Revision based on Commission Decision COM(2003) 386
to
Directive 93/42/EEC
First Draft

Notes:

1. These proposals are based on the areas identified in Annex V of the Commission communication **and** additional input from Member States and industry. They do not, therefore, represent the Commission Services position and do not commit the European Commission.
2. Some general articles may be realigned depending on the review of new approach directives currently underway and the review of comitology procedures.
3. Comments are invited that promote regulatory convergence through use of GHTF principals and documents.
4. The necessary preambles will be drawn up for the second draft of this document.
5. Comm.Ref. = Reference to the Commission Communication (2003) 386final, MDEG Ref. = Reference to the MDEG Report on the Functioning of the Medical Device Directive of 05.06.2002, G4 = DG Enterprise, Unit G4, MS = Member State(s)

1. Amendment to Biocides Directive

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
1) Exclusion of in vitro diagnostic medical devices from the scope of the Directive covering Biocides.	none	Amend the Biocides directive *Article 1* **Amendments** 1. In Article 1 (2) the following point shall be added: (s) Council Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices ([xx]). [xx] OJ reference	Comm. Ref.: None specific MDEG Ref.: 7.10.3, Action 24

2. Amendments to 93/42/EEC

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
Preamble			
1) Introduce concept whereby device design needs to reflect state of the art	Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;	Two alternatives: Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of placing on the market and of technical and economical considerations compatible with a high level of protection of health and safety; **or** Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and placing on the market and of technical and economical considerations compatible with a high level of protection of health and safety;	MS This may give rise to conflict with the validity period of design approvals.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
		and add to end of recital: With respect to safety requirements for devices set out in the Annexes to this Directive the manufacturer has to observe continuously the development of the state of the science.	
2) Elaborate recital (4) and add new recital (5) to reflect changes to Article 14 b (see below).	Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;	Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices, and to determine conditions for availability of such devices; whereas, therefore, these provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with. Proposed new Recital (5): Whereas, when a Member State considers that, as regards a given product or group of products, it is necessary, in order to protect health and safety and/or ensure compliance with the imperatives of public health, to withdrawn it from the market, or its placing on the market and putting into service should be prohibited or restricted, it may take any necessary and justified measures, whereas, in such cases, the Commission, whenever possible, consults the interested parties and the Member States and, if the national measures are justified, adopts the necessary Community measures in	G4 See also changes proposed to Article 14 b.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
		accordance with the procedure referred to in Article 7 (2).	
Article 1			
3) Use GHTF definition of a medical device	(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;	(a) 'medical device' means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, - investigation, replacement, modification, or support of the anatomy or of a physiological process, - supporting or sustaining life, - control of conception, - disinfection of medical devices, - providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.	G4 This would then lead to deletion of the definition of a in vitro medical device It may also affect the types of products that would be considered accessories
4) Clarify the situation in regard to Personal protective equipment to allow both Directives to apply.	6. This Directive does not apply to personal protective equipment covered by directive 89/686/EEC. In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal intended purpose of the product.	Delete	Comm. Ref.: None specific MDEG Ref.: 7.10.4 no specific action

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
5) Propose also the deletion of point 5 (d) cosmetic products covered by Directive 76/768/EEC, as this is redundant/serves no purpose.	(d) cosmetic products covered by Directive 76/768/EEC (1);	Delete	G4 Redundant/serves no purpose.
6) Editorial – Update medicines directive reference	In Article 1 5.(c) (c) medicinal products covered by Directive 65/65/EEC, including medicinal products derived from blood as covered by Directive 89/381/EEC;	(c) medicinal products covered by Directive 2001/83/EC([xx]); [xx] OJ reference	G4
7) Reuse Amend the second indent of article 1.2.f of the directive as follows:	(f) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;	(f) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name as well as to those natural or legal persons who reprocess medical devices, outside the specifications given by their manufacturer, for subsequent reuse. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;	Eucomed We consider that reuse is outside the scope of the Directive and hence this point should not be introduced.
8) To provide a method for determining whether products fall	none		MS

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
within the scope of the directive. modify Article 1 by adding new 8 & 9			Guidance documents and the committee procedure under Article 7.4 would seem to sufficiently address this issue.
Article 4			
9) Parallel imports	4. Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another community language, when a device reaches the final user, regardless of whether it is for professional or other use.	4. Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another community language, when a device reaches the final user, regardless of whether it is for professional or other use. This information must be made publicly available by the manufacturer free of charge.	Follow up to discussion at December 2003 MDEG.
Article 5			
10) Provide for possibility to review standards prior to publication in the OJ	*Article 5* **Reference to standards** 1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the *Official Journal of the European Communities;* Member States shall publish the references of such national standards. 2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European *Pharmacopoeia* notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the *Official Journal of the European Communities*.	*Article 5* **Reference to standards** 1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the Official Journal of the European Communities; Member States shall publish the references of such national standards. Before publishing a reference to a harmonized standard in the Official Journal of the European Communities the Commission informs the Competent Authorities of the Member States. If within of 60 days after this information a member state raised substantiated concerns that a standard do not entirely meet the essential requirements referred to in Article 3. The Commission has to submit a draft of the measures to be taken to the	MS For Commission Services this is a major deviation in the standards process and current procedures common to all new approach directives.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
To speed up the procedure to contest published standards amend paragraph 3 and add a new paragraph 4.	3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2).	Committee referred to in Article 7 for acceptance. 3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the matter has to be taken to the committee referred to in Article 7. If the committee comes to the conclusion that the harmonised standard in question do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2). 4.Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices designed and manufactured in conformity with common technical specifications. The common technical specifications shall be adopted in accordance with the procedure mentioned in Article 7(2) and be published in the Official Journal of the European Communities. Manufacturers shall as a general rule be required to comply with the common technical specifications; if for duly justified reasons manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto. Where, in this Directive, reference is made to harmonised standards, this is also meant to refer to the common technical specifications.	MDEG report on the functioning of the Directive took note that there was insufficient support for this idea, ref MDEG 7.7.3.
Article 7			
11) To provide a method for determining whether products fall	*Article 7* **Committee on Medical Devices**	*Article 7* **Committee on Medical Devices**	MS

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
within the scope of the directive	1. The Commission shall be assisted by the Committee set up by Article 6 (2) of Directive 90/385/EEC. 2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority. If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission. 4. The Committee may examine any question connected with implementation of this Directive.	1. The Commission shall be assisted by the Committee set up by Article 6 (2) of Directive 90/385/EEC. 2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority. If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission. 4. The Committee may examine any question connected with implementation of this Directive. 5. The Committee may decide which products are in the scope of this directive.	This Article is subject to the general review of the comitology procedure. Is the amendment required since under paragraph 4 the committee can examine any question and MDEG guidance is seen as sufficient? Also reference must be made to committee procedure as opposed to decision.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
Article 8			
12) Propose regulatory change to ensure that national measures that restrict the placing on the market of medical devices will be communicated to all Member States.	*Article 8* **Safeguard clause** 1. Where a Member State ascertains that the devices referred to in Article 4 (1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to: 2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that: — the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 6 (1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6, — the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his	*Article 8* *Safeguard clause* 1. Where a Member State ascertains that a product referred to in Article X (Article on the free movement), when correctly installed, maintained and used for its intended purpose or in a reasonably foreseeable way, may compromise the health and/or safety of persons (or other public interests covered by this Directive), it shall take all appropriate provisional measures to prohibit or restrict its placing on the market and/or putting into service and/or to withdraw it from its market. The Member State concerned shall immediately notify the Commission and inform the other Member States of the measure, indicating the reasons for it in the form of a summary report and specifying in particular, whether the non-compliance with the Directive is due to: (a) failure of the product to meet the essential requirements set out in this Directive; (b) incorrect application of the standards referred to in Article Z (Article on the presumption of conformity), in so far as it is claimed that these standards have been applied; (c) shortcomings in the standards, referred to in point (b), themselves. In its notification to the Commission, the Member State concerned shall also enclose the supporting evidence for the measure. The supporting documentation shall be made available to the other Member States upon request.	Comm. Ref.: 6.2 MDEG Ref.: 7.12 no specific action The proposed text results from current discussions on the review of New Approach Directives; the Commission may align the text of Article 8 with the general approach. Input from this review may change the current text.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	authorized representative established within the Community. 3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof. 4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.	2. The Commission shall, as soon as possible, enter into consultation with the parties concerned, in particular the Member States, the manufacturer and, as the case may be, the notified body involved and shall proceed to the evaluation of the measure, taking into account the supporting documentation and any further data received. 3. The Commission shall, on the basis of the results of this evaluation, adopt its opinion, indicating whether the measure is considered to be justified or not. Where the manufacturer does not object to the finding that the product is non-compliant, the notified measure is considered to be justified. 4. The Commission shall immediately notify all Member States of its opinion. It shall communicate its opinion to all other parties concerned. Member States shall inform the Commission about the actions taken pursuant to its opinion. 5. Where the notified measure is considered to be justified and is attributed to shortcomings in the standards referred to in point 1(c), the Commission shall initiate the procedure referred to in Article Y (Article on the Committee on technical standards and regulations / formal objections).	
Article 9			

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
13) Clarifying responsibilities since competent authorities can only take administrative actions against persons in their territory.	*Article 9* **Classification** 1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX. 2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject. 3. The classification rules set out in Annex IX may be adapted in accordance with the procedure referred to in Article 7 (2) in the light of technical progress and any information which becomes available under the information system provided for in Article 10.	*Article 9* **Classification** 1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX. 2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the manufacturer or his authorised representative is subject. 3. The classification rules set out in Annex IX may be adapted in accordance with the procedure referred to in Article 7 (2) in the light of technical progress and any information which becomes available under the information system provided for in Article 10.	MS If this were the case what are the means of intervention and to whom are they directed.
14) GHTF classification	1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.	1. Devices shall be divided into Classes A, B, C and D. Classification shall be carried out in accordance with Annex IX.	G4
Article 10			
15) Proposal to put Article 10. 5 of IVDD into MDD			MS This will be done through Eudamed decision
Article 11			
16) Redefine period of validity of conformity assessment certificates	11. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the	11. Decisions taken by the notified bodies in accordance with Annexes Annexes II, III, V and VI shall be valid for a maximum of five years and may be extended on application, made at a time	Comm. Ref.: None Specific MDEG Ref.: 7.2.2, Action 4 An expiry date under Annex

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	contract signed by both parties, for further periods of five years.	agreed in the contract signed by both parties, for further periods of maximum length five years.	IV would not seem relevant.
17) Transparency.	13. By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health.	13. By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health.. Such authorisations shall be communicated, indicating in particular the reasons for the decision, to the Commission and all other Member States.	Comm. Ref.: 6.2 MDEG Ref.: 7.12 no specific action
Article 13			
18) Transparency.	*Article 13* **Decisions with regard to classification, derogation clause** 1. Where a Member State considers that: (a) application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices; or (b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex IX, in another class; or (c) the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 11, by applying solely one of the given procedures chosen from among those referred to in Article 11, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the	*Article 13* **Decisions with regard to classification, derogation clause** 1. Where a Member State considers that: (a) application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices; or (b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex IX, in another class; or (c) the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 11, by applying solely one of the given procedures chosen from among those referred to in Article 11, it shall: – inform all other Member States of its decision and	Comm. Ref.: 6.2 MDEG Ref.: 7.12 no specific action

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	procedure referred to in Article 7 (2). 2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the *Official Journal of the European Communities*.	– submit a duly substantiated request to the Commission, and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7 (2). 2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the *Official Journal of the European Communities*.	
Article 14			
19) Rewrite article 14 b.	*Article 14b* **Particular health monitoring measures** Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures in accordance with the procedure referred to in Article 7(2).	*Article 14b* **Health Protection Measures** Where a Member State considers in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited or restricted, it may take any necessary and justified measures. It shall then inform the Commission and all other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States. Where the national measures are justified, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 7(2). In case the national measures are unjustified, the Commission shall inform all Member States.	G4 To clarify the scope of the measures covered as described in separate background document on Article 14 b sent on the 19 March 2004.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
Article 15			
20) Transparency.	In Article 15 2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy.	 2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such notifications to the contrary shall be communicated, indicating in particular the reasons for the decision, to all other competent authorities.	Comm. Ref.: 6.2 MDEG Ref.: 7.12 no specific action
21) Clarification of obligations under annex X	*Article 15* **Clinical investigation** 1. In the case of devices intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted. 2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Member States may however authorize manufacturers to commence the relevant clinical investigations before the expiry of the period of 60	*Article 15* **Clinical investigation** 1. In the case of devices intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted. 2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Member States may however authorize manufacturers to commence the relevant clinical investigations before the expiry of the period of 60	MS

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	days, in so far as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question. 3. In the case of devices other than those referred to in the second paragraph, Member States may authorize manufacturers to commence clinical investigations, immediately after the date of notification, provided that the ethics committee concerned has delivered a favourable opinion with regard to the investigational plan. 4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3, may be made subject to authorization from the competent authority. 5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The provisions of Annex X may be adjusted in accordance with the procedure laid down in Article 7 (2). 6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy.	days, in so far as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question including the proofed clinical investigation plan referred into Article 1. 3. In the case of devices other than those referred to in the second paragraph, Member States may authorize manufacturers to commence clinical investigations, immediately after the date of notification, provided that the ethics committee concerned has delivered a favourable opinion with regard to the proofed clinical investigation~~al~~ plan referred to in Article 1. 4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3, may be made subject to authorization from the competent authority. 5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The provisions of Annex X may be adjusted in accordance with the procedure laid down in Article 7 (2). 6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy.	
Article 16			
22) Transparency; Make possible the publication of information concerning the assessment of medical devices.	5. The notified body shall inform the other notified bodies and the competent authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. It shall also make available, on request, all additional relevant information.	5. The notified body shall inform the other notified bodies and the competent authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. It shall also make available to the competent authority the relevant data required for Eudamed and, on request, all additional relevant information.	Comm. Ref.: 6.2 MDEG Ref.: 7.12 no specific action Make possible the publication of information concerning the assessment of medical devices

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
Article 18			
23) Clarification.	*Article 18* **Wrongly affixed CE marking** Without prejudice to Article 8: (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State; (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8. Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.	*Article 18* **Wrongly affixed CE marking** Without prejudice to Article 8: (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State; (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8 (3). Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.	G4 This makes the existing text more precise as otherwise there would be no difference between the safeguard clause and the procedure under Article 18. Note also that the reference will be updated in line with modifications to Article 8.
Article 20			
24) Make possible the publication of information concerning the assessment of medical devices. Review the Directive provision for confidentiality (article20).	*Article 20* **Confidentiality** Without prejudice to the existing national provisions and practices on medical secrets, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings,	*Article 20* **Confidentiality** 1. Without prejudice to the existing national provisions and practices on medical secrets, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the exchange of information between Member States and notified bodies with	Comm. Ref.: 6.2 MDEG Ref.: 7.12 no specific action The Commission Services confirmed that Member States have the obligation to disseminate among themselves information on the implementation of the directive, but they cannot

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	nor the obligations of the persons concerned to provide information under criminal law.	regard to all aspects of the implementation of this Directive and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law. 2. Paragraph 1 does not affect the possibility to make the following information publicly available: a) information on the registration of persons responsible for placing devices on the market in accordance with Article 14, b) competent authority vigilance reports in accordance with Article 10 (3), c) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused.	make public confidential information. Additional comment: Is this list of information that can be made publicly available sufficient (e.g. should clinical data be included) and/or should we foresee a mechanism to add to it through Comitology or co-decision procedure?
New Article			
25) Legal basis for administrative cooperation and international activity.		*Article XX* **Cooperation** Member States shall take appropriate measures in order to encourage the authorities responsible for implementing this Directive to cooperate with each other and provide each other and the Commission with information in order to assist the functioning of this Directive. Without prejudice to the provisions of this Directive the Commission and Member States may participate in initiatives at global level to achieve regulatory and administrative convergence.	G4 This will provide legal basis for administrative cooperation and international activities.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
Annex 1			
26) Software requirements update	None	See comment	MD Software working group position/text expected.
27) To include requirement to validate medical software	None	New clause 9.4 9.4 For devices which incorporate software or are medical software itself this software must be validated according to state of the art.	MS
28) Introduce expiry dating for sterile medical devices	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	(e) where appropriate, and for devices covered by (c), an indication of the date by which the device should be used, in safety, expressed as the year and month;	Comm. Ref.: None specific MDEG Ref.: 7.17.4 no specific action
29) Stability data Propose add to Annex 1, section 13.3 (e)	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month, in particular for sterile products such a date must be given based on meaningful stability data;	MS
30) to allow e-labelling	13. **Information supplied by the manufacturer** 13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of	13. **Information supplied by the manufacturer** 13.1. Each device must be supplied with the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely should be set out on the device itself and/or on the packaging or, where appropriate, on the sales packaging. The information must be supplied with	Eucomed This new version would allow, in selected cases, to supply the required information with, for example, electronic means. This would allow the use, for example, of CD Roms

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such	one or more devices. Instructions for use shall be readily available for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such	
31) Propose a modification of part 7.4 of Annex I of the Medical Devices Directive clarifying the legislative intent when the discussions between Commission, national authorities and EMEA do not lead to a meaningful accepted interpretation and mode of operation.	7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall seek a scientific opinion from the European Agency for the Evaluation of Medicinal Products (EMEA) on the quality and safety of the derivative, taking account of the appropriate Community provisions and, in particular, by analogy with the provisions of Directives 75/318/EEC and 89/381/EEC. The usefulness of the derivative as a part of the medical device shall be verified, taking account of the intended purpose of the device.	Two alternatives Alternative 1: 7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall seek a scientific opinion from the European Agency for the Evaluation of Medicinal Products (EMEA) on the quality and safety of the derivative, as such, taking account of the appropriate Community provisions and, in particular, by analogy with the provisions of Directives 75/318/EEC and 89/381/EEC. The manufacturing process aiming at incorporating the human blood derivative into the device can also be object of evaluation of EMEA, to ascertain the effect of such process on the quality and safety of	Comm. Ref.: 5.3 MDEG Ref.: 7.15 Eucomed

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	In accordance with Article 4(3) of Directive 89/381/EEC, a sample from each batch of bulk and/or finished product of the human blood derivative shall be tested by a State laboratory or a laboratory designated for that purpose by a Member State.	the human blood derivative.The usefulness of the derivative as a part of the medical device shall be verified, by the notified body, taking account of the intended purpose of the device. In accordance with Article 4(3) of Directive 89/381/EEC, a sample from each batch of bulk and/or finished product of the human blood derivative shall be tested by a State laboratory or a laboratory designated for that purpose by a Member State. Alternative 2. a shorter version of alternative 1: 7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall seek a scientific opinion from the European Agency for the Evaluation of Medicinal Products (EMEA) on the quality and safety of the derivative, taking account of the appropriate Community provisions and, in particular, by analogy with the provisions of Directives 75/318/EEC and 89/381/EEC. The usefulness of the derivative as a part of the medical device shall be verified by the notified body, taking account of the intended	

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
		purpose of the device. In accordance with Article 4(3) of Directive 89/381/EEC, a sample from each batch of bulk and/or finished product of the human blood derivative shall be tested by a State laboratory or a laboratory designated for that purpose by a Member State.	
Annex II			
32) Annex II: clarification of obligation of design evaluation under quality assurance.	3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one number with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes. The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.	Three alternatives Alternative 1, modify section 3.3. 3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment of representative example(s) of design dossier(s) for the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes. The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment. Alternative 2, modify section 7.	Comm. Ref.: 6.1.1 MDEG Ref.: 7.2.1, Action 3 G4 In a subsequent phase guidance will be developed on how representative examples are chosen. MS

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	7. **Application to devices in Classes IIa and IIb** In line with Article 11 (2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply.	**7. Application to devices in Classes IIa and IIb** In line with Article 11 (2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply. In the case of a product in class IIa the Notified Body has to examine the technical documentation provided according to 3.2 (c) on a random basis, in particular the adequacy of clinical data. In the case of a product in class IIb the Notified Body has to examine at least one technical documentation provided according to 3.2 (c) for a product family. Alternative 3, modify section 7. **7. Application to devices in Classes IIa and IIb** In line with Article 11 (2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply. In the case of a product in class IIb the Notified Body has to examine clinical data provided according to 3.2 (c) for every product.	MS
33) Definition for the period of retention of product files.	6. **Administrative provisions** 6.1. The manufacturer must, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities: — the declaration of conformity, — the documentation referred to in the fourth indent of Section 3.1, — the changes referred to in Section 3.4, — the documentation referred to in Section 4.2, and — the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4. 6.3. In respect of devices subject to the procedure	6. **Administrative provisions** 6.1. The manufacturer must, for a period at least equivalent to the expected lifetime of the product, as defined by the manufacturer, but not less than two years from the date of manufacture, keep at the disposal of the national authorities: — the declaration of conformity, — the documentation referred to in the fourth indent of Section 3.1, — the changes referred to in Section 3.4, — the documentation referred to in Section 4.2, and — the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.	Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38 The period of retention should be related to the expected lifetime of the medical device. The text suggested is based on ISO 13485 record retention requirements.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	in Section 4, when neither the manufacturer nor his authorized representative is established in the Community, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the Community market or the importer referred to in Annex I, Section 13.3 (a).	6.3. In respect of devices subject to the procedure in Section 4, when neither the manufacturer nor his authorized representative is established in the Community, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the Community market or the importer referred to in Annex I, Section 13.3 (a).	
Annex III			
34) Definition for the period of retention of product files.	7. **Administrative provisions** 7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed. 7.3. The manufacturer or his authorized representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. 7.4. When neither the manufacturer nor his authorized representative is established in the Community, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the Community market or the importer referred to in Annex I, Section 13.3 (a).		Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38 Will be updated in line with the decision on 33 above.
Annex IV			
35) Definition for the period of retention of product files.	7. **Administrative provisions** The manufacturer or his authorized representative must, for a period ending at least five years after		Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	the last product has been manufactured, make available to the national authorities: — the declaration of conformity, — the documentation referred to in Section 2, — the certificates referred to in Sections 5.2 and 6.4, — where appropriate, the type-examination certificate referred to in Annex III.		Will be updated in line with the decision on 33 above.
36) To clarify tasks of notified body.	8. **Application to devices in Class IIa** In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following exemptions: 8.1. in derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them; 8.2. in derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class IIa with the technical documentation referred to in Section 3 of Annex VII.		Comm. Ref.: 6.1.1 MDEG Ref.: 7.2.1, Action 3 Will be updated in line with the decision on 32 above.
Annex V			
37) Definition for the period of retention of product files.	5. **Administrative provisions** 5.1. The manufacturer must, for a period ending at least five years after the last product has been manufactured, make available to the national authorities: — the declaration of conformity, — the documentation referred to in the fourth indent of Section 3.1, — the changes referred to in Section 3.4,		Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38 Will be updated in line with the decision on 33 above.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	— the documentation referred to in the seventh indent of Section 3.1, — the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4, — where appropriate, the type-examination certificate referred to in Annex III.		
38) To clarify tasks of notified body.	6. **Application to devices in Class IIa** In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following exemption: 6.1. in derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.		Comm. Ref.: 6.1.1 MDEG Ref.: 7.2.1, Action 3 Will be updated in line with the decision on 32 above.
Annex VI			
39) Definition for the period of retention of product files.	5. **Administrative provisions** 5.1. The manufacturer must, for a period ending at least five years after the last product has been manufactured, make available to the national authorities: — the declaration of conformity, — the documentation referred to in the seventh indent of Section 3.1, — the changes referred to in Section 3.4, — the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4, — where appropriate, the certificate of conformity referred to in Annex III.	5. **Administrative provisions** 5.1. The manufacturer must, for a period at least equivalent to the expected lifetime of the product, but not less than two years from the date of manufacture, make available to the national authorities: — the declaration of conformity, — the documentation referred to in the seventh indent of Section 3.1, — the changes referred to in Section 3.4, — the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4, — where appropriate, the certificate of conformity referred to in Annex III.	Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38 Will be updated in line with the decision on 33 above.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
40) To clarify tasks of notified body.	6. **Application to devices in Class IIa** In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to this derogation: 6.1. by derogation from Sections 2, 3.1 and 3.2 by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.		Comm. Ref.: 6.1.1 MDEG Ref.: 7.2.1, Action 3 Will be updated in line with the decision on 32 above.
Annex VII			
41) Definition for the period of retention of product files. Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38	2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorized representative established in the Community must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured.		Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38 Will be updated in line with the decision on 33 above.
42) Clinical data required for class I	— the test reports and, where appropriate, clinical data in accordance with Annex X,	— the test reports and~~, where appropriate,~~ clinical data in accordance with Annex X,	MS
Annex VIII			
43) Definition for the period of retention of product files. Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38	4. The information contained in the declarations concerned by this Annex should be kept for a period of time of at least five years.		Comm. Ref.: None Specific MDEG Ref.: 7.17.2, Action 38 Will be updated in line with the decision on 33 above.

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
Annex IX[1]			
44) Addition to Annex IX	None	Where a Member State considers that the application of the classification rules set out in Annex IX shall be adapted in accordance with the procedure referred to in Article 7 (2) in the light of technical progress and any information which becomes available under the information system provided for in Article 10 it shall submit a corresponding request to the Commission and ask it to take the necessary measures.	MS This is already covered under Article 9.
45) Modification of the classification criteria in annex IX to eliminate certain classification anomalies.	1.7. *Central circulatory system* For the purposes of this Directive, 'central circulatory system' means the following vessels: *arteriae pulmonales, aorta ascendens, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales,truncus brachicephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior*.	1.7. *Central circulatory system* For the purposes of this Directive, 'central circulatory system' means the following vessels: *arteriae pulmonales, aorta ascendens, aorta descendens, bifurcatio aortae,* arteriae *coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachicephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior*.	Comm. Ref.: None specific MDEG Ref.: 7.1.2, Action 2 Inclusion of descending aorta in definition of central circulatory system:
46) Modification of the classification criteria in annex IX to eliminate certain classification anomalies.	I DEFINITIONS 1.3. *Reusable surgical instrument* Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.	I DEFINITIONS Delete definition and renumber accordingly.	Comm. Ref.: None specific MDEG Ref.: 7.1.2, Action 2 Removal of incongruity whereby a disposable surgical instrument is class IIa and a reusable surgical instrument is class I and add concept of contact with the central nervous system.

[1] Q: Should we incorporate the reclassification directives? A: At the occasion of the breast implant reclassification it was discussed at MDEG level that incorporating reclassifications into the annex would not increase transparency. Member States are free to incorporate these directives at any level. The Commission may consolidate all such directives on the web-site

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	2.2. *Rule 6* All surgically invasive devices intended for transient use are in Class IIa unless they are: — intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, — reusable surgical instruments, in which case they are in Class I, — intended to supply energy in the form of ionizing radiation in which case they are in Class IIb, — intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb, — intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.	2.2. *Rule 6* All surgically invasive devices intended for transient use are in Class IIa unless they are: — intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, ~~— reusable surgical instruments, in which case they are in Class I,~~ — or specifically for use in direct contact with the central nervous system, in which case they are in Class III, — intended to supply energy in the form of ionizing radiation in which case they are in Class IIb, — intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb, — intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.	Note there is another interpretation explaining disposable surgical instruments being of a higher class. As disposable surgical instruments tend to be of a less durable nature than reusable instruments, this increases their risk factor. In line with increased risk these devices become class IIa and third party intervention is required. Therefore the modification can either be to leave the rule as it stands or make disposable surgical instruments class I.
Annex X			
47) Clarification of the text of Annex X on clinical evaluation.		See comment	Comm. Ref.: 5.2 MDEG Ref.: 7.4 no specific action CETF position/text expected
48) To clarify that clinical data is required for all classes of devices.	*ANNEX X* **CLINICAL EVALUATION** 1. **General provisions** 1.1. As a general rule, confirmation of conformity	*ANNEX X* **CLINICAL EVALUATION** 1. **General provisions** 1.1. As a general rule, confirmation of conformity	MS

Areas identified for regulatory modification.	Current Text	Proposed Text	Source & Comments
	with the requirements concerning the characteristics and performances referred to in Sections 1and 3 of Annex I under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data in particular in the case of implantable devices and devices in Class III. Taking account of any relevant harmonized standards, where appropriate, the adequacy of the clinical data must be based on: 1.1.1. either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation; 1.1.2. or the results of all the clinical investigations made, including those carried out in conformity with Section 2. 1.2. All the data must remain confidential, in accordance with the provisions of Article 20.	with the requirements concerning the characteristics and performances referred to in Sections 1and 3 of Annex I under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data ~~in particular in the case of implantable devices and devices in Class III~~. Taking account of any relevant harmonized standards, where appropriate, the adequacy of the clinical data must be based on: 1.1.1. either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation; 1.1.2. or the results of all the clinical investigations made, including those carried out in conformity with Section 2. 1.2In the case of implantable devices and devices in class III clinical investigations shall be performed unless it is duly justified to rely on existing data. 1.3. All the data must remain confidential, in accordance with the provisions of Article 20.	

3. Amendments to 90/385/EEC; Alignment of the Active Implantable Medical Devices Directive with the Medical Devices Directive.

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
1) Inclusion of provision similar to Article 14 b of MDD	None	Article X Health Protection Measures Where a Member State considers in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited or restricted, it may take any necessary and justified measures. It shall then inform the Commission and all other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States. Where the national measures are justified, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 6 (2). In case the national measures are unjustified, the Commission shall inform all Member States.	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38
2) Extension of database EUDAMED to active implantable devices	None	Insert new article to capture custom made devices and require notified bodies to furnish Eudamed information in Article 9. *Article XX* 1. Any manufacturer who, under his own name,	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		places devices on the market in accordance with the procedures referred to in Article 9 (2) shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned. Member States may request to be informed of all data allowing for identification of devices together with the label and the instructions for use when such devices are put into service within their territory. 2. Where a manufacturer who places devices referred to in paragraph 1 on the market under his own name does not have a registered place of business in a Member State, he shall designate the person(s) responsible for marketing them who is (are) established in the Community. These persons shall inform the competent authorities of the Member State in which they have their registered place of business of the address of the registered place of business and the description of the devices concerned. 3. The Member States shall on request inform the other Member States and the Commission of the details referred to in paragraphs 1 and 2. **European databank** 1. Regulatory data in accordance with this Directive shall be stored in a European databank accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis. The databank shall contain the following: (a) data relating to registration of manufacturers and devices in accordance with Article XX;	

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		(b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedure as laid down in Annexes 2 to 5; (c) data obtained in accordance with the vigilance procedure as defined in Article 8. 2. Data shall be forwarded in a standardised format. 3. The procedures implementing this Article shall be adopted in accordance with the procedure laid down in Article 6(2). In Article 9 insert new point 8 and renumber accordingly: 8. The notified body shall inform the other notified bodies and the competent authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. It shall also make available to the competent authority the relevant data required for Eudamed and, on request, all additional relevant information.	
3) Addendum for EC type-examination certificates	7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the addenda to them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned application is made and after the manufacturer has been informed.	None	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38 This may have already been achieved by Amending Directive 93/68/EEC
4) Requirements regarding new devices	None	Article YY The notification referred to in Article XX shall also include any new device. In addition, where, in the context of such notification, a device notified,	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		bearing the CE marking, is a 'new product', the manufacturer shall indicate this fact on his notification. For the purposes of this Article, a device is 'new' if: (a) there has been no such device continuously available on the Community market during the previous three years;	This item needs further discussion as to its applicability in this directive as all devices are subject to third party intervention and it would result the imposition of a registration requirement.
5) One single person (manufacturer or authorised representative) responsible for placing on the market in the Community		None suggested see comment	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38 Is this statement looking for clarification that either the manufacturer or the authorised representative is "fully" responsible for devices on the market? If it is, then this may not be addressed as there is currently differing interpretation as to the extent of the roles and responsibilities of the authorised representative.
6) Reference to the importer	14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols: 14.1. On the sterile pack: — the method of sterilization, — an indication permitting this packaging to be recognized as such, — the name and address of the manufacturer,	Insert in 14.1 3rd indent: and make it the first indent - the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38 Does reference to the importer add anything to

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
	— a description of the device, — if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations', — if the device is custom-made, the words 'custom-made device', — a declaration that the implantable device is in a sterile condition, — the month and year of manufacture, — an indication of the time limit for implanting a device safely. 14.2. On the sales packaging: — the name and address of the manufacturer, — a description of the device, — the purpose of the device, — the relevant characteristics for its use, — if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations', — if the device is custom-made, the words: 'custom-made device', — a declaration that the implantable device is in a sterile condition, — the month and year of manufacture, — an indication of the time limit for implanting a device safely, — the conditions for transporting and staring the device.	of the manufacturer established within the Community or of the importer established within the Community, as appropriate; Also insert same text in 14.2 1st indent	the AIMD, it is not referenced in the IVDD either. So another proposal could be to remove importer from the MDD
7) Requirement to designate an authorised representative	No definition of term 'authorized representative'	Add definition (also see extension of Eudamed above) (j) 'authorised representative' means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		regard to the latter's obligations under this Directive.	
8) Documentation of the quality system in the technical documentation In Annex 2	4.2. The application shall describe the design, manufacture, and performances of the product in question and shall include the necessary particulars which make it possible to evaluate whether it complies with the requirements of this Directive. It shall include *inter alia*: — the design specifications, including the standards which have been applied, — the necessary proof of their appropriations, in particular where the standards referred to in Article 5 have not been applied in full. This proof must include the results of the appropriate tests carried out by the manufacturer or carried out under his responsibility, — a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted, — the clinical data referred to in Annex 7, — the draft instruction leaflet.	4.2. The application shall describe the design, manufacture, and performances of the product in question and it must include the documents needed to assess whether the product conforms to the requirements of this Directive, as referred to in Section 3.2 (c) and (d). It shall include *inter alia*: — the design specifications, including the standards which have been applied, — the necessary proof of their appropriations, in particular where the standards referred to in Article 5 have not been applied in full. This proof must include the results of the appropriate tests carried out by the manufacturer or carried out under his responsibility, — a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 10 of Annex 1, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted, — the clinical data referred to in Annex 7, — the draft instruction leaflet.	Comm. Ref.: None specific MDEG Ref.: 7.16 action 38
9) Apply Directive 2000/70/EC to AIMD		*Article 1* Directive 90/385/EEC is hereby amended as follows: 1. Article 1 shall be amended as follows: (a) the following paragraph shall be inserted: ‘4 a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or	MS Apply 2000/70/EC requirements by analogy

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		human plasma within the meaning of Article 1 of Directive 89/381/EEC (*) and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a "human blood derivative", that device must be assessed and authorised in accordance with this Directive. (b) add a new paragraph 6: 'This directive does not apply to human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in paragraph 4a; 2. Annex 1 shall be amended as follows: (a) in section 10, the following subparagraphs shall be added: 'Where a device incorporates, as an integral part, a human blood derivative, the notified body shall seek a scientific opinion from the European Agency for the Evaluation of Medicinal Products (EMEA) on the quality and safety of the derivative, taking account of the appropriate Community provisions and, in particular, by analogy with the provisions of Directives 75/318/EEC and 89/381/EEC. The usefulness of the derivative as a part of the medical device shall be verified, taking account of the intended purpose of the device. In accordance with Article 4(3) of Directive 89/381/EEC, a sample from each batch of bulk and/or finished product of the human blood derivative shall be tested by a State laboratory or a laboratory designated for that purpose by a Member State.' (b) in section 14.1, the following indent shall be added: '— in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.'	

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		3. Annex 2 shall be amended as follows: (a) in section 3.2(c), add a new indent: '— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 10 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device.'; (b) in section 4.3, add two new subparagraphs: 'In the case of devices referred to in Annex I, section 10, first subparagraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 65/65/EEC before taking a decision. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned. In the case of devices referred to in Annex I, section 10, second subparagraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.'; (c) the following section shall be added: '7. Application to the devices referred to Article 1(4a): Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the	

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 4(3) of Directive 89/381/EEC.' 4. Annex 3 shall be amended as follows: (a) in section 3, the sixth indent shall be replaced by the following: '— a declaration stating whether or not the device incorporates, as an integral part, a substance or human blood derivative, referred to in section 10 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device.'; (b) in section 5, add two new subparagraphs: 'In the case of devices referred to in Annex I, section 10, first subparagraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 65/65/EEC before taking a decision. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned. In the case of devices referred to in Annex I, section 10, second subparagraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.'	

Areas identified for regulatory modification.	Current Text	Proposed Text	Comments
		5. In Annex IV, the following section shall be added: '7. Application to devices referred to in Article 1(4a): In the case of verification under section 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 4(3) of Directive 89/381/EEC.' 6. In Annex V, the following section shall be added: '5. Application to devices referred to in Article 1(4a): Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 4(3) of Directive 89/381/EEC.'	