-viable, to allow assessment of the process which renders the material non-viable, process residues, endotoxins, TSE potential, etc. It is not intended to capture animal origin material which, by its nature does not need to be rendered non-viable because it was never viable in the first instance – e.g. silk sutures, milk derived materials such as caesin used in toothpastes which make claims beyond oral health, beeswax, stearates used as catheter lubricants,etc Of more recent times, devices containing new	Amend the rule to read – All devices manufactured from, or incorporating animal or human cells/tissues/derivatives thereof, whether viable, or have been rendered non-viable, are Class D. It would also be prudent to add a note to the effect animal origin materials which have not needed to be rendered non-viable are not covered by this rule. The paragraph relating to …non-viable… intact skin class A still applies to those products.	Not accepted. **Bookmark** for discussion at first revision or discussion as a separate work item.

			materials, particularly of recombinant origin, genetically modified material, or materials of microbial origin have caused some concern, in part because of the imprecise nature of the manufacturing processes, process residues in the finished product, and the unknown nature of potential long term effects on patient safety, especially for implanted devices.		
69.	Page 20 / Section 8.0 / Rule 14	Ed	14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D, **NOTE**: In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts. Examples: porcine heart valves (Class II); catgut sutures (Class II). Currently some are Class II others are Class III for FDA but could consider higher classification into Class D.	Revise the last phrase in the rule box by replacing "are Class D" with "are in Class D, if regulated as through the device authorities (see Note).	Proposed change not accepted. However, the bullet point in the rationale for this rule (Section 8.1) is modified to read:- 'The possible risks associated with the transmission of infectious agents through materials used in such devices, e.g. Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD), demand a high classification.'
70.	Page 20 / Section 8.0 / Line 29 / Rule 14	Technical	Similar to the comment above, "combination products" made up of a device component and a tissue component, should have the device component classified on its own merits and characteristics. Most RA's around the world have decided to classify minimally processed tissue products separately from medical devices	This paragraph requires re-writing to remove the automatic requirement of a Class D classification on any tissue containing device. Medical device classification of combination products should be made on the	Not accepted. **Bookmark** for discussion at first revision or discussion as a separate work item.

			and regulate them separately. Therefore, medical device classification rules should not apply to the tissue component of such combination products. For instance, an amniotic tissue membrane, attached to an eye conformer should have a medical device classification based on the eye conformer alone. Obviously, the tissue component would have to meet the tissue guidelines and regulations where the product is sold. As a result, the eye conformer would be classified as a Class II (GHTF Class B) in the USA since eye conformers are Class II in that jurisdiction, and Class III (in Canada (Class IIb in the EEC) since these conformers may be left on the surface of the cornea for more than 30 days. To impose the tissue regulations/classifications (Class D) on products that have been judged not bo be tissues for the purposes of the medical device regulations (as in the case of minimally processed tissue) is inconsistent and illogical.	basis of the medical device component of the product alone, recognizing that other regulatory requirements will adequately control the tissue component of the device.	Also, see comment 68.
71.	Page 20 Rule 15	Technical	Split classification of disinfectants for medical devices in to two classifications Consistent with applying a higher level of scrutiny to devices which are used to disinfect invasive devices with consequent higher infectivity risk, over non-invasive devices	All devices intended specifically to be used for disinfecting or sterilising medical devices are Class B **Unless** they are intended for disinfecting or sterilizing invasive medical devices, in which case they are Class C	Not accepted as proposed. Modify Rule 15 to read: Rule 15: All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class C. **Unless** they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class B Modify the flow diagram to suit.

					Review the examples given.
72.	Page 20 / Section 8.0 / Rule 15	Tech	Rule 15: All devices intended specifically to be used for disinfecting or sterilizing medical devices are in Class B. This means that washers-disinfectors, liquid chemical sterilants, sterilizers, chemical or biological indicators, or disinfectants for hemodialyzers are not subject to design controls. This is not adequate.	We suggest that rule 15 be changed that all devices intended specifically to be used for disinfecting or sterilizing medical devices are classified into Class C	Addressed above through comment 71
73.	Page 21 / Section 8.0 / Line 2 / Rule 15	Technical	Some differentiation needs to be made between devices intended for sterilizing devices (e.g. autoclaves, ethylene oxide retorts) and simple accessory products that are used in the sterilization process (e.g. sterilization tray).	Addition of "sterilization trays and associated equipment" should be added to the list of exceptions to this rule. Such devices should be considered to be Class A.	Not accepted. Sterilization trays are an accessory and in Class A
74.	Page 21 / Section 8.1 / Line 6 Rule 13 Rationale	Ed	Devices incorporating a medicinal product • The regulations applying to medicinal products require different acceptance procedures to those for medical devices. • The behaviour of a medicinal product used in conjunction with a medical device may differ from that covered by its approved use as a medicine alone. • The public perception of possible risks associated with such devices demands a high classification. Currently some are Class II others are Class III for FDA but could live with higher classification into Class D.	Suggest revising the last phrase in the rule box by replacing "are in Class D" with "are in Class D, if regulated as through the device authorities (see Note); Also suggest an accompanying note to say: "In some jurisdictions, such products are regulated as medicinal products or through other regulatory controls." (or something like this).	Suggested addition to the rule is not accepted. The suggested change to the accompanying note has been addressed.
75.	Page 22 / Section 8.1 / Rule 14 Rationale	Ed	Devices incorporating animal or human tissues • There is an absence of global regulatory controls for such devices. • Classification needs to acknowledge the many different ethical and religious cultures throughout the world have an opinion on such devices.	Suggest revising the last phrase in the rule box by replacing "are Class D" with "are in Class D, if regulated as through the device authorities (see Note).	Suggested addition to the rule is not accepted. The wording of the accompanying note is considered adequate.

			• The public perception of possible risks associated with such devices, particularly after the problems caused by Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD), demands a high classification. FDA has many HTCP and animal based products are Class II and others Class III but could live with higher classification into Class D.		
76.	Page 20 Rule 15	Technical	Split classification of disinfectants for medical devices in to two classifications Consistent with applying a higher level of scrutiny to devices which are used to disinfect invasive devices with consequent higher infectivity risk, over non-invasive devices	All devices intended specifically to be used for disinfecting or sterilising medical devices are Class B **Unless** they are intended for disinfecting invasive medical devices, in which case they are Class C	Addressed through a change to the rule as described in comment 71 above.
77.	Page 21 Rule 17	Technical	At a previous meeting, a rule classifying non-active devices for recording of x-ray images as class B was deleted. The consequence of this deletion is that there are no mandatory QMS requirements for the manufacture of x-ray film – they have become Class A devices. Consistent quality in production of x-ray film is essential to ensure consistency of film performance and image quality. Of more recent times active medical devices (digital image capture devices) are rapidly becoming the norm in imaging work.	New Rule (or re-instatement of old rule, depending on how you look at it !!) Medical devices specifically intended for recording diagnostic images are Class B.	Not accepted.

			The image captured on either of these devices is often the only basis for a diagnosis, and it is essential the image obtained at the point of capture is of the highest quality achievable bearing in mind the ALARA principles for radiation dosage, and the need to minimise the need for re-exposure because the initial image was inadequate. Both of these devices should be subject to, at the minimum a production QMS. Suggest an additional rule which, by derogation makes these devices Class B to implement an independently assessed QMS in their manufacture. This same principle should also be applied to films used to record diagnostic images not captured using x-ray techniques – e.g. optical film used in laser or multi-format camera's attached to other diagnostic imaging modalities such as ultrasound, CT, MRI, etc		
78.	Page 21 / Table / first Note	Editorial	The note as written applies to contact lens solutions whereas the next note applies to contact lens solutions	The note should read: "This rule applies to products that are intended to clean medical devices other than contact lenses……"	Delete "other than contact lenses from the first note.
79.	Page22	Technical	We propose to add the justification rule to modify the classification where this guidance document introduced into the national regulation in each jurisdiction. In SG1/N40, we already introduced such justification rule. We think that we had better introduce same idea into this guidance document. We referred clause 6.2 in SG1/N40.	We suggest adding the following text:- 8.2 Classification considerations There are situations when characteristics of the device and/or its manufacturer may cause the RA in some jurisdiction, by exception, to modify its requirements relating to classification.	While this approach is appropriate within a conformity assessment document it is not appropriate to device classification. The underlying concern is already addressed within the existing text on Page 4; Page 9 Section 6.1 last bullet; and Page 10 Section 6.2 last paragraph. **Bookmark** for consideration at the first

				For example, the RA may specify the lower class when: ·the device incorporates well-established technology that is present in the market; ·the RA and/or CAB is familiar with the manufacturer's capabilities and its products; ·the device is an updated version of a compliant device from the same manufacturer that contains little substantive change; ·the RA and/or CAB has particular experience with a comparable device; ·internationally recognised standards are available to cover the main aspects of the device and have been used by the manufacturer. Similarly, the RA may specify the higher classification when: ·the device incorporates innovative technology; ·an existing compliant device is being used for a new intended use; ·the device is new to the manufacturer; ·the device type tends to be associated with an excessive	revision of this document, a procedure to modify classification (either up or down) of a device when new evidence emerges.

				number of adverse events, including use errors; ·the device incorporates innovative or potentially hazardous materials; ·the device type raises specific public health concerns. It should be emphasised that there must be a fully justified and documented case before the RA modifies in any way the relationship between device class and the associated conformity assessment procedure.	
80.	Pg. 24 (Appendix A):	Tech	Chart would imply a leukoreduction filter would be Class B; Part 8.0, Rule 3 indicates Class C.	Change chart to show Class C if the device changes blood composition or introduces heat, etc.	Update when document revised.
81.	Pages 24-28	Technical	The diagrams require modification to be consistent with the requested changes.	The diagrams should be modified in order to be consistent with the above requested changes, where the changes are accepted by the Task Force.	Accepted.
82.		Tech	Given the inconsistent handling of assistive reproductive technologies across jurisdictions would GHTF recommend consistent designation and handling across jurisdictions.	None	This comment raises complex issues that will require further discussion within member jurisdictions. If SG1 was to take this up in the future, it would require approval as a new Work Item by the GHTF Steering Committee.