

NBRG/276/03



## **“Consensus statements“**

**of Notified Bodies Medical Devices**

**(NB-MED)**

**on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**

**(completed by comments of the Notified Body Recommendations Group - NBRG)**

**Issue 01/2003**


**VdTÜV**

Technical Secretariat NB-MED  
PO Box 10 38 34  
D-45038 Essen

Hermann Dinkler (- 187)  
Kurfürstenstraße 56  
D-45138 Essen

Phone: ++49/201/8987- 0  
Fax: ++49/201/8987- 120  
eMail: [vdtuev.dr.dinkler@t-online.de](mailto:vdtuev.dr.dinkler@t-online.de)



	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Introduction</b></p>
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## 1. Introduction

This document reproduces key statements recorded in the minutes of NB-MED meetings and bases on the former "Resolutions-document". On meeting of the NBR-group on 29./30.09.97 it was proposed to change the title of the document from "Resolution" to "Consensus Statement". The word "Resolution" was found not to cover the what was contained in the document, while the expression "Consensus Statements" describes the content of the document in a better way.

In the minutes of the NB-MED meetings prior to 1995, there is no decision taken that is not covered by a separate NB-MED Recommendation or a MedDev-document.

The „consensus statements“

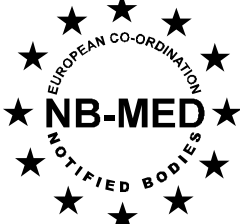
- (i) reflect consensus of those present / represented at the time of the relevant meeting.

Note: Opinion may change in the light of experience and / or detailed consideration of the issue, for example, by those involved in drafting „Recommendations“ in the area, and thus a particular „statement“ may be superseded.

- (ii) may take the form of questions and answers, often qualified in relation to specific circumstances, products etc.


Note: The answer given may not be appropriate to other circumstances, products etc.

- (iii) will include text in italics below each „statement“
- (a) indicating the actions agreed as necessary that are planned or have been taken
  - (b) referring to specific relevant NB-MED „Recommendation(s)“ in the area
  - (c) indicating where a „statement“ has been superseded, with appropriate cross-references


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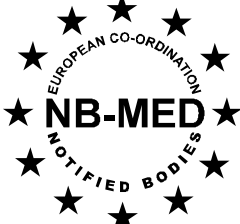
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### 3. Consensus statements of NB-MED

#### **S/01/95 Subcontracting of design and production**

From the definition of the manufacturer included in the medical device directive it is obvious that there is no restriction and that both design and production can be subcontracted but the manufacturer keeps full responsibility for the product.

*8. Meeting NB-MED on 06.04.95, Item 7.2a*

*(NBRG-Meeting on 26.06.97: No further action required.)*

#### **S/02/95 Demarcation with Medical Laboratory Equipment**

J. R. raised the question: Is a mixing device used in a laboratory for mixing liquid drugs for later injection or infusion but used off-line of a patient could be considered as a medical device? J. R. proposed to define a borderline: if the product is used on-line or off-line to the patient. It is used immediately on-line for supply to the patient it can be considered as a medical device. If it is used off-line, it will be considered as a laboratory equipment.

*8. Meeting NB-MED on 06.04.95, Item 7.5*

*(NBRG-Meeting on 26.06.97: No further action required.)*

*NBRG-Meeting on 11./12.06.98: See also S/01/98.)*

#### **S/03/95 European representative from manufacturers from outside the Community**


J. R. questioned the members on the necessity in any case for a manufacturer located outside Europe to have an authorized European representative who will appear on the certificate and would should be mentioned in the application of the conformity assessment. N. A. referred to Annex 1 point 13.3a where there is:

- a requirement for labelling and instructions for use of a product to have an importer or authorized representative.
- a need for the manufacturer to have a person responsible established in the Community to put the product on the market and to provide, if necessary, documents on request to Competent Authorities for surveillance (the relevant references in the directives are: Annex 2, section 6.3, Annex 3, section 7.4, Annex 7, section 2).

*8. Meeting NB-MED on 06.04.95, Item 7.6*

*(NBRG-Meeting on 26.06.97: No further action required.)*

*NBRG-Meeting on 11./12.06.98: See also S/03/96.)*

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**S/04/95            Expiration date on packaging for sterile products**

N. A. suggested to write a statement: The claims of the manufacturers must be indicated in view of limits to the safe use of the product including the capability of the packaging to maintain the product sterile. The manufacturer can either claim for a defined period or, by explicit statement, for a unlimited period. In both cases, the claim must be based on appropriate validation data. As a general rule if the device is labelled sterile it is necessary to indicate the limited period which corresponds to the relevant validation.

9. Meeting NB-MED on 11./12.09.95, Item 7.1

*(NBRG-Meeting on 26.06.97: Was also discussed at Medical Device Expert Group Meeting (March 1996). Furthermore it will be developed by NB-MED recommendation No. 2.2/Rec4 „Expiry dating of medical devices“ (old number: 3.4.2e; at present: stage hold); then this Consensus Statement will get an additional sentence: „covered by NB-MED recommendation 2.2/Rec4“.*

*NBRG-Meeting on 29./30.09.97: This subject and also the draft NB-MED recommendation No. 2.2/Rec4 is now covered by the NB-MED recommendation No. 2.2/Rec3 „Use-by“ date for medical devices“. Whether this Consensus Statement is to be deleted if the NB-MED/2.2/Rec3 is approved, is for the NB-MED to decide.*

*NBRG-Meeting on 27./28.09.99: This consensus statement is **superseded** by NB-MED Recommendation No. 2.2/Rec3 „Use-by“ date for medical devices“.)*

**S/05/95            Packaging for instruments sterilized by the user**

Question from M.-L.: Packaging for instruments to be sterilized by the user (NBM/025/95). This question concerns packaging of products which are sold non-sterile and sterilized at a later stage in hospitals. It was brought up by several manufacturers and they felt that section 8.6 in Annex 1 of the MDD is not clear: "Packaging systems for non-sterile devices must keep the products without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer". J. R. explained that this paragraph is intended for products which can be sterilized in their packaging. The normal packaging is a shipping packaging.


9. Meeting NB-MED on 11./12.09.95, Item 7.2

*(NBRG-Meeting on 26.06.97: No further action required.)*


**S/06/95            Product testing as part of the surveillance of QS**

Where necessary Notified Bodies may carry out product tests as part of the surveillance of quality systems to verify that quality systems ensure that the products meet the requirements laid down in the MDD and AIMD [see answer on a written question to the European Commission, Official Journal of the European Communities No C 6 dated January 9, 1995]. Results of discussion: tests mentioned in Annex II section 5.4 and Annex V section 4.4 can also be product tests.

9. Meeting NB-MED on 11./12.09.95, Item 8.5(4)

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*(NBRG-Meeting on 26.06.97: No further action required.)*

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**S/01/96            Validation of the technical documentation as part of auditing under Annex V and VI**

Question: How far the third party should go in the auditing activities?

Answer: The Notified Bodies shall include audit activities concerning the technical documentation mentioned in Annex VII in the surveillance of the quality system according to Annex V (production quality) and Annex VI (product quality). The audit should not be as detailed as the review procedure set out in Annex II but it shall include in case of substantial doubts a validation of the technical documentation mentioned in Annex VII section 3. That means that the definition of products included in its intended use and the classification shall always be audited.

10. Meeting NB-MED on 17.01.96, Item 5.1(3)

*(NBRG-Meeting on 26.06.97: No further action required.)*

**S/02/96            Classification of ear thermometers**

Question: Do they belong to class I or IIa? They are part of active device but they do not deliver energy.

Answer: It was decided after discussion to classify this product according to rule 10 for electrical medical devices as class IIa.

10. Meeting NB-MED on 17.01.96, Item 5.1(6)

11. Meeting NB-MED on 29./30.04.96, Item 2

*(NBRG-Meeting on 26.06.97: Pass on to the **Commission Classification Group** including all relevant information out of the minutes of 10./11. meeting of NB-MED.)*

**S/03/96            Authorized representative**


Question: Do manufacturers who are located outside Europe have to designate an authorised representative in all cases or does this only applied to devices according to article 14?

Answer: Only in cases mentioned in article 14 of MDD the manufacturer located outside the MS shall designate a responsible person. An authorised representative as mentioned in article 11 point 8 is optional.

10. Meeting NB-MED on 17.01.96, Item 5.1(1)

*(NBRG-Meeting on 26.06.97: Remark: MS means „Member state“. No further action required.*

*NBRG-Meeting on 27./28.09.99: See also S/03/95.)*

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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### **S/04/96      CE marking of refurbished devices**

Question: Do refurbished devices, which will be marketed as second hand devices require CE marking?

Answer: Repair of a medical device using components, conforming to the original specification, where no transfer of a device in terms of placing on the market occurs, does not require CE-marking or re-CE-marking. B. L. referred to the paper from COCIR (NBM/010/96) circulated during the meeting and proposed that the answer should be: No, if the equipped product has been in the EU market before with the following comment: only fully refurbished medical devices intended to be placed on the market must be CE marked by that organisation.

10. Meeting NB-MED on 17.01.96, Item 5.1(2)

*(NBRG-Meeting on 26.06.97: Discussion concerning „refurbished“ and „fully refurbished“. Furthermore this Consensus Statement will be developed as a NB-MED recommendation by working group (Mr. B., Mr. J., Dr. L., Dr. W.) until NBRG-Meeting on September 29./30., 1997.*

*NBRG-Meeting on 29./30.09.97: This subject is now covered by the NB-MED recommendation No. 2.1/Rec5 „Placing on the market of fully refurbished medical devices“. Whether this Consensus Statement is to be deleted if the NB-MED/2.1/Rec5 is approved, is for the NB-MED to decide.*

*NBRG-Meeting on 27./28.09.99: This consensus statement is **superseded** by NB-MED Recommendation No. 2.1/Rec5 „Placing on the market of fully refurbished medical devices“.)*

### **S/05/96      CE marking of class I devices**

Question: A manufacturer of a Class I device (non sterile, non measuring) applies a full quality assurance system (Annex II). After certification by a Notified Body the manufacturer wants to affix CE marking with NB-number. Is this allowed?

Answer: No, it is not allowed. Class I device (non sterile, non measuring) must always be marked CE without Notified Body number according to the medical device directive.

10. Meeting NB-MED on 17.01.96, Item 5.1(4)

*(NBRG-Meeting on 26.06.97: No further action required.)*


### **S/06/96      Declaration of reversed osmotic systems**

Question: Are reversed osmotic system for water purification for dialysis medical devices according to the MDD?

Answer: Yes, if specifically intended to be an accessory to a medical device.

10. Meeting NB-MED on 17.01.96, Item 5.1(7)

*(NBRG-Meeting on 26.06.97: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p><b>Consensus statements</b></p>
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**S/07/96            Classification of devices for disinfecting, cleaning, rinsing, hydrating**

Answer: All such devices should be classified as Class IIa except if rule 15, 1st sentence applies: All devices intended specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are IIb.

10. Meeting NB-MED on 17.01.96, Item 5.1(8)

*(NBRG-Meeting on 26.06.97: Pass on to the **Commission Classification Group** including all relevant information out of the minutes of 10. meeting of NB-MED.)*

**S/08/96            Quality systems in case of complete subcontracting**

J. R. referred also to the paper from the Medical Products Agency of Sweden (NBM/3/96) which covers a very subject.

Question: Company A has designed and specified a class I sterile medical device. The complete production process, including steps to secure sterility, is carried out by a subcontractor Company B. Company A has not established a quality system. Could it under MDD be required that Company A shall operate with a quality system or some part of a quality system.

Answer: The company A must have a quality system. The quality system should focus in the given case on activities which have been subcontracted, but the quality system should be installed by the labelled manufacturing company.

10. Meeting NB-MED on 17.01.96, Item 7.1

*(NBRG-Meeting on 26.06.97: No further action required.)*

**S/09/96            Beautician equipment**

It was concluded that it depends on the purpose of the device and the use of this device by a doctor does not change the intended purpose of the device.

10. Meeting NB-MED on 17.01.96, Item 7.6

*(NBRG-Meeting on 26.06.97: No further action required.)*


*NBRG-Meeting on 27./28.09.99: See also S/03/97.)*

**S/10/96            Road motor vehicle for handicapped persons**

J. R. stated that it is necessary to look at the claim of the manufacturer. If the manufacturer claims that the device is a medical device, then some of the scope of the medical device directive applies besides being under the scope of the road traffic regulation which applies in parallel. But if the general purpose of the device is a vehicle which can be used also by an handicapped person it will not be considered as a medical device.

10. Meeting NB-MED on 17.01.96, Item 7.6

*(NBRG-Meeting on 26.06.97: No further action required.)*

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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### **S/11/96      CE marking of separate sold devices**

J. R. referred to the paper tabled by M.-L. on CE marking of a set of two medical devices certified by two different Notified Bodies.

Question: The CE marked devices are sold separately and as a set. Can the package of the set bear the CE mark?

Answer: The manufacturer has the choice between two possibilities:

1. The components have a CE mark (Article 12 -systems and procedure pack), no additional certification is required and no additional CE mark shall be affixed to the set and on the package.
2. The components have an independent purpose for use and so article 12 does not apply. CE marking must be affixed clearly visible on the package of the set to know which CE mark belongs to which product.

11. Meeting NB-MED on 29./30.04.96, Item 8.6

*(NBRG-Meeting on 26.06.97: No further action required.)*

### **S/12/96      Oven in dental laboratories**

Question: Can an oven be considered as a medical device? Or as an accessory? The oven is intended to be used by dental laboratories of the production of prostheses from dental alloys, and could be considered a medical device as sterilizers are.

Comments and answer: J. R. and M. F. stated that a sterilizer used in the manufacture of medical device is not a medical device, but sterilizer used in a medical device environment or an hospital environment for reuse of medical device is an accessory of a medical device (reusable surgical instrument). R. V. pointed out that if this oven is placed on the market for the specified purpose of preparing prostheses from substances which are medical devices by supplying specific temperatures and/or other physical parameters, or if it is specifically intended by the manufacturer to be used in conjunction with medical devices, then it is an accessory of medical devices. He added that the concept of intended purpose and specific use stated by the manufacturer is the basic element to determine whether the device is an accessory of a medical device.


11. Meeting NB-MED on 29./30.04.96, Item 8.7

*(NBRG-Meeting on 26.06.97: Discussion concerning the demarcation of „accessory“ and „device“. Furthermore this Consensus Statement should be developed as a NB-MED recommendation in a more general way.*

*NBRG-Meeting on 29./30.09.97: A proposal for a recommendation made by Mr. B. will be redrafted until NBRG-Meeting on January, 1998.*

*NBRG-Meeting on 22./23.01.98: The draft document „Demarcation Medical devices, accessories and production or laboratory devices“ was presented by Mr. B.. Criteria for „When are accessories under the MDD“ are Use in medical environment and Time on use. So: oven in the dental laboratory to manufacture is not a MD; amalgam mixer used by the dentist is a MD. Mr. B. was asked to prepare a new document for the next Medical Devices Experts Group on 09./10.02.98.*



	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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*NBRG-Meeting on 03./04.03.98: A proposal for a explaining statement concerning „Demarcation Medical Devices, Accessories and Production or Laboratory Devices“ made by Mr. B. was agreed by the Medical devices Experts Group meeting on 09./10.02.98. NB-MED agreed that the old consensus statement will be superseded by the new one; NBRG should find the right wording at their meeting on April, 1998.*

*NBRG-Meeting on 20./21.04.98: A new statement was elaborated and accepted; the old consensus statement S/12/96 is **superseded** by **S/01/98.**)*

### **S/13/96          Time limits of certificates**

J. R. referred to the wording of the directive where a limited time certificate should be 5 years. There is only an unlimited certificate for Annex 5.4 and 6.

*12. Meeting NB-MED on 24./25.09.96, Item 8.6*

*(NBRG-Meeting on 26.06.97: Remark: only the reference to „Annex 4, 5 and 6“. No further action required.)*


### **S/14/96          Certification of subcontractor**

The question was : „What is the appropriate certificate for sterilisation subcontractor?“ A possibility is a certificate under EN 46002 or ISO 9002 by a Notified Body able to issue such a certificate. J. R. stated that an audit report from a Notified Body for an inspection should be used by the following Notified Bodies. Any existing document can be used by the subsequent Notified Body and could prevent the second Notified Body to again audit the sterilisation company. The Notified Body should be of course competent with the area already audited.

*12. Meeting NB-MED on 24./25.09.96, Item 8.7*

*(NBRG-Meeting on 26.06.97: No further action required.*

*NBRG-Meeting on 27./28.09.99: see also NB-MED Recommendation No. 2.15/Rec1 „Voluntary certification at an intermediate stage of manufacturer“.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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### **S/01/97 Nasal rinsing and humidifying solutions; Classification**

As regards the question whether nasal rinsing and humidifying solutions are medical devices, reference is made to document MedDev 2.1/3, section A.3.

13. Meeting NB-MED on 04./05.02.97, Item 5.1(3)

*(NBRG-Meeting on 26.06.97: No further action required.)*

### **S/02/97 Custom-made mouth guards; Classification**

Custom-made mouth guards are only medical devices if they were to be used for medical purposes.

13. Meeting NB-MED on 04./05.02.97, Item 5.1(3)

*(NBRG-Meeting on 26.06.97: No further action required.)*

### **S/03/97 Laser equipment; Classification**

Laser equipment intended for permanent depilation is to be classified as medical devices if its application, to be documented by the manufacturer, was aimed at changing the anatomy in a permanent nature including also at least when medical purpose.

13. Meeting NB-MED on 04./05.02.97, Item 5.1(3)

*(NBRG-Meeting on 26.06.97: Discussion concerning the demarcation of „cosmetics and beautician equipments“ and „medical device“. In view of S/09/96 NBRG gives the recommendation to NB-MED to develop a NB-MED recommendation.*

*NBRG-Meeting on 27./28.09.99: The advice from NBRG has not followed.)*


### **S/04/97 Gas distribution networks in hospitals**

G-MED brought up the question as to the case in which gas distribution networks in hospitals are medical devices. R. V. pointed out that two MedDev documents give some explanation on this subject. Primary containers for gases were thus medicinal products according to MedDev 2.1/3 (rev. 5.1), paragraph A4, section 4.1. According to the explanations on rule 11 in MedDev 2.4/1 (rev. 5), pressure regulators for medical gases were medical devices. It could be assumed from this that products arranged after primary containers were medical devices, unless they were permanently installed piping systems. F. pointed out that the CEN/TC 215 was concerned with the question of defining such products.

13. Meeting NB-MED on 04./05.02.97, Item 8(1)

*(NBRG-Meeting on 26.06.97: Proposal to NB-MED to ask for correct and suitable wording concerning the sentence „...after primary containers were medical devices, unless they were permanently installed piping systems.“. Dr. W. made the proposal to delete the sentence after the coma and the headline should be extended to „Medical gas distribution networks in hospitals“. Rational will follow by Dr. W.*

*NBRG-Meeting on 22./23.01.98: Dr. W. was asked to draft a new consensus statement and a rationale for presentation at the next plenary. Questions are: Who is the manufacturer? What is placed on the market? When is a MD generated?*

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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*NBRG-Meeting on 11./12.06.98: A new consensus statement was accepted on the NB-MED meeting on 09./10.06.98; therefore this old consensus statement S/04/97 is **superseded** by the new one S/06/98.)*

**S/05/97            Borderline products between medical devices and home training devices, or devices for comfort, or cosmetic devices**

The definition depended essentially on the purpose for which the products were intended. Medical devices were concerned if the manufacturer offered them, for example for diagnostic or therapeutic purposes. If, on the other hand, the manufacture intended them as training devices for those engaged in sports, they were not to be considered as medical devices. If the intended use was not clear, the manufacturer should be asked for more exact details to clarify whether a medical device was concerned or not.

*13. Meeting NB-MED on 04./05.02.97, Item 8(3)*

*(NBRG-Meeting on 26.06.97: Proposal to NB-MED to keep this Consensus Statement together with S/09/96 and S/03/97. No further action required.*

*NBRG-Meeting on 27./28.09.99: The advice from NBRG has not followed.)*

**S/06/97            Classification of surgical instruments**

R. V. mentioned that this question referred to a medical device intended for short-time use in cardiac surgery for tissue stabilisation. Between the manufacturer and the NB their interpretation of rules 6 and 7 in MedDev 2.4/1 (Rev. 5) differed. If footnote 2 of rule 6 will be taken into account in the application of rule 7 and the device was not used for correcting a defect of the heart, but as an accessory (e.g. as a clamp), it would be possible to assign a class II classification, and not class III.

*13. Meeting NB-MED on 04./05.02.97, Item 8.1*

*(NBRG-Meeting on 26.06.97: Pass on to the **Commission Classification Group** including all relevant information out of the minutes of 13. meeting of NB-MED.)*


**S/07/97            Status of coatings of implants**

Taking a concrete case, R. V. pointed out that coatings of hip prostheses may not be given CE marking, because coatings as such are not medical devices. They are not finished products but only parts/components of Medical Devices. It was proposed that if a manufacturer did not produce the coatings himself, but obtained them from a sub-supplier, it was possible for the Notified Body to issue a "certificate of competence". The Commission is going to draw up sample certificates. This also included a sample for a corresponding "certificate of competence".

*13. Meeting NB-MED on 04./05.02.97, Item 8.2*

*(NBRG-Meeting on 26.06.97: No further action required.*

*NBRG-Meeting on 27./28.09.99: see also NB-MED Recommendation No. 2.15/Rec1 „Voluntary certification at an intermediate stage of manufacturer“.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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**S/08/97            Withdrawal or refusal of certificates**

N. A. brought up the question as to what follow-up measures had to be taken by a Notified Body when the conditions for granting a certificate had not been met or are no longer met anymore. In such cases the Notified Body had to take all measures to withdraw relevant certificates. It was disputable whether, in cases where the manufacturer did not take adequate measures, the Notified Body had to inform the competent authority. N. A. was of the view that such a notification was necessary in such cases.

*13. Meeting NB-MED on 04./05.02.97, Item 8.3*

*(NBRG-Meeting on 26.06.97: No further action required.)*

*NBRG-Meeting on 27./28.09.99: at least information has to be given to EUDAMED.)*

**S/09/97            Classification of dialysis concentrates**

J. R. explained that dialysis concentrates are medical devices (see MedDev 2.1/3 (rev. 5.1), section A.3). The question had to be clarified as to how these concentrates should be classified. Since the concentrates normally contained medicinal substances, such as bicarbonate, Rule 13 had to be applied, i.e. the concentrates were to be classified as class III. J. R. proposed that corresponding clarification be given in the document MedDev 2.4/1 (rev. 5).

*13. Meeting NB-MED on 04./05.02.97, Item 8.6*

*(NBRG-Meeting on 26.06.97: Pass on to the **Commission Classification Group** including all relevant information out of the minutes of 13. meeting of NB-MED.)*

N. A. pointed out that where two rules apply, the higher classification applies.

*14. Meeting NB-MED on 24./25.06.97, Item 2.4*


**S/10/97            Quality certificates for single products**

J. T. reported that some Notified Bodies were demanding a list of each individual product type in the certificates according to Annex II or V. The Notified Bodies had found that such a detailed list in the certificate could not be demanded. An indication of a product category was sufficient. Even so the related documents had to make clear which individual products the certificate related to.

*13. Meeting NB-MED on 04./05.02.97, Item 10.4*

*(NBRG-Meeting on 26.06.97: No further action required.)*

*NBRG-Meeting on 27./28.09.99: see also NB-MED Recommendation No. 2.5.1/Rec4 „Content of mandatory certificates“.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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**S/11/97            OEM Products; certification**

Whoever removed the name of the manufacturer and put the product on the market under his own name then this person could be seen as the manufacturer. NB-MED decided after the discussion that removing the label of the original manufacturer puts the device in position where it is no longer assembly but subcontracting. If there is a change of manufacturer the labelling will clearly reflect that and of course all of the requirements under the directive attach to the new manufacturer.

*14. Meeting NB-MED on 24./25.06.97, Item 3.4(1)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/12/97            Certification of class IIb products in combination of Annexes II and V of the MDD**

NB-MED decided after the discussion that Annex V is a subset of Annex II and therefore without further auditing a certificate according to Annex V can be issued when Annex II for the same range of products of course has already been successfully audited.

*14. Meeting NB-MED on 24./25.06.97, Item 3.4(2)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/13/97            Hearing aids**

The NB-MED decided after the discussion that the essential requirements must be met because they are mandatory. The risk analysis attaching to that has to be addressed by the manufacturer either in terms of having a “fail to safety type system“ but it must be addressed.

*14. Meeting NB-MED on 24./25.06.97, Item 3.4(4)*


*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/14/97            Programmable electrical Medical Systems**

The NB-MED decided after the discussion that standard IEC 601-1-4 can be used.

*14. Meeting NB-MED on 24./25.06.97, Item 3.4(5)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p><b>Consensus statements</b></p>
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**S/15/97            Classification of a medical-diagnostic device for determining woman's fertile and infertile period**

N. A. explained that in the tabled case the device is not covered by the MDD because the device is used for in vitro diagnosis. N. A. also supported that a medical device which are part of a kit, e.g. invitro diagnostic kit, should be CE marked. R. V. explained that a accessory for a product which itself is not a medical device could be a medical device (e.g. container for human bones; the human bone is by definition excluded from the MDD and this container could be an accessory for this product); this is addressed in the classification rule 2 and also in the MedDev document relating to drug/device borderline issues. A container for transportation e.g. human bone falls under rule 2; it is a non-invasive device intended for storing tissue.

*14. Meeting NB-MED on 24./25.06.97, Item 3.4(8)*

*(NBRG-Meeting on 11./12.06.98: No further action required.*


*NBRG-Meeting on 27./28.09.99: see IVD Directive.)*

**S/16/97            Resuscitation masks; categorisation**

This product seems to be a device which intended purpose is to protect not the patient but the resuscitator. In this case the device is a PPE (personal protection equipment). But the used wording "re-animation mask" or "resuscitation mask" is misleading because a "re-suscitator" is in general a device used for the patient and not for the person who saves the patient. If this product has a medical function as well as a PPE function then it will be classed as a medical device. If e.g. this products at the same time prevents transmission of infectious agents from the rescuer to the patient as well as visa versa then it is not a PPE but it is a medical device. N. A. referred to the MedDev document concerning the demarcation between medical devices and personal protective equipment where some examples are given. The question is what is the main purpose of the product and one example given in this context was "clothing for breath protection against ionising radiation" and in this context there is a set of products which are used for clothing to protect either patients or to protect medical staff against radiation and in this case the MedDev document decides it is a personal protective equipment; it is also used in the context of medical environment but the "PPE purpose" is unequivocal prevailing. Also this tabled product seems to be a similar kind of these products. On the other hand the MedDev document considers medical gloves as medical devices because there is a purpose which is related to the patient as well as a purpose related to the physician. But the MedDev document considers protective gloves e.g. for use in a medical laboratory as personal protective equipment. NB-MED decided that the resuscitation masks has to classify as a personal protective equipment because a personal protective purpose is prevailing.

*14. Meeting NB-MED on 24./25.06.97, Item 3.4(10)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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**S/17/97            Wigs and toupees; Classification**

They are not medical devices since there is no permanent modification of the anatomy.  
14. Meeting NB-MED on 24./25.06.97, Item 5(1)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/18/97            Arms rests installed in buildings for handicapped persons; Classification**

They are not medical devices.  
14. Meeting NB-MED on 24./25.06.97, Item 5(1)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/19/97            Brushers with disinfectants for use by healthcare personnel; Classification**

These products are not medical devices because their intended purpose is to clean a part of the body not to clean a medical device.  
14. Meeting NB-MED on 24./25.06.97, Item 5(1)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/20/97            Software programmes used for patients to provide rehabilitation; Classification**


Where software were designed specifically to treat or diagnose a handicap then these products could be considered as medical devices as referred to in MedDev 2.1/1.  
14. Meeting NB-MED on 24./25.06.97, Item 5(1)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*


**S/21/97            Products made from latex**

Discussion (Medical Device Experts Group meeting on 25.02.97) about allergic reaction arisen by products made from latex or containing natural latex (increasing sensitisation to natural latex). Notified Bodies should be aware of this situation and during conformity assessment ensure minimisation of allergens due to natural latex.  
14. Meeting NB-MED on 24./25.06.97, Item 5(1)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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**S/22/97                    Data Management and Exchange**

One of the important outcomes was that Notified Bodies will retain numbering of the certificates as given.

14. Meeting NB-MED on 24./25.06.97, Item 5(4)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/23/97                    Storage solutions for organs; classification**

It was resolved (Working Group "Drug/Device Issues", April 21, 1997) that agents specifically designed for ex vivo use for transport and storage of organs, tissues or cells intended for transplantation, where the action is principally for preservation or maintenance should be added as an example of medical device to the draft document MedDev 2.1/3 and that rule 13 of Annex IX of the MDD should apply to such products, i.e. they would be class III.

14. Meeting NB-MED on 24./25.06.97, Item 5(5)

*(NBRG-Meeting on 11./12.06.98: Working Group "Drug/Device Issues" has made a decision on this subject in the meanwhile; this consensus statement was **superseded** by S/35/97.)*

**S/24/97                    Complex salt solution for irrigation; classification**

"Complex salt solution for irrigation", e.g. of the anterior chamber of the eye during surgery, are medical devices resolved (Working Group "Drug/Device Issues", April 21, 1997) unless their principal intended action refers to metabolism. The question of classification has yet to be clarified (class IIa or class II according MDD, Annex IX, rule 13?).

14. Meeting NB-MED on 24./25.06.97, Item 5(5)


*(NBRG-Meeting on 11./12.06.98: No further action required.)*

*(NBRG-Meeting on 27./28.09.99: Working Group "Drug/Device Issues" has made a decision on this subject in the meanwhile; this consensus statement was **superseded** by S/36/97.)*


**S/25/97                    Independence of the auditors**

It was proposed (Study Group 4 of the Global Harmonisation Task Force, February 1997) to add - in revision 5 of MedDev document concerning auditing - a note "the medical use of a device is not considered as a commercial use". Concerning the responsibility of the auditor it was proposed that one of the responsibility of the auditor is to help the manufacturer to understand the regulatory requirement. Concerning the issue "responsibility of auditees which are not manufacturers" (e.g. subcontractor) it was proposed to add "the scope of the audit remains the responsibility of the manufacturers and not to the subcontractor".

14. Meeting NB-MED on 24./25.06.97, Item 5(7)

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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**S/26/97          Products in the distribution chain and the impact of that in relation to the end of the transition period**

N. A. pointed out that the transitional period with regard to placing on the market will not be changed at all. By June 15, 1998 only CE marked devices may be placed on the market. Concerning the question “What does happen with those products (without CE mark) which have already been placed on the market by June 14, 1997 (by putting in the distribution chain)?” N. A. explained that the council in the context of IVDD set a “cut off date”. Those products which have been placed on the market by June 15, 1998 can still reach the final user until June 30, 2001. There will be a re-definition of the concept of “putting into service”, in fact it will mean these products can be transferred to the final user until June 30, 2001. Products which e.g. left by manufacturer into an hospital but are not used by the hospital are placed on the market; they have even been put into service and can be used. The payment and the ownership are not conditions for placing a product on the market or for putting into service. The question is: “Is the product available e.g. for the physician?” In this case the product has been put into service.

*14. Meeting NB-MED on 24./25.06.97, Item 6.6*

*(NBRG-Meeting on 11./12.06.98: see also „communication document“ made by the Commission, distributed on the NB-MED meeting on 09./10.06.98 as document NBM/102/98.*

*Remark of the Technical Secretariat: see also „Commission’s communication document“ NBM/150/98.)*

**S/27/97          Categorisation of devices for preparation of solution bags**

NB-MED decided that this presented device for preparation of solution bags has not to be considered as a medical device or as an accessory to a medical device.


*15. Meeting NB-MED on 18./19.11.97, Item 3.4 (1)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*


**S/28/97          Declaration specifying that no application has been lodged with any other Notified Body for the same product/product related quality system**

The Notified Bodies made practicable proposals for a solution. E.g. in the application form between Notified Body and the manufacturer, the manufacturer should declare „An other application has not been made to an other Notified Body“. Normally the manufacturer declares that he has not been involved with an other Notified Body. In the case that such an declaration is not given the „new“ Notified Body requests from the manufacturer to release his former Notified Body from the obligation of confidentiality versus the „new“ Notified Body; than the „new“ Notified Body could make contact with the former Notified Body.

*15. Meeting NB-MED on 18./19.11.97, Item 3.4 (2)*

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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**S/29/97                    Categorisation of thermosealing machine**

NB-MED decided that a thermosealing machine is only a processing equipment (see also NBM/105/97). An accessory to an accessory of a medical device is not a medical device.  
15. Meeting NB-MED on 18./19.11.97, Item 3.4 (3)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/30/97                    Are devices for storage of blood, human cells and sperm which are determined to be returned to the human body medical devices or not?**

R. V. explained the intended purpose given by the manufacturer answers the question: in case of a multipurpose device (see MedDev document) this device becomes a medical device only when a specified intended medical purpose is signed by its manufacturer for e.g. preservation of organs. If a manufacturer of containers for liquid nitrogen places this device on the market without claiming any specific purpose than it is not a medical device. In this context R. V. mentioned that e.g. a bloodwarmer used on-line for infusion is a medical device. NB-MED agreed with this interpretations. It was decided that the storage device itself falls under rule 2.

15. Meeting NB-MED on 18./19.11.97, Item 3.4 (7)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/31/97                    Devices for use in heart surgery; Classification**

Some class I products were used in direct contact with the heart, and rule 6 did not address the cardiac use of medical devices. Suggestion: all such devices should be class III e.g. Coronary - Artery Probe and Aortic Punch. An urgent meeting of Classification Working Group was proposed. The Commission services considered that rule 5 applied for examination gloves (class I) and rule 6 applied for surgical gloves (class IIa).

15. Meeting NB-MED on 18./19.11.97, Item 5 (1)


*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/32/97                    Gloves; Classification**

If reclassification is required then an detailed rationale must be made

15. Meeting NB-MED on 18./19.11.97, Item 5 (1)

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p><b>Consensus statements</b></p>
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**S/33/97          Nebulizers (used to administer a medicinal product, which was potentially hazardous in reference to rule II, annex II) ; Classification**

This device is a class IIb because it is active, multi-use and also the potentially hazardous nature of the substance used (need for a respiratory filter due to the route of administration) ref. rule 11. Other such nebulizers are still classed as class IIa devices.

*15. Meeting NB-MED on 18./19.11.97, Item 5 (1)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/34/97          Products intended for rinsing; Classification**

A distinction must be made between cleaning and disinfecting claims per rule 15. In any case, the rinsing solutions would be regarded as an accessory to a medical device. Disinfectants which also make claims to fight hospital based infections (MRSA) should be classified as class IIb devices in keeping with higher risk. The reclassification would have to be done on basis on article 13 of MDD.

*15. Meeting NB-MED on 18./19.11.97, Item 5 (1)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

**S/35/97          Storage solutions for organs; Classification**

Working Group “Drug/Device Issues“, 02.10.97: a former decision that „Storage solutions for organs“ have to be considered as class III devices (draft document MedDev 2.1/3 and rule 13 of Annex IX, MDD) was revised: now they are not medical devices but they are regulated by the drug law.

*15. Meeting NB-MED on 18./19.11.97, Item 5 (7)*

*(NBRG-Meeting on 27./28.09.99: the old consensus statement S/23/97 is superseded by this one.)*


**S/36/97          Complex salt solution for irrigation; Classification**

Working Group “Drug/Device Issues“, 02.10.97: it was fixed that “Complex salt solution for irrigation“ have to be considered as class III devices.

*15. Meeting NB-MED on 18./19.11.97, Item 5 (7)*

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

*NBRG-Meeting on 27./28.09.99: the old consensus statement S/24/97 is superseded by this one.)*

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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**S/37/97            Proteins - produced by genetic means - which are used with devices  
for bone repairing**

R. V. made some indications concerning proteins - produced by genetic means - which are used with devices for bone repairing: when the bone filler consists in a matrix and when this matrix acts by physical means and the bone filler assists by a substance to promote the osteoinduction than it is a medical device; but when it can not be proofed that the action of the substance which promotes osteoinduction is ancillary to the action of the matrix than the product has to be considered as a pharmaceutical.

15. Meeting NB-MED on 18./19.11.97, Item 5 (7)

*(NBRG-Meeting on 11./12.06.98: No further action required.*

*NBRG-Meeting on 27./28.09.99: see also MedDev 2.1/3 on "Drug/device borderline".)*

**S/38/97            Dental filling material**

Dental filling material used for retrograde filling has to be considered as class IIa.

15. Meeting NB-MED on 18./19.11.97, Item 5 (8)

*(NBRG-Meeting on 11./12.06.98: No further action required.*

*NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the minutes of 15. meeting of NB-MED.)*

**S/39/97            Products made from latex**

see also S/21/97

Medical Device Experts Group meeting on 25.02.97:


The role of the Notified Bodies was to check that the manufacturers used the best available technology to reduce allergies content and ensure the labelling „contains natural latex“.

1. Notified Bodies to be aware of their responsibilities

2. Labelling, at least „this product contains latex“

15. Meeting NB-MED on 18./19.11.97, Item 6.3

*(NBRG-Meeting on 11./12.06.98: No further action required.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p><b>Consensus statements</b></p>
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**S/01/98          Demarcation Medical Devices, Accessories and Production or Laboratory Devices**

It was agreed that the old consensus statement (S/12/96) will be updated by the new one.  
16. Meeting NB-MED on 03./04.03.98, Item 3.3 (2)

*(NBRG-Meeting on 20./21.04.98: A new statement was elaborated and accepted:*

**„Demarcation Medical Devices and Non-Medical Devices**

**Substances or materials or equipment, needed to manufacture medical devices without becoming part of the medical devices or without use on the patient, are neither medical devices nor accessories to medical devices**

**If the equipment**

- **must be used in the immediate medical environment and**
- **is used by the final user for the preparation of a medical device directly for the time of use and**
- **is specifically intended for this special purpose and**
- **the medical device cannot be prepared without this special equipment,**

**then this equipment may be considered as an accessory to a medical device.“**

*the old consensus statement S/12/96 is superseded by this one; see also S/02/95.)*

**S/02/98          Lasers for skin treatment (low level laser therapy); classification**

NB-MED agreed that the classification of lasers as class IIa or class IIb products depends on the level of risk factor (e.g. on potential hazard or on level of energy or frequency); EN 6825 considers also these issues. R. V. mentioned that if the use of lasers is potentially hazardous for e.g. the eye of the surgeon or of the operator (laser classification 3b or higher) then these devices have to be classified as class IIb.

16. Meeting NB-MED on 03./04.03.98, Item 3.4 (6)


*(NBRG-Meeting on 11./12.06.98: No further action required.*

*NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the minutes of 16. meeting of NB-MED.)*

**S/03/98          Samples of certificates**

The conclusion at the NBRG meeting on January 1998 was to have a list of the minimal contents which should be in the certificates; also some principles were agreed (NBM/17/98). The Medical Devices Experts Group has received some comments of the member states concerning the Commission's proposal; most of them wish a harmonisation of the content of certificates, some see the need for consideration of the class of the device on the certificates. No consensus in the Medical Devices Experts Group has been achieved. The NB-MED agreed that the samples of certificates should define the minimum that should appear on the certificates; the legal is the basis for the given details but everybody is free to add more details. The wording of the tabled document shall be suited



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largely to the EUDAMED database „nomenclature“, but R. V. reminded that not all information of this document will appear within the EUDAMED database e.g. the link with the dossier at the Notified Body.

16. Meeting NB-MED on 03./04.03.98, Item 5.5

*(NBRG-Meeting on 27./28.09.99: This consensus statement is **superseded** by NB-MED Recommendations No. 2.5.1/Rec4 „Content of mandatory certificates“ and No. 2.15/Rec1 „Voluntary certification at an intermediate stage of manufacturer“.)*

### **S/04/98            Blood bags with preservation solution**

At the last NB-MED meeting the Commission was asked - in the light of a inconclusive discussion at that time - to think over their interpretation in the classification guidelines concerning rule 18 for blood bags with preservation solution; rule 18 defines blood bags to be class IIb independent if they have preservation solution in it which is a medicinal product. Dr. R. explained once again the discrepancy of annex II, clause II.4 and annex III (plus e.g. V), 5 2nd clause concerning the consultation with drug authority. That means this classification depends when there is e.g. a conformity assessment „annex III plus V“; concerning annex III the Notified Body has to consult with a drug authority because there is some drug inside. By making an annex II procedure the Notified Body has to skip the design examination without consultation of the drug authority. ... R. V. asked the NB-MED to consider this MedDev document as a stable document so far no changes will be made.

16. Meeting NB-MED on 03./04.03.98, Item 5.9

*(NBRG-Meeting on 27./28.09.99: this consensus statement is **superseded** by S/12/98.)*


### **S/05/98            Decoupling of certificates**

The NB-MED recognizes that the Medical Devices Directives do not permit decoupling of the design examination certificate from the Annex II quality system certificate. The design examination forms an integral part of the Annex II conformity procedure for class III devices, it is not independent of the other requirements of Annex I.

A Notified Body cannot issue a design examination certificate in isolation. Any product approved on a design examination certificate must also be covered by an Annex II quality system approval certificate from the same Notified Body that issued the design examination certificate. The entire conformity procedure must be applied by a single Notified Body for the class III devices concerned. This requirement does not preclude a manufacturer from using different Notified Bodies for different class III devices, nor does it prevent a manufacturer from terminating any agreements with a particular Notified Body.

NB-MED agreed to adopt this Consensus Statement which will replace also the former NB-MED Recommendation NB-MED/2.5.1/Rec3 *Certificates - decoupling*.

17. Meeting NB-MED on 09./10.06.98, Item 3.3 (1)

	<p style="text-align: center;"><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p style="text-align: center;"><b>Consensus statements</b></p>
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**S/06/98      Medical gas pipeline systems in hospitals**

*There are several scenarios where different bodies take the role of the "manufacturer" responsible for designing, manufacturing, installing and commissioning. References to EN standards in this statement are made in light of the use of harmonised standards to demonstrate compliance with the essential requirements according to article 5 of the MDD.*

**1 Scenario 1**

*In one possible scenario, the designer, installer and commissioner is the "manufacturer".*

**1.1 Product to be placed on the market**

*A medical gas pipeline system's installation for medical gases and vacuum according to EN 737-3 which may include components such as*

- manifold and line pressure regulators according to EN 738-2
- terminal units according to EN 737-1,
- medical supply units (inc. ceiling mounted pendants) according to EN 793,
- copper tubing for medical gases according to prEN 13348,
- terminal unites for anaesthetic gas scavenging AGS systems according to EN 737-4

*and others.*


*Besides the requirements for the components (e.g. see standards above), requirements for the completed installation are given in EN 737-3 for pipeline systems and in EN 737-2 for AGS disposal systems.*

**1.2 Classification**

*This medical device channels compressed medical gases or vacuum from a source to the patient, so rule 2 applies.*

*Pneumatic pressure source or vacuum makes it an active medical device, which administers or removes energy and substances to or from the human body in a potentially hazardous way, so rule 9 and 11 apply.*

*Resulting class for the complete system according to EN 737-3 is class IIb.*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p><b>Consensus statements</b></p>
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*Anaesthetic gas scavenging systems and components channel anaesthetic gases from the patient, operator or third parties in a non potentially hazardous way per rule 9 and 11 resulting in class IIa.*

*Classification of components (if considered as separate medical devices).*

<i>Manifold and line pressure regulators acc. to EN 738-2:</i>	<i>rule 2, 9 and 11</i>	<i>class II b</i>
<i>Terminal units acc. to EN 737-1:</i>	<i>rule 2, 9 and 11</i>	<i>class II b</i>
<i>Medical supply units (inc. ceiling mounted pendants) acc. to EN 793:</i>	<i>rule 2, 9 and 11</i>	<i>class II b</i>
<i>Copper tubings for medical gases acc. to prEN 13348:</i>	<i>rule 2</i>	<i>class II a</i>
<i>Terminal units for AGS systems acc. to EN 737-4:</i>	<i>rule 2, 9 and 11</i>	<i>class II a</i>
<i>AGS disposal system:</i>	<i>rule 2, 9 and 11</i>	<i>class II a</i>

*Associated risks are over- and under-pressure, loss of gas specificity, leakage of oxidizing gas, loss of continuity of supply.*

*The medical device is generated when the design, the installation and the commissioning (final testing and inspection) are performed (in compliance with EN 737-3 or EN 737-2).*

*Note: Classification to be confirmed by CEC classification working group.*


### **1.3 Conformity assessment**

*Possible conformity assessment procedures are annex II.3, annexes III + IV, annexes III + V, annexes III + VI; furtheron there is also the possibility to follow article 12 (system).*

## **2 Scenario 2**

*In an other possible scenario, the hospital gets such a system installed by contractors according to its own design; in this case, no "placing on the market" of the complete installation takes place, CE-marking of the final installation is not applicable.*

*In this scenario, the hospital assumes the responsibility of the manufacturer in the meaning of the directive and it is the task of the national authorities to assure compliance with national requirements for the safety e.g. by complying with the standards mentioned above. See also IVDD article 1 clause 5 with regard to the right of Member State to subject such activities to appropriate protection requirements.*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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### **3 Extension of existing medical gas pipeline systems**

*Extension of existing medical gas pipeline systems not CE-marked and not designed, installed and commissioned in compliance with the standards mentioned above may have to consider the NB-MED Recommendation on combination of CE-marked devices with non-CE-marked devices as guidance to comply with the directive.”*

NB-MED agreed to adopt the document and to supersede the old consensus statement S/04/97 *Gas distribution networks in hospitals* by this new one. The document was further developed on the following meetings:

- 17. Meeting NB-MED on 09./10.06.98, Item 3.3 (1)
- 18. Meeting NB-MED on 03./04.11.98, Item 3.3 (2)
- 19. Meeting NB-MED on 02./03.03.99, Item 3.3 (2)
- 21. Meeting NB-MED on 02./03.11.99, Item 3.3 (2)

*(NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the former minutes of NB-MED.)*

With regard to the Consensus Statement S/06/98 “Medical gas pipeline systems in hospitals” Dr. W. mentioned that some Competent Authorities do not consider these as covered by MDD and he reported about a special case in UK (ceiling panel as part of a medical device system fell down from the ceiling). Mr. B. confirmed that between the UK’s MDA, industrial representatives and Notified Bodies there is no consensus on that particular issue “medical gas pipeline” especially to consider these as medical devices .

- 22. Meeting NB-MED on 29.02./01.03.2000, Item 3.3 (1)


#### **S/07/98            Retention periods for documents and quality records**

Dr. P. gave an introduction to document NBM/46/98; the main question was: How long must documents and quality records be retained?“ Different statements are given in relevant harmonized standards and the directive itself. The problems came up with the harmonised standard EN 46000 which brought in an except from the 5 years after which a product is developed by considering the „life time of the product“. In light of the requirements of the directive (Annex II, 6.1) NB-MED agreed to consider the statement given in the directive „... the manufacturer must, for a period ending at least five years...“ as a obligatory minimum. Therefore NB-MED has seen no necessity to develop a NB-MED recommendation. But also the lifetime of the product has to be considered. The undertaken risk analysis will also give the retention period for documents and quality records.

- 17. Meeting NB-MED on 09./10.06.98, Item 3.4 (4)

#### **S/08/98            Sterile patient drapes; Classification**


Mrs. B. introduced the document NBM/75/98. First Mrs. B. clarified a typing error (instead of „absorbable“: read „absorbent“). NB-MED decided in the content of the intended use of

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the product to consider sterile patient drapes as class I devices with additional sterile requirements per annex VII per rule 9 of classification-MedDev.

17. Meeting NB-MED on 09./10.06.98, Item 3.4 (6)

*(NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the 17. minutes of NB-MED.)*

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED)</b> on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p>	<p><b>Consensus statements</b></p>
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**S/09/98            Oximeter; Classification**

Mrs. B. introduced the document NBM/76/98. Mrs. B. clarified that this inquiry refers to pulse-oximeter. NB-MED decided to consider pulse-oximeter as class IIb devices following rule 10 of the classification-MedDev in case of use in an intensive care monitoring system with alarm function. But if the pulse oximeter is not used for alarming (e.g. just to make a measurement) it is a class IIa device following rule 10 (3rd indent, 1st sentence). Mr. V. clarified that the question whether energy is supplied to the human body is not relevant for applying rule 10 in this particular case (classification of pulse-oximeters), not in general. Dr. W. also mentioned the harmonised standard EN 865 on pulse oximeters which requires alarms.

17. Meeting NB-MED on 09./10.06.98, Item 3.4 (7)

18. Meeting NB-MED on 03./04.11.98, Item 2.4


*(NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the 17./18. minutes of NB-MED.)*

**S/10/98            Auditing of internal audits performed by a manufacturer within his  
                          QS**


Dr. R. introduced the document NBM/98/98. This problem came up specially when US-manufacturer are audited. FDA has the policy not to audit the results of internal audits of the manufacturer. Manufacturers say if such internal audit results are audited, it could lead to the internal auditor no longer writing up findings (problem of confidentiality). Mr. R.-H. mentioned that the manufacturer uses his internal audit system to improve his quality system. Therefore the manufacturer should prove the existence of an internal audit system and the auditor/Notified Body can prove whether it works without recourse to internal audit reports. Mr. D. stated that the Notified Body has in principle to look into the internal audit system. Mr. R. mentioned that the FDA got into an impasse by questioning the legality of supplying medical devices from a quality system that is known to be defective by the manufacturer. Mr. V. referred to the annexes relating to quality system, section surveillance, 5.2: „The manufacturer must authorize the Notified Body to carry out all the necessary inspections and supply it with all relevant information, in particular:

- the documentation on the quality system,
- ...
- the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports ...“.

NB-MED discussed that in view of the requirements of the directive the proposed solution b) („all Notified Bodies insist on looking into the internal audit results“) shall be taken into account, but in light of the sensitivity of this issue all involved parties are requested to follow the solution b) in a sensible way. The aim for the Notified Body is to see that the internal system for monitoring is effectively operating. NB-MED asked the NBRG to think about the development of a recommendation with regard to this subject.

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17. Meeting NB-MED on 09./10.06.98, Item 3.4 (10)

	<p><b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b></p>	<p><b>Consensus statements</b></p>
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Dr. R. reported that already on occasion of the NBRG meeting in November '98 it was agreed to observe the relevant activities within the GHTF SG4; there was developed a guidance paper on auditing which was distributed also as MedDev document. In case that this document covers all relevant aspects the NBRG would like to recommend not to develop a NB-MED Recommendation. But a formal decision was not taken on this subject, a consensus was not yet reached. NB-MED took note of this.

19. Meeting NB-MED on 02./03.03.99, Item 3.4 (2)

Dr. R. explained that in the meanwhile some informal discussion with some industrial representatives has taken place and maybe the new aspects could be written down in a new draft document for one of the next meetings. Mr. D. reported that he has approached the UK-Competent Authority with this issue; a short letter of response ended with the sentence "... the Notified Body must have access to records of the manufacturer's internal audits". Therefore Mr. D. estimated that this issue could not make any further progress. NB-MED took note of this and the chairperson summarised that at this point of time the item should be removed from the agenda.

20. Meeting NB-MED on 08./09.06.99, Item 3.4 (1)

### **S/11/98            Gases for driving medical tools**


In the context that gases for driving medical tools are considered as medical devices it was clarified that atmospheric compressed air can be considered as technical gas and is therefore no medical device. Dr. W. explained additionally that compressed air for breathing is defined in EN 737-3.

17. Meeting NB-MED on 09./10.06.98, Item 5.8

### **S/12/98            Blood bags with preservation solution**

Mr. V. reported that this question (remark of Technical Secretariat: see S/04/98) was discussed within the Commission. Blood bags are classified as class IIb devices, not as class III, so it can follow annex II (without consultation process), but also no consultation process in case of annexes III + V, because the consultation process was intended for devices with medicinal products, which are by consequence class III devices. The purpose of the consultation process was to consult a medicinal authority when a device contains a pharmaceutical product. The problem for blood bags was that they are classified as IIb by derogation. Before the Notified Body comes to the conclusion to consider such devices as class IIb devices, the Notified Body has to perform the necessary assessment and to have to take into account the results of the risk analysis. Mr. J. mentioned that the MDA gave the UK Notified Bodies clear guidance: as long as the medicinal products were only for preservation then no consultation is necessary; but if things will be put in the bags that would be for more than preservation then rule 13 will apply and it could make a



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class III device. The NB-MED asked the Commission to be informed about further decisions within the Commission.

17. Meeting NB-MED on 09./10.06.98, Item 5.9

*(NBRG-Meeting on 27./28.09.99: the old consensus statement S/04/98 is superseded by this one; further: pass on to the **Commission Classification Group** including all relevant information out of the 17./18. minutes of NB-MED.)*


Mr. H. reported about a similar question coming up in the borderline task force. Dr. R. mentioned that this subject is no borderline issue but more an inconsistency in the directive with the application of the conformity assessment procedures. In case of application of Annex III plus V (preservation solution is considered to be a drug with auxiliary function) consultation with the drug authority is required but in case that the products are classified as IIb (Annex II.3) no consultation is required. Mr. V. reminded that the position as already got in the past was that the specific rule will be applied; this means that blood bags even containing preservation solutions should be classified as class IIb. Mr. J. mentioned that the revised MedDev document on classification give some clarification per rule 18: class IIb and in some cases class III. Mr. V. gave his interpretation: blood bags should be classified as class IIb devices, not as class III, so it can follow annex II (without consultation process, section 4), but also no consultation process in case of annexes III plus V, because the consultation process was intended for devices with medicinal products, which are by consequence class III devices. Dr. R. informed that TPS does not consult for such moment, following a former statement given by Mr. Anselmann: consultation is not needed even in case that procedure Annex III plus V will be followed because it is a class IIb device. Mr. V. pointed out that ER 7.4 requires a full assessment of the usefulness of the used drug which will not be an official consultation procedure. Mr. F. mentioned that also the European pharmacopoeia monographias could be considered to this special subject.

NB-MED took note of this and felt that clarification was needed. The Commission was asked to keep in mind this potential problem.

22. Meeting NB-MED on 29.02./01.03.2000, Item 5.6

### **S/13/98      Own brand labelling**

It was reported that the Medical Devices Experts Group has not yet concluded the issue. The MDA's legal department opinion has not yet reached the Commission. The item was also removed from the agenda of the last Medical Devices Experts Group Meeting on 19./20.10.98. Mr. P. explained that the answer is very clearly stated in the directive. The name of the manufacturer must be on the label, indicated by words like "manufactured by" or "manufacturer is". Mr. T. proposed for further clarification the following wording: "Where more than one name appears on the label it must be clear which is the name of the person having the legal responsibilities as manufacturer". Mr. P. agreed. He also said that it should be clearly identified who is the manufacturer or the responsible authorized

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representative. Mr. D. repeated that the UK-Notified Bodies are under the clear mandate to act in a certain way and therefore this subject should be discussed within the Medical Devices Experts Group to reach a common position. Mr. P. responded that for this special subject he does not need the opinion of Medical Devices Experts Group. It is a task for the Commission to solve this problem with the MDA with the possible consequence to develop a document on behalf of the Commission and not a MedDev-document. Anybody who disagree with the position of the Commission could finally turn to the court of justice in Luxembourg. In response to Mr. J. Mr. P. offered to inform the Member States about this subject by letter. NB-MED took note of this discussion.

18. Meeting NB-MED on 03./04.11.98, Item 3.4(1)

### **S/14/98      Refillable glass capsule containing sodium-hydrogen carbonate (used to produce a bicarbonate solution during dialysis)**

Mr. M. introduced document NBM/156/98. The question is: How is a refillable glass capsule containing sodium-hydrogen carbonate and used to produce a bicarbonate solution during dialysis to be classified under Annex IX of MDD? The glass capsule is filled with sodium-Hydrogen carbonate and is flushed during dialysis with water produced by reverse osmosis, which produces a saturated bicarbonate solution. The solution is drawn into the dialysis unit, mixed with patient-specific substances and fed to the dialysis filter. The following cases were discussed concerning the system "Refillable glass capsule plus the concentrate":

- a) The glass capsule is regarded as part of the dialysis unit depending on the manufacturer's decision concerning the placing on the market; the whole system is to be classified as class IIb in accordance with rule 11.
- b) The glass capsule "only" serves to produce a saturated saline solution. The concentration is monitored by the dialysis unit. As a simple system for the passage of a liquid in conjunction with an active system, the capsule is to be grouped into class IIa according to rule 2.


NB-MED agreed with these solutions. The representatives of the Commission were asked to bring this subject also to the agenda of the classification group.

18. Meeting NB-MED on 03./04.11.98, Item 3.4(4)

*(NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the 18. minutes of NB-MED.)*

### **S/15/98      Surveillance - Inability to carry out unannounced visits in Non-EU States**

Mr. D. introduced document NBM/159/98. The background of this inquiry is that certain countries (e.g. China) require "Letters of invitation" from clients to support VISA application, prior to granting entry to the country thus preventing the ability of a Notified Body to

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enter the country and company unannounced. The question is "How unannounced is unannounced?", that means a question of the timeframe between the announcement/note and the visit itself. If the Notified Body does not get the visa to visit the country within this timeframe and the company does not invite the Notified Body instantly then it is allowed to the Notified Body to cancel the certificate because the conditions for an EC-certification are no longer fulfilled. NB-MED agreed with this pragmatic procedure, but every case has to be considered individually.

18. Meeting NB-MED on 03./04.11.98, Item 3.4(7)

### **S/16/98            Sterilisation of reusable medical devices**

Dr. G. introduced document NBM/160/98. The question is: Is Art. 12.3 to be applied in case of manufacturer sterilising reusable medical devices on behalf of a hospital owner of the same devices? It was discussed that in this sterilisation was not for the purpose of placing devices on the market and therefore not regulated by the MDD. Sterilisation activity is to be regulated by national laws or else the hospital can require voluntary certification of its subcontractor. NB-MED agreed with the proposed solution.


18. Meeting NB-MED on 03./04.11.98, Item 3.4(8)

### **S/17/98            Low pressure regulators; Classification**

Dr. G. gave an introduction to document NBM/162/98. The background of this inquiry is that - considering EN 738-1 definitions and requirements as well as the classification proposed by Medical Devices Experts Group in application of rule 11 - is it possible to assume that low pressure regulators (< 1400 kPa) are not potentially hazardous and can they therefore be classified in class IIa? Dr. W. explained that he can not see any reason – when a risk analysis was made – why “> 1400 kPa” should be a high risk and “< 1400 kPa” should be a low risk. The risk of pressure regulator in medical application is to blow up the lung if one exceeds the pressure of "atmosphere plus some mbar". Risk will not go away in this pressure level. Dr. W. proposed therefore to stay with class IIb as already agreed in the classification-MedDev document; pressure regulators are given as example for high risk devices to be treated as class IIb. Mr. V. strongly supported this statement; the hazardous situation came from the fact that one has to administer a drug e. g. oxygen to a patient. The hazardous situation has nothing to do with the fact that the pressure is high or below. NB-MED agreed therefore to classify low pressure regulators as class IIb devices.

18. Meeting NB-MED on 03./04.11.98, Item 3.4(10)

*(NBRG-Meeting on 27./28.09.99: Pass on to the **Commission Classification Group** including all relevant information out of the 18. minutes of NB-MED.)*

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**S/18/98            Sterilizers used for final sterilisation of medical devices to be put on the market**


Dr. G. gave an introduction to document NBM/163/98. The question is: Would sterilizers used directly by a manufacturer of medical devices commercialised as "sterile" or used by a subcontractor for final sterilisation of medical devices to be put on the market be considered as accessories of medical devices and therefore subjected to the MDD? NB-MED discussed that only sterilizers used in medical or hospital environment, or by subcontractor sterilising reusable medical devices have to be considered accessories of medical devices and therefore be subjected to the MDD. Those devices sold to the hospitals (so called "clinical environment") for sterilising reusable surgical instruments are medical devices and need CE-marking; for the others it is up to the manufacturer how he wants to declare them. NB-MED agreed with the proposed procedure.

18. Meeting NB-MED on 03./04.11.98, Item 3.4(11)

**S/19/98            Re-use of single use devices**

Mrs. O'C. distributed to the members of NB-MED a document of the Commission referring a communication from the CDRH Centre of Devices and Radiological Health on the re-use of single use devices. Mr. P. made clear in his point of view that single use devices should never be re-used. There is a need to discuss this subject with the manufacturer but if the manufacturer has good reasons to indicate a device only for single use then it should not be so easy to bring the re-use for this device in the debate. Prof. L. emphasised that the re-use of single use devices is often the reason for accidents. Mr. B. articulated his opinion that it seems fundamentally wrong that in some cases it is allowed to re-use a device what is intended and validated for single use. If either clinicians and/or manufacturers reached the conclusion that a particular type of device is most economically made as one that can be reprocessed and re-used then it simply needs to be validated and then relabelled as a re-usable device. The members of NB-MED were asked to send any feedback to the Technical Secretariat.

18. Meeting NB-MED on 03./04.11.98, Item 7.2


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**S/01/99 Declaration of conformity**

The manufacturer must draw up a written Declaration of Conformity (DoC). The content will depend on various circumstances, including the conformity assessment procedure followed and the Class and type of device concerned. As a minimum, the DoC should contain the following information:

<b>Type of information</b>	<b>Text</b>
Title of the document	Declaration of Conformity
Identification of the legal entity	Name and address of the manufacturer, or where permitted, the name and address of the authorized representative
Identification of the device(s) concerned	Name, type or model
Identification of a given number of products and/or identified specimens, where required for the selected conformity assessment procedure	The DoC may cover particular lots, batches or serial numbers and/or particular products types and/or particular periods of manufacture
A statement that the identified devices meet the applicable provisions of the Directive	'We hereby declare that the above mentioned devices comply with the <u>(legislation of the member states where the Notified Body is located - if a Notified Body is involved -) transposing</u> European Medical Devices Directive 93/42/EEC'
Date of validity	Date from which the DoC is valid
Identification of the person authorized to sign on behalf of the manufacturer	Name, position and signature of the authorized person, who is approving the DoC

Mr. P. mentioned that there is no way to declare conformity with the directive; the Notified Body can only declare conformity to the relevant national legislation that applies to the manufacturer who is involved. The manufacturer must comply with the legislation where the Notified Body is established. With e. g. the respect to the use of languages it is not to consider the national legislation of this country where the Notified Body is established, but it is to consider the legislation of the country in which the product will be sold. In the directives the essential requirements do not apply to the use of language; the directives are asking for all the information and all necessary documentation etc. that is produced by the manufacturer to be evaluated by the Notified Body in the language used by the Notified


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Body. If the product is produced and put on the market in an other country, that country has the possibility to make sure that the translations have been performed correctly. In case that no Notified Body is involved (class I devices) it is the decision of the manufacturer to which national legislation – transposing the directives – he declares the conformity. This explained principles are covered by the system so-called “Mutual Recognition” on which the directives are based. In the context that there is no need for the manufacturer to compare or to “know” the difference national legislations Mr. P. reminded the Notified Bodies not to work as “consultants” to industry; Notified Bodies are looking at the products and not – at the same time – advising the manufacturer. In general Mr. P. stated very clearly that the declaration of conformity - when the type approval has been obtained - is not to the legislation but to the type.

19. Meeting NB-MED on 02./03.03.99, Item 3.2 (3)

### **S/02/99            Software; Classification**

Mr. R. introduced the inquiry-document NBM/28/99. It was proposed to consider software as an active medical device because software itself can not have an effect on a patient and it is always required that software runs on a computer; the computer usually is powered by electrical energy. Another argument for this recommendation is given in Annex IX, 1.6, MDD: Active medical device for diagnosis: “Any active medical device, whether alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring ...”. Mr. R. presented further – supported by overhead-projector – some software driven devices. Also Mr. R. introduced the more general document NBM/36/99 which describes the available information on medical software and what is regarded as medical software. The reason for finding more clarification on this matter is that active medical devices include more and more software which leads to exchange of medical data including arising some problems (e. g. in the context of internet-use). Mr. B. mentioned that in case of commercially available software this software has not any relation to medical device regulations. Mr. B. said that under special circumstances software is to be considered as medical device; the question whether software is an active medical device is just under consideration within EUROM VI without solution. But at the end of March '99 a decision could be found. Mr. P. reminded that it should not be forgotten in the discussion of the definition of a medical device that it should be intended to be put on the market to the end-user; if products are bought from subcontractors or are bought in the open market between professionals the directive normally does not apply. The directives apply to free circulation of products that have been intended to be put to the end-user. Dr. R. explained that the presented examples are showing software which is really put and sold to the end-user; in the past there was the case that software has been delivered to the manufacturer of the computer, considered as a supplier to the manufacturer. The problem is not software that runs on medical devices because here we have the guideline this is classified as the medical devices itself. The real problem comes because computers can be bought from the shelves as general purpose computers and are not under the MDD as such and then additional software can be bought that runs on that computer; so it can not be said to classify the software in the same class as the device in

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which it runs because this device is not a medical device. Mr. S.-A. emphasised that there are manufacturers who make software intended specifically for medical purpose to do e. g. either analysis, diagnosis or control the instruments; so used software should be considered as medical device because there is an high risk involved. Mr. R. and Mr. B. offered to elaborate a common position on this subject for presenting it on the next NB-MED meeting in June. NB-MED agreed to handle this subject as proposed.


19. Meeting NB-MED on 02./03.03.99, Item 3.4 (6)

Prof. L. mentioned that the document NBM/98/99 proposes that software is an active medical devices because it requires a hardware environment; he could not follow this statement because otherwise any accessory might be an active medical device (e. g. ECG-electrode because it can fulfil its intended purpose only in combination with an ECG-recording system). Mr. V. explained that there is an other element of the definition of "active device"; "any medical device operation of which depends on a source of electrical energy or any source of power other than direct generated by the human body on gravity and which acts by converting this energy". The part of sentence "and acts by converting ..." was used to say that some electrodes were not active; this aspect should be discussed in the context of such a Recommendation. An other member of NB-MED stated that it is possible ever to think of "software as a medical device"; software is part of a system which might be a medical device. This detail was missed if it was tried to classify software on its own. Dr. R. added that a medical device could be e. g. hardware, software, substances as written in the Directive; also the relevant MedDev is saying: software that has a medical intended purpose can fulfil the definition of a medical device. The members of NB-MED were asked for sending additional comments to the tabled document NBM/98/99 directly to Mr. B.; further consideration will be made within the NBRG. Hopefully a revised document could be presented on the next NB-MED meeting in November in the format of a NB-MED Recommendation.

20. Meeting NB-MED on 08./09.06.99, Item 3.4 (4)

### **S/03/99 Pools for training disabled persons**


Mr. B. introduced the inquiry-document NBM/29/99. He proposed that pools intended for training of disabled persons are to be consider as medical devices because the pool is installed in hospitals and care facilities. The intended purpose is for physical training of disabled persons in order to regain strength and movability as a part of rehabilitation. Mr. V. mentioned that already similar cases have been discussed e. g. "air conditioning in hospitals for using in operating theatres"; in this cases it was decided to consider these products not as medical devices. A criteria for such a decision could be whether the products could be used for other purposes. Dr. R. added that not every subject that is used for a medical treatment is automatically a medical device. Mr. J. explained that if pool is made and destined by a manufacturer for medical purposes then it is a medical device. Mr. P. stated as a general statement for any case that it should be avoided that for commercial reasons a product will be classified as a medical device. NB-MED emphasised that the decision to consider e. g. pools for training disabled persons as medical device depends

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on the intended use of the product given by the manufacturer. Therefore some pools might be medical devices with a well defined and justified intended purpose.

19. Meeting NB-MED on 02./03.03.99, Item 3.4 (8)



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**S/04/99      Free movement, device intended for special purpose**

Mr. Sch. reported about the background of this item (see document NBM/30/99). "Free movement" and "devices intended for special purposes" is the headline of article 4 MDD. The French ministry of employment demands from manufacturers of some special product families very sensitive data, e. g. all what is in the technical file like calculations, the design risk analysis etc. The manufacturer has to do this before he can purchase his medical device in France otherwise the purchase of the products will be forbidden in France. Today 4 product categories are covered by this regulation: physiological parameters supervision monitors, high-frequency surgical equipment, pacemakers and lung's ventilators. COCIR considers this behaviour as a barrier to a trade within Europe. Notified Bodies are designated for carrying out the tasks pertaining to the procedures referred to in article 11 (see article 16 of MDD); Notified Bodies must carry out the assessment and verification operations with the highest degree of integrity and competence. The conclusion of COCIR, EMIG and EUROM VI is that for some product categories the French authorities do not trust the work of Notified Bodies; these industrial federations have asked for rejection of this French regulations. Mr. B. added that the LCIE in regard to the French ministry also is asking for equipment for testing again even the products are have already CE marked. Mr. J. mentioned that the French regulations are also relevant concerning materials for absorbing carbondioxid where effectively France has asked from all manufactures samples and has issued then non-compliance (without CE-marking) or vigilance note where there is no safety implication. Notified Bodies get asked for advice but Notified Bodies are not in the position to advice manufactures in the relation with their Competent Authorities. Mr. P. mentioned that the NB-MED is not the appropriate forum to discuss such a matter. The Commission is aware that also some other member states are thinking about to handle this subject similar. Hopefully this item will be discussed further on at the next meeting on the Medical Devices Experts Group on 16./17.03.99; all parties involved will be invited. It is really important to find out exactly what is the understanding of what member states can or can not do in the context of market surveillance where the products are on the market; it could not be discussed on measures that are intended to stop products to be put on the market that means e. g. the pre-market evaluation whether a Notified Body has to react responsibilities. Concerning the French activities the Commission is espying an approach by the French Authorities as a systematic evaluation of all products of a given category. NB-MED took note of this explanations and asked the Commission for further information on this matter.

19. Meeting NB-MED on 02./03.03.99, Item 3.4 (9)

**S/05/99      Carotid shunt; Classification**

Mr. V. introduced the inquiry-document NBM/46/99. The classification of carotid shunt depends on the interpretation of rule 6 concerning the word "to ... correct a defect ... of the central circulatory system" (2<sup>nd</sup> dash). Carotid shunts were used to divert the flow from element of the circulatory system to an other element (diversion of the blood flow between

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the primitive carotid and internal carotid). In some cases it has been classified as class IIa product on the fact that “to correct a defect” does not apply and in other cases it has been classified as class III product on the fact that “to correct a defect” applies. Mr. V. proposed to classify carotid shunt as class III product because during a short period of time (less about one hour) the function of the carotidian system is taken over by the shunt therefore the wording “to correct a defect of” applies and includes the case that there is a substitution of the function. Mr. R.-H. suggested to bring all subjects dealing with cardiovascular products like arterial probes to the Medical Devices Experts Group/Classification Group to receive a common interpretation whether these products are to be considered as class IIa, IIb or III. Dr. R. supported what was said by Mr. V. that correction of e. g. the heart by replacing some part of it by an other device is included in the term “correction”; so an heart valve replaces the natural one but in total the function of the heart is corrected by this means. Mr. R.-H. answered that exactly these arguments could also be used the other way around by saying if you have an implant like an heart valve or an hip then you have a correction, but if you have a temporary help during a procedure like a clamp then all the clamps are class III products. There should not only be the focus to “correction” itself also its “short term use” rather than an implant. NB-MED asked the representatives of the Commission to bring this subject to the agenda of the Medical Devices Experts Group because NB-MED could not come to a clear agreement anywhere.


19. Meeting NB-MED on 02./03.03.99, Item 3.4 (11)

Mr. H. reported more general that a.s.a.p. the finalised MedDev 2.4/1 on classification will be issued and therefore also this subject will be covered. But that particular MedDev could not clarify all open questions of classification because views/estimations on these depend on consensus and consensus is not always reached. Mrs. S. said that carotid shunts are included in the new draft issue of the classification’s MedDev (per rule 7). NB-MED took note of this; carotid shunts are class III devices per rule 7 of the revised MedDev on classification.

22. Meeting NB-MED on 29.02./01.03.2000, Item 3.4 (5)

### **S/06/99      Aqueous eosin solution; Classification**

Mr. V. introduced the inquiry-document NBM/47/99. Aqueous eosin solution is a substance and following the claim of the manufacturer three cases could be considered: case 1: indication for use as topical disinfectant property, therefore covered by the “drug”-directive 65/65/EEC; case 2 indication for use as hygiene device, therefore covered by the “cosmetics”-directive 76/768/EEC; case 3: indication for use to manage environment of a wound, of an injured skin (wound dressing impregnated with the solution), therefore the definition of medical device applies (93/42/EEC) as class IIa product per rule 4, annex IX, 3<sup>rd</sup> alinea. Mr. v. M. mentioned the principle question if the substance is used separately whether it is then covered by “drug”-directive 65/65/EEC; in this case the product becomes a class III device with a consulting process, and not a class IIa device. Mr. B. described three other cases: case 1: use for disinfecting or cleaning of medical devices,


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therefore covered by the MDD; case 2: use for disinfecting or cleaning the body or the wound, therefore covered by the “drug”-directive 65/65/EEC; case 3: use for hygienic purposes like cleaning the floor, therefore covered by the future “biocide”-directive. Mr. V. offered to prepare a more general statement to the “borderline-problem” for some other raised devices concerning their class IIa/III-classification. NB-MED agreed to handle this subject as proposed; further consideration should be made by NBRG and on proposal by Mr. V. for presentation to the Medical Devices Experts Group.

19. Meeting NB-MED on 02./03.03.99, Item 3.4 (12)

**S/07/99            Which directives must be named in the "declaration of conformity" of active electrical laboratory equipment**


Mr. P. introduced the inquiry-document NBM/51/99. He proposed that active electrical laboratory equipment must fulfil the requirements of the LVD (low voltage directive) and EMC (electromagnetic compatibility directive) until first application of IVD-directive on 07.06.2000. Therefore both directives must be mentioned in the declaration of conformity because – as first reason - LVD-annex II makes an exemption for electrical medical devices. Active electrical laboratory equipments are divided into this group of electrical medical devices by some manufacturers. The expression “electrical medical device” is defined in the MDD harmonized standard EN 60601-1. The electrical medical device must have a connection to the patient which is not given by active electrical laboratory equipment. Therefore they cannot be announced as electrical medical devices. As a second reason the standard EN 61010 is an harmonized standard under the LVD. Mr. B. explained laboratory equipment belong to the standard IEC 61010 as mentioned in the LVD; this standard is going to become a mandatory standard within the MDD because of the sterilizers and the washer-disinfectors. Laboratory equipment are normally no medical devices except they are belonging to the special area of the IVD-directive. This should be separated. Dr. R. pointed out that it should be considered: when in the LVD electrical medical devices are excluded it is not possible to refer to the definition of medical devices made in the IEC 60601 but it must be referred to the definition within the MDD as an overall definition, which includes in-vitro diagnostic medical devices; the LVD does not apply to electrical in-vitro diagnostic medical devices. Mr. V. explained that in his view electrical laboratory equipment used for general laboratory activities and which does not correspond with the definition of in-vitro diagnostic medical devices are not excluded from LVD and EMC-directive. The same problem was faced for medical devices during the transitional period of MDD but after the date where the EMC directive was made mandatory; the solution in this case was to indicate in the accompanying documents which directive is complied with and what does CE mark mean. Mr. B. simplified that first laboratory equipment always belong to IEC 61010 and second the intended use is to consider: either they are in-vitro diagnostica equipment then they belong to the IVD-directive or they are laboratory equipment in general use then they belong to LVD and EMC-directive so long the IVD-directive is not applicable. Mr. V. mentioned that also the draft document Certif 98/1 “Guide to the implementation of Directives based on New Approach and Global Approach”

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tries to explain this kind of situation (paragraph 2.2 “Simultaneous application of directives”). Dr. R. said that now – where the IVD-directive is not in force - in-vitro diagnostic devices are medical devices as a subset of medical devices and therefore excluded from the LVD; for electrical in-vitro diagnostic medical devices only the EMC-directive is applicable at that moment. Also the definition of a medical device is already in force but in the MDD. Mrs. O’C. proposed that since NB-MED deals in the areas of other directives also the other relevant Notified Bodies Groups should be asked to get further clarification. The Technical Secretariat was asked to bring this subject forward in this sense. NB-MED agreed with this proposed procedure.

19. Meeting NB-MED on 02./03.03.99, Item 3.4 (13)

Mrs. O’C. reminded that this subject was tabled on occasion of the March ’99 meeting as an inquiry (see NBM/51/99); The Technical Secretariat was asked at that time to bring this inquiry also to the other relevant Notified Bodies Groups. This was made and an answer was presented by Mr. Jan Coenrads (Chairman of the NB-group for the EMC directive) as document NBM/95/99 (quotation: “Dear Mr. Hoepfner, ..., my comments are as follows: 1. The DOC shall always make reference to all Directives being applied to the product and that moment. Of course there is the choice to make one DOC mentioning all relevant Directives or use separate DOC’s for each Directive applied. 2. The definition of medical equipment as given in the MDD is the official definition. The definition in a Standard (harmonised or not) is not relevant and certainly cannot overrule the MD Directive in any sense. As far as I know the MDD does not reference the connection to a patient (this is only done in some Standards) or not, so this cannot be a criteria to judge if the MDD is applicable or not. (This same situation occurs for other Directives where the harmonised Standards may have wider or narrower scopes than the Directive, but it is clear that the Directive is the legal text and only if products are under the scope of a Directive than a DOC is necessary for those products.) 3. As long as the IVD Directive is not fully mandatory the EMC Directive is applicable (if we are atleast talking about electrical equipment that is capable of having EMC problems) The general approach is that apparatus covered by the IVD will be excluded from the application of the EMC Directive, this IVD being specific with respect to the EMC Directive (89/336/EEC), in accordance with Article 2.2, upon the date of entry into force of this IVD. “). Mr. B. agreed with the proposed answer given within document NBM/95/99 with the exception of item 3 “As long as the IVD directive is not fully mandatory the EMC Directive is applicable”; not only the EMC but also the Low voltage directive is applicable. With respect to the last minutes (see NBM/82/99, page 151/152: “Dr. R. said that now – where the IVD-directive is not in force - in-vitro diagnostic devices are medical devices ...”) Mr. B. added that there is - in his view - a misunderstanding: in-vitro diagnostic devices are not medical devices. Dr. R. answered that it must be differentiated between the scope of the MDD and the definition of a “medical device”; the definition of “medical device” within the MDD includes also active implantable medical devices and also in-vitro diagnostic medical devices. If in the LVD is an exclusion of medical devices then all medical devices are excluded from the LVD (inclusively in-vitro diagnostic devices). Mr. B. agreed for this case that the IVD-directive is in force; as long as this is not the case in-vitro diagnostic equipment and devices are excluded from the MDD with reference to article 1 paragraph 5a. Dr. R. concreted that the MDD does not apply to in-vitro diagnostic devices but the definition of medical device surely also applies to in-vitro diagnostic devices; the exclusion of certain devices in the LVD does not refer to any directive, it just refers to medical devices. Mr. B. responded that - following this argument - then in-vitro diagnostic devices are not covered


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by any directive for the time being; as long as there is no other directive these devices are covered by the LVD. Mr. V. clarified that an answer to this subject could be given within the new draft document on "Guide to the implementation of directives based on New Approach and Global Approach" (Certif 98/1); this document considers also the case when several directives (could) apply to the same device. Mrs. O'C. proposed to refer to the Certif 98/1 ("blue guide") document to find final clarification. NB-MED agreed to handle this subject more pragmatically.


20. Meeting NB-MED on 08./09.06.99, Item 3.4 (9)

### **S/08/99            Computer for programming hearing aids**

Mr. S.-A. introduced the inquiry-document NBM/52/99; today people can buy themselves hearing aids which are actually sitting in the channel of the ear not visible from the outside (not implantable as cochlea implants). Those hearing aids must be programmed at that place, that means that the patient must give back a response to the doctor whether it is adjusted correctly. In order to do that normally the manufacturers are using a programming device like commercially available PC with special interface and software or a proprietary device specially designed for the task. Actually there is in circulation a special software for adjusting hearing aids in such a situation which follows a standard among manufactures of hearing aids. For a period of about ten minutes the patient is connected to this programming device while the programming of his micro processor in the hearing aids is taking place; this is a galvanic connection from the hearing aid back to the programming device. Some manufacturers do consider this "accessory" as an accessory to the medical device and therefore it becomes also a medical device. Other manufacturers follow the recommendation of the relevant manufacturer's association to consider such devices not as medical devices. To get clarification on it – also in a light of a reported incident in Scandinavia – Mr. S.-A. suggested that the programming system for "In the ear", "In the channel" and similar small Hearing Aids where the intended use is programming the Hearing Aids in situ should always be considered an accessory to a medical device according to the MDD. Dr. R. supported this proposal but the exception of the PC as a programming device with an interface and software could lead to the consideration that the software and the interface will become a medical device but not the PC; is it a special designed device put on the market under the name of the medical devices manufacturer then the complete programming device is – as accessory - a medical device. Mr. S.-A. clarified that always the interface between the computer and the hearing aid is separate available; the question is of course if there could a brake-down in the software running of the PC be able to harm the hearing capability of the patient. Mr. S. mentioned that the proposal should consider the standard IEC EN 60601-1-2 as a system standard instead IEC EN 60601-1. Mr. S.-A. mentioned that some manufacturers do not consider the presented system as a medical device system and so - as first step – computers for programming hearing aids should be considered as an accessory to a medical device and therefore it becomes a medical device according to the MDD. NB-MED agreed with the proposed solution; also the relevant system standard should be considered.

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19. Meeting NB-MED on 02./03.03.99, Item 3.4 (14)

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### **S/09/99          Conformity assessment procedures of breast implants**

Mrs. O'C. reported that the NBRG has been reviewing the current MedDev-document (see NBM/125/98). The comments were submitted to the Commission (see NBM/31/99). Mr. P. mentioned that the Commission has received a letter from the French authority with respect to the situation of the authorisation of putting on the market breast implants in France; the letter gives the expression to make the MedDev-document mandatory and that the European standard that has been developed is not sufficient and not appropriate. The Commission denied the first petition; MedDev-documents will never be made mandatory anywhere. But the Commission agreed with the second French opinion that the European standard is not sufficient; this European standard needs some further review. Therefore France is promising that if a product conforming to the standard would be put on the French market it would be withdrawn from this market immediately because the presumption of conformity is not be given to that standard. Mr. P. said that therefore a solution must be found to make sure that CE-marked breast implants will be authorised on the French market. Mr. G. mentioned that the French ban which has been published in a decree is not limited to breast implant but to other implants made by silicon; therefore a expected solution made by the Commission should also cover all these products. NB-MED took note of this.

19. Meeting NB-MED on 02./03.03.99, Item 5.2

### **S/10/99          Misuse of Notified Body Identification Number**

Mr. J. reported it was the first time that a Notified Body had really taken away a whole certificate from a company against their will after three audits; every audit led to an increasing number of major non-compliance in critical areas. The Notified Body had suspended the certificate but the company continued to produce products using the Notified Body number; so at the end the Notified Body withdrew the whole certificate. The Notified Body informed then the Competent Authority in the country where the company was settled; this informed Competent Authority then wrote around to the other Competent Authorities. Also this company was using the Notified Body number outside the given limited scope on products which were not approved. Eventually this company was certified by an other Notified Body because most Notified Bodies had not been informed about 6 month after the letter going out on this non-compliance. Mr. C. reported the he had made the same experience - informed by the field of a customer - with a company placing the Notified Body number on the product without authority; in parallel the Competent Authority in that country the manufacturer is placed and the own Competent Authority were informed. But the question is how could the right information be given to the market; the Notified Body is not be able to do something. Mr. J. added that it was also thought about to publish the event but in this case legal problems could arise. So the Competent Authority should make a decision whether e. g. a recall or a note to the market should be required. Mr. V. reminded that article 18 MDD addresses this problem. Mr. P. mentioned that nobody has the property of the CE mark and that the number is not the important

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point; normally the Notified Body is the only one who can withdraw the certificate. In case of reasons to withdraw a certificate first the manufacturer shall be informed about it; he must be given the opportunity to act and to take the appropriate measures. In case of withdrawn of a certificate the responsibility of the Notified Body ends with this action. Everything what is happening after that is exclusively the responsibility of the Member States. There are no opportunity for the Notified Body to take action against the manufacturer, against products or to inform people. Only the public authorities shall be informed and the advice could be given to withdrawn the product from the market. In reason of the limitation to their own territory this Competent Authority is responsible for informing also the other Member States and the Commission. In case of safety aspects now the area of safeguard clause will be covered; in case of administrative non-compliance the article 18 will be covered as complement to the safeguard clause. Mr. P. suggested to put this subject on the agenda of the next Medical Devices Experts Group meeting to make sure that the Competent Authorities be aware of their responsibilities. Mr. J. asked what is to do in this case when a Notified Body number will be used by a manufacturer without any connection/contract to the Notified Body. Mr. P. clarified that is must be distinguished what is covered in the framework of the directive. But the presented case is fraud and outside of the directive, therefore other appropriate instruments have to be used to stop such behaviour. Mr. P. described as relevant case the putting of CE-marked products on the market which are not covered by the directive; if a product is not covered by the directive all the measures that need to be taken and need to be available should have been taken by the public authorities when the decision on the certification has been produced by the Commission. NB-MED took note of this.

19. Meeting NB-MED on 02./03.03.99, Item 7.4

### **S/11/99            CE marking and other marks**


Mr. P. mentioned that at the next Medical Devices Experts Group meeting a discussion will take place on the coexistence or non-coexistence of *quality marks* and the CE-mark. He said that he can not accept quality marks to be in competition with CE marking if they have no clearly well defined added value. Therefore he asked the members of NB-MED on their view a.s.a.p. best before 16.03.99.

19. Meeting NB-MED on 02./03.03.99, Item 7.4

Mrs. H. reported from the Medical Devices Experts Group meeting on 16./17.03.99; Mrs. H. summarised that any other marks which might be on the product (product label or accompanying information) should not give the idea that they are for placing the CE-mark and also should not be in conflict with CE-marking. The CE-mark shows the safety and performance of the product. NB-MED took note of this; the Commission was asked for a general statement on this issue.

20. Meeting NB-MED on 08./09.06.99, Item 7.4



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Mrs. H. reported that no further discussion was made within the Medical Devices Experts Group since their meeting on 16./17.03.99 and there was no disagreement between the member states (Remark of the Technical Secretariat: Last time Mrs. H. summarised that any other marks which might be on the product (product label or accompanying information) should not give the idea that they are for placing the CE-mark and also should not be in conflict with CE-marking. The CE-mark shows the safety and performance of the product.)


Mr. R. asked for clarification as to what is and is not in conflict with the medical devices CE mark. Mrs. H. explained the consensus made within the MDEG that e. g. ergonomic or environmental features, which are not covered by the essential requirements of the directives itself, could be considered as additional aspects to the CE mark for medical devices. Mr. R. completed his question saying if the additional mark covers items that are covered by the medical devices directives but actually extend them to a greater degree of technical advancement in some way, then it is not conflicting with the directive but adding to it; a particular case is e. g. for more stringent EMC requirements than are required by the harmonised standards, e. g. for use in ambulances. Mrs. H. answered that the additional marks must not take away from the CE mark where the CE mark is not thought of its like a "minimum level of quality"; the CE mark is the level. Any additional elements that are covering over and above the essential requirements actually extending the essential requirements in the way as described would be in contravention because they should be included as part of the assessment for the essential requirements.

NB-MED took note of this.

21. Meeting NB-MED on 02./03.11.99, Item 7.5

## **S/12/99            Coloration of contact lenses**

Mr. V. introduced the inquiry-document NBM/45/99. Contact lenses which are used for the correction of defects are of course Medical Devices; contact lenses which are only used for colouring the eye – for cosmetics reasons – are not Medical Devices as always agreed. But it happens that an optician proposes to take CE-marked contact lenses – which are for the correction of the vision – for colouring for cosmetics reasons. The result is a contact lens which corrects the vision and in addition colours the eye; this product is of course a medical device but the question is, whether the optician becomes a manufacturer throughout the additional process. Mr. V. proposed that he becomes a manufacturer throughout the addition because it is a new product and new risks could be arising when coloration is made (e. g. the optical performance could be changed, biocompatibility). In case that the colouring is not CE marked, the optician is a manufacturer; in case that the colouring is CE marked, the optician is not a manufacturer as he assembles two devices for an individual patient (this case supposes that the manufacturer of contact lenses allows the coloration of its contact lenses). Mr. H. mentioned that normally the lenses are tinted by the manufacturer and only in exception by the optician. In the second case the manufacturer must give information on compatibility of the tint or tint solution with the eye but also with the conduct lenses care

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products. In every case the optician who makes this process is fully responsible but in his view it is not clear whether the optician can act or could be considered as a manufacturer for medical devices in the sense of the directive because he does not change the definition for contact lens as a medical device, he adds only a cosmetical effect on the lens. Only the optical effect is this what the medical device makes as a contact lens. Mr. V. could not imagine that every product like this should be considered as a new product at every time of processes and that everybody who execute this becomes a manufacturer. Mr. T. proposed to take this enquiry to discuss “coloured lenses” more general within the Medical Devices Experts Group (also so-called “social lenses”). Mr. V. clarified that his inquiry deals only with the case where an optician takes a contact lens for correcting the sight and modifies it for other purposes without telling anything to the (first) manufacturer; he changes the intended purpose of the medical devices and therefore this activity is in line with the definition of “manufacturer”. Mr. P. shared the proposal for consideration within the Medical Devices Experts Group because probably some additional elements need to be added e. g. to the definition of the “manufacturer”. But could somebody - who makes some additional activities to the existing device - be qualified in general as a manufacturer without having – in light of the definition of “manufacturer” - impact/responsibility on the design or manufacturing of the product? Mr. V. mentioned that maybe there could be some analogy with the placing of the market of “fully refurbished devices”. Mr. T. suggested that this subject should be put to NBRG to try come forwards with a solution before presentation to and considering within the Medical Devices Experts Group.

19. Meeting NB-MED on 02./03.03.99, Item 3.4 (10)

NB-MED agreed to handle this subject by writing the following **Consensus Statement**:


## ***Coloration of contact lenses***

### ***1. Purpose***

*The purpose of this Consensus Statement is to provide information to the Medical Devices Experts Group on Inquiry Nr. 39 ‘Colouration of contact lenses’ submitted by G-MED of France (document NBM/45/99) to the Notified Bodies Group Plenary session of 2-3 March 1999 and referred to the Recommendations Group for advice.*

### ***2. Relevant information***

- *Currently there are three broad categories of circumstance under which colouration in some form is applied to a contact lens:*
  - a) *In the form of a ‘tint’ to assist handling (i. e. to make the lens more easily visible), to enhance the natural colour of the iris, to give protection to a patient who is suffering from photophobia and (by using a red tint on one lens) and to give a clearer colour definition to a patient who is colour-blind. The manufacturing*

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*processes by which these types of tint are applied are of long-standing use and the colouration part of the process is subject to the rigours of clinical trial.*

- b) *Colouration or some form of decoration for purely 'social' purposes, which might equally well be applied to corrective lenses as to lenses without power (Plano lenses). In either case, the colouring or decorative process can be done as part of the manufacturing process and subject to the rigour of clinical trial. The only detected danger of these types of lens is that they may affect the clarity of vision for brief periods at night and so could be a hazard if worn by anyone driving a motor vehicle etc.*
- c) *Colouration of Plano lenses for social purposes using methods not subject to the rigours of clinical trial.*

*The question of practitioner advice arises in each context. The eyes of some humans are not suited to the wear of any kind of contact lens; a situation which may not be immediately obvious when a potential wearer tries a lens on his or her eye. Alternatively, unsuitability may become apparent only after a period of wear. In the latter case, discomfort or even damage to the eye may result. Therefore practitioner advice should be sought by every new contact lens wearer.*

### **3. Risks**


*Studies into the risks associated with the wear of tinted, coloured (including lenses coloured after manufacture) and false pupil/decorated pupil contact lenses and wear of any contact lens without the advice or supervision of an optical practitioner have been carried out separately, and are on-going, under the direction of Doctor Pierre Lumbroso, MD of the Department of Ophthalmology of the Hospital Gabriel Montpied, Clermont-Ferrand, France and Professor Hans-Walter Roth, MD of the Institutes for Contact Lens Research, Ulm, Germany and Washington DC. Relevant extracts from their findings to date are reported below:*

**- Tinted lenses and lenses coloured during the manufacturing process:**


- *'All tinted lenses reduce night vision. While this is minimal for normal eyes, colour-blind persons could have difficulty in interpreting traffic lights' (Roth).*
- *'Plano lenses can often induce important variations on the corneal dioptic power. No decrease in visual acuity has been noticed in the current state of the clinical investigation'. (Lumbroso, January 1997).*

**- Lenses coloured after manufacture:**

- *'Chemical interaction between the tear fluid and the dye during wear can lead to release of the dye into the tear fluid and so onto the surface of the eye and re-released particles of the dye may be taken up (absorbed) by eye tissues.' (Roth)*

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- *'Cleaning and disinfectant solutions may interact with the dye; solutions containing peroxide would have the strongest effect' (Roth).*
- *'Colours not tested for toxic or allergic responses on the eye show a high incidence of keratopathia allergo-toxica or blepharitis'. (Roth).*

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**- Painted pupil or decorated pupil contact lenses:**

- *'The edge of the painted pupil doesn't fit with the edge of the real pupil, so the patient sees the nasal edge of the painted pupil which blocks part of the visual field'. (Lumbroso).*
- *'Vision is reduced by the small diameter of the artificial (painted) pupil rendering the eye unable to react fully to reduced light'. (Roth).*

**- Contact lens wear without advice of an optical practitioner:**


- *'Patients describe a reduction of the peripheral visual field, mostly due to the too large diameter of the contact lens'. (Lumbroso).*
- *'Lenses worn only for cosmetic effects have a higher than normal incidence of contact lens damage because the eye and patient are not trained'. (Roth).*
- *'Based on our findings, contact lenses tinted for cosmetic reasons should not be dispensed without intensive ophthalmological monitoring'. (Roth).*

**4. Application of existing EU legislation to the colouring of contact lenses**

- *The Cosmetics Products Directive 76/786/EEC is not applicable for this purpose as its scope, as set out in Article 1 of the Directive, does not include the human eye.*
- *The Medical Devices Directive 93/42/EEC regulates the colouration of corrective lenses where the colouration is part of the manufacturing process, but not to the colouration of Plano lenses as they are not defined as medical devices when used in a purely social context. There is no legislative requirement to warn wearers of coloured lenses (whether corrective or not) of the hazards of driving at night while wearing them.*

**5. "Recommendation"**

- *Where qualified optical practitioner applies colouration to a corrective contact lens for a patient he makes a design change. If this change is made in compliance with instructions provided by the manufacturer of the lens then responsibility under the Directive remains with the manufacturer. If the change is made without instructions from the manufacturer, the optician assumes the responsibilities of the 'manufacturer' as defined in the Directive. (This answer could apply to any medical device to which a design change is made).*
- *With regard to recently perceived risks related to the colouration of contact lenses raised by G-MED in their inquiry, NB-MED is reliably informed that some brief impairment of vision may be experienced by wearers of coloured contact lenses in certain circumstances. More seriously, wearers of coloured or decorated lenses not manufactured to the standard of corrective lenses or not maintained to a health*

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*regime recommended by a suitably qualified practitioner are likely to suffer infection and consequent damage to the eye.*

- *As not all coloured or decorated lenses fall within the definition of a 'medical device', it is recommended that the manufacturers' federation should present a case for consumer health protection to DG XXIV."*

20. Meeting NB-MED on 08./09.06.99, Item 3.4 (6)

### **S/13/99            Blood bank refrigerators**

Dr. G. introduced document NBM/73/99. The question is: Are blood bank refrigerators medical devices (or accessories) according to MDD 93/42/CEE? If yes, could they be classified IIa, according to annex IX, rule 2? Dr. G. proposed that blood bank refrigerators are class IIa accessories of medical devices because blood bank refrigerators are intended specifically by their manufacturers to be used together with medical devices (blood bags, for example) therefore enabling them to be used in accordance with the use of the device intended by device manufacturer. Dr. R. said that blood bank refrigerators are not medical devices because of the special situation of blood. Blood could be an organ (as collected by blood-donation and as used for infusion) and falls e. g. in Germany under the drug regulations; so in the same way to use e. g. a refrigerator for other drugs this refrigerator does not fall under the medical device directives. In addition Mr. V. explained that the refrigerator could also not considered as an accessory of the blood bag. Dr. d. L. supported this both statements. NB-MED agreed with the discussed solution; blood bank refrigerators are not medical devices.


20. Meeting NB-MED on 08./09.06.99, Item 3.4 (10)

### **S/14/99            Role of Notified Body - French Competent Authority's Fiche D'Enregistrement CERFA 10851 01 section E**

Mr. J. introduced document NBM/88/99; the Competent Authority appears to be expecting NBs to check all details, sign and stamp the manufacturers registration document and act as the link between the manufacturer and CA. Mr. J. asked whether this is a proper role of the Notified Body under Directive 93/42/EEC and he proposed "no" because the certificate issued by the Notified Body should be sufficient and the registration is a requirement on the manufacturer. NB-MED took note of these arguments for general information purposes and the consensus view was that this is not a proper task for the Notified Bodies; the Technical Secretariat was asked to pass on the relevant part of the minutes to the French Authority.

20. Meeting NB-MED on 08./09.06.99, Item 3.4 (11)

### **S/15/99            Contact lenses and liquid for hydrating contact lenses; Classification**


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Dr. G. introduced document NBM/91/99. The question is: Contact lenses are usually sold immersed in a hydrating or disinfecting solution. Is this product a class IIa device (considering the contact lens only) or a class IIb device (considering that the contact lenses are immersed in a class IIb device, according to rule 15)? Dr. G. proposed that Contact lenses - sold immersed in a hydrating or disinfecting solution - are class IIa devices because the liquid is to be considered an accessory for medical devices only when is sold separately; in this case the liquid is to be considered as a preservation system, integrating the contact lenses package. Mr. T. fully agreed with this proposal but the wording in the question should be changed to "Most but not all contact lenses are sold immersed ...". Further Mr. T. explained that the reason is not really correct; it should be argued: "The liquid is an accessory for a medical device and that is explained by rule 15". Mr. V. contradicted that article 12 from MDD should be applied. Then two cases - chosen by the manufacturer - are given; first: the preservation solution is CE-marked apart, the contact lenses are CE-marked apart and both are combined in the product; then in according to article 12 contact lenses are class IIa devices and the preservation solution is - in according to rule 15 - class IIb. Second case: contact lenses - not CE- marked as such - will be put in the preservation solution and this combination represents the product; this product has to be CE-marked as system in according to class IIb because the higher class should be applied. Mr. T. remarked that this view/consideration (class IIb) would result in an alteration to the classification of 90 % of contact lenses; rule 15 was put in specifically to deal with care products. Mr. F. added that this is a matter of "how the manufacturer wants to place the product on the market". as e. g. procedure packs in according to article 12 or separately but for joining together and separately CE-marked. Dr. R. said that the contact lens immersed in the solution should be considered as class IIa device; the solution should be considered as a part of the packaging of the medical device and should therefore not influence the classification. Mr. v. M. took the same view of this subject. NB-MED agreed with the discussed solution; contact lenses - placed on the marked immersed in a hydrating or disinfecting solution - are class IIa products although the hydrating and disinfecting solution are themselves class IIb in accordance with special rule 15.

20. Meeting NB-MED on 08./09.06.99, Item 3.4 (12)

### **S/16/99      Rigid containers for sterilisation and maintaining sterility**


Mrs. B. introduced document NBM/100/99. The question is: Should rigid containers for sterilisation and maintaining sterility - incorporating a filter - be classified as class IIa or class I? Mrs. Bakken distinguished two solution: a) These containers could be classified as class I according to rule 1; b) classified as class IIa according to rule 15; when the intended use claims to maintain the sterility for a certain time the product should be classified according to rule 15 as accessory to steam steriliser. Mr. B. explained that rule 15 is talking about "disinfecting" or "sterilising" of medical devices but not about "maintaining"; therefore these containers should stay in class I. NB-MED agreed with the

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discussed solution; rigid containers for sterilisation and maintaining sterility have to be considered as class I products.

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**S/17/99      Artificial liver**

The answer whether artificial liver are medical device or not depends on how this product is put together given that there are exclusions for human tissue.

20. Meeting NB-MED on 08./09.06.99, Item 6 (1)

**S/18/99      Mercury and non-mercury containing thermometers**

Mercury and non-mercury containing thermometers; in France mercury thermometers are being band/banished since March '98; final decision was not yet reached within the MDEG.

20. Meeting NB-MED on 08./09.06.99, Item 6 (1)

**S/19/99      Class I devices – certificates following MDD (Annex I)**


Mr. B. introduced that also class I devices are mentioned on certificates for manufacturers having class II, IIb and III devices following e. g. Annex II of MDD. This has worked the last six years but now there is a clear statement made by German accreditation body that all these class I devices must be eliminated from the certificate and could - perhaps - still allowed in the other Member States. The Technical Secretariat draw the attention to the Consensus Statement S/05/96 CE marking of class I devices (given on occasion of 10. Meeting NB-MED on 17.01.96, Item 5.1(4)). Mr. J. shared this opinion; no UK Notified Body would put a class I device on a certificate. NB-MED confirmed once again to handle this item as discussed and as written in the Consensus Statement S/05/96; it was suggested to all Notified Bodies to review older certificates by withdrawing or replacing without mentioning class I devices.

20. Meeting NB-MED on 08./09.06.99, Item 7.5

**S/20/99      Washing machine for instruments**

Dr. G. introduced document NBM/118/99. The question is: Is a washing machine for instruments - e. g. used in order to wash dental instruments before the sterilisation process – medical device? The French Competent Authority has given the answer “yes”.

As an introduction Mr. V. mentioned that the presented opinion of the French CA could bases on an older estimation; therefore the manufacturer should ask the French CA for the current opinion. As an accessory to an accessory of a medical device it is to be considered as a medical device (class I, rule 15 does not apply). As an accessory to medical device it is to be considered as medical device (class IIa, according to rule 15). Mr. B. explained that rule 15 applies only for “disinfecting”; if this machine disinfects, then it is a “washer disinfectant” and is a class IIa device. In case that there is no “disinfection” but only “cleaning” or “washing” then this product is not a medical device and the CE-mark

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stands for fulfilling the “Low Voltage Directive”. Mr. J. answered that this product probably could be considered as an accessory to the dental instruments; therefore it could be CE-marked. As an accessory to the steriliser it become a class I device. Dr. R. mentioned that the classification rules do never decide if a device is a medical device or not; they just decide - if it is a medical device - which class it is. Therefore the exemption in rule 15 – the restriction of class IIa devices for disinfecting - could not be taken to decide that this presented product is not a medical device; cleaning before sterilising is a necessary process for such an instrument. Following the intended use of this device “Appliance to wash dental instruments, necessary before the sterilisation process” this device is to be considered as medical device, class I. Mr. v. M. said that this product is a class IIa device because of the use for a simple thermal disinfection (“Rinse at 85 °C”). Mr. V. compared this case with sterilisation indicators. Dr. G. reminded to the older Consensus Statement S/01/98 “Demarcation Medical Devices, Accessories and Production or Laboratory Devices” where it was stated: “If the equipment

- must be used in the immediate medical environment and
  - is used by the final user for the preparation of a medical device directly for the time of use and
  - is specifically intended for this special purpose and
  - the medical device cannot be prepared without this special equipment,
- then this equipment may be considered as an accessory to a medical device.” Dr. G. summarised that the medical device can be prepared without this washer; therefore the washer could not be considered as medical device.

Mrs. O’C. summarised that only one argument was given to say that the washer is no medical device, namely: this product is an accessory to an accessory. For all other cases or given intended uses the product could be a medical device. The question is: Is this product an accessory to the steriliser or is it a 2<sup>nd</sup> accessory for the dental instrument. Mr. S. said that once again the key issue is the intended purpose of the product; it is up to the Notified Body to evaluate that intended purpose. Mr. F. reminded to a Commission’s decision - probably 5 years ago - that an accessory to an other accessory really is too far back in the process; it is a “process” but not a medical device or an accessory to the medical device. The members of NB-MED were asked to handle similar cases in such a common discussed sense; such special products have been checked to their special role in the process. Mr. S. offered to bring this subject to the agenda of the Classification Group’s meeting.

21. Meeting NB-MED on 02./03.11.99, Item 3.4(6)

Mr. B. stated once again that the real washing machine for surgical instruments is not a medical device but accessory. Mr. H. emphasised that there is no need to discuss once again within the MDEG “accessory to an accessory”. According to the Directive an accessory is something what is to be used in connection with a medical device; i.e. there is only one level of accessory. But a medical device can have several accessories; as a comparable case Mr. H. explained that a sterilizer is an accessory to a medical device and not a medical device in itself. But with regard to the indicators this discussion is still open since member states have not yet reached consensus on “out or in MDD”(MDD or

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accessory) (and in this context sometimes the discussion on “sterilizers” flared up in meetings of MDEG).

NB-MED took note of this - that the real washing machine for surgical instruments is only an accessory to a medical device - but also on the sometimes controversial opinions of the member states.

22. Meeting NB-MED on 29.02./01.03.2000, Item 3.4(7)

**S/21/99            Class I devices placed on the market in sterile condition or with a measurement function**

see also S/19/99


Mr. V. introduced document NBM/132/99; the main question is it is possible to include a class I medical device (in a sterile state or with measurement function) in the scope of an annex II.3 certificate. This issue especially relates to companies with existing annex II.3 certificate (for class IIa to class III devices), who apply for class I (sterile/measuring function) CE marking. The proposed answer to this inquiry is “No”.

NB-MED agreed with the proposed answer; such devices cannot be included in annex II.3 certificates. Article 11 section 5 refers to annex VII. This subject was already discussed during the last meeting (see top 7.5 “Class I devices – certificates following MDD (Annex I)” where it was confirmed once again to handle this item as discussed and as written in the Consensus Statement S/05/96; it was suggested to all Notified Bodies to review older certificates by withdrawing or replacing without mentioning class I devices.

21. Meeting NB-MED on 02./03.11.99, Item 3.4(7)

**S/22/99            Custom-made products - otoplastics to take hearing aids**

Dr. P. explained the tabled problem (see document NBM/133/99): For hearing aids worn in the ear it is necessary to manufacture an individual housing for the patient. This is normally made by a hearing aid acoustics technician. Are such housings mass-produced devices which are adapted in series? Who may undertake the CE marking of the complete hearing aid, the housing and/or the electronic hearing aid without housing, and under what conditions? Dr. Pinkwart proposed the following solution: The otoplastics described which are intended for accommodating hearing aids are custom-made devices in the meaning of Article 1 Par. 2 d) of the Directive 93/42/EEC. The devices are made specially according to specific design features and are intended for the sole use of a particular patient. The electronic hearing aid (face plate) inserted in the otoplastic is an independent medical product in the meaning of the Directive 92/42/EEC which is normally manufactured in series - even if not yet ready for use. It can thus be marketed with a CE mark in accordance with the provisions of the Medical Device law. The material used to make the housing (otoplastic) is also deemed to be a medical device in the meaning of

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the Directive on account of its intended purpose. Intermediate products intended for use in the manufacture of custom-made products by so-called health craftsmen (opticians, hearing aid acoustics technicians, orthopaedic technicians, orthopaedic shoemakers, dental technicians) are regarded as medical devices (compare to MedDev 2.1/1, I. 1.1 c). These intermediate products may be given a CE mark and marketed according to the Directive 93/42/EEC provided their intended use is as described. Persons who assemble and adapt a finished hearing aid for a named person from the aforementioned, already marketed products are manufacturers of custom-made devices who must issue a declaration according to Annex VIII number 2.1 of the Directive 93/42/EEC and must enclose this declaration with custom-made products of the classes IIa, IIb and III when handing them over. The custom-made device will not bear a CE mark.

NB-MED agreed with the proposed solution; intermediate products may be given a CE mark and custom-made device will not bear a CE mark.

21. Meeting NB-MED on 02./03.11.99, Item 3.4(8)


### **S/23/99            Medical devices vs. pressure equipment**

Dr. G. introduced document NBM/135/99. The question is: Which Directives must be applied in order to put on the market sterilization autoclaves including pressure equipment? As from 1999-11-29, pressure equipment will be submitted to the regulation of 97/23/EEC Directive. This Directive requires a transitory period up to 2002-05-29. Which requirements will have to be satisfied in that period in order to put on the market the sterilization autoclaves showing the CE marking for the 93/42/EEC Directive? Is it possible to state that the conformity to this Directive only is not enough to put on the market such devices?

Mr. V. mentioned that the Commission's guide to the implementation of Directives based on New Approach and Global Approach (issued in July 99) addresses also this problem (on page 22): "The placing on the market and putting into service can only take place when the product complies with provisions of all applicable directives and when the conformity assessment has been carried out in accordance with all applicable directive" and "Where the same product or hazard is covered by two or more directives the application of other directives can sometimes be excluded following an approach that includes a risk analysis of the product with a view to intended use as defined by the manufacturer." The CE marking only reflects the conformity to one directive; it should be mentioned in the accompanying documents if another (applicable) directive is in the transitional period. Mr. H. said that the CE marking according to the pressure vessels directive is for time being not prescribed, it could be applied if the manufacturer so this wishes (transition period!). But it will be mandatory in May 2002. CE marking for pressure vessel and medical devices apply because neither of them excludes the other.

NB-MED took note of this.

21. Meeting NB-MED on 02./03.11.99, Item 3.4(10)

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## **S/24/99          Devices for weight-monitoring; Classification**

Dr. G. introduced document NBM/136/99. He explained the following problem: The device concerned is meant for monitoring the weight of a patient subjected to dialysis. In this way, the medical staff can compare the real ponderal shortage with the parameters measured by the dialysis appliance. The accuracy of the measure supplies some information about the effect of the dialysis' treatment. Can the examined device be put on the market whether it is in conformity with the 93/42/EEC Directive only or must it be also submitted to the requirements provided by the 90/384/EEC Directive (relating non-automatic weighing instruments)? In fact, even if this last Directive covers in its application range also the instruments used for the check of the mass of a body in the medical praxis (article 1.2.a) 4.), it is recognised that the requirements of 93/42/EEC Directive provide in any case accuracy and precision in the measurement, which must be submitted to the assessment of a Notified Body. On the contrary, the application of both Directives compels the manufacturer to fulfil several administration duties, and in many cases to apply to different Notified Bodies. In Italy, for example, no Notified Body for 93/42/EEC Directive is concerned about the 90/384/EEC one, and vice versa. Dr. G. proposed that the conformity to 93/42/EEC should be sufficient to put the device on the market.

NB-MED discussed that the presented problem is similar to the above mentioned item 3.4 (10). Mr. H. mentioned that - for the moment - the text in the directives does not exclude devices from the weighting instruments directive; there could be situations where both directives apply. But this depends also from the intended use.

NB-MED took note of this.

21. Meeting NB-MED on 02./03.11.99, Item 3.4(11)


## **S/25/99          Harmonised standard EN 285**

Dr. G. introduced document NBM/137/99. The question is: Is harmonised standard EN 285 to be considered mandatory in order to demonstrate compliance of sterilizers with the MDD essential requirements? Some Competent Authorities - but also some Notified Bodies - consider harmonised standards - especially in the case of EN 285 - as to use mandatory. Dr. G. proposed "No", EN 285 can be used but it is not mandatory, because Article 5 does not mean that harmonised standards have to be considered mandatory.

NB-MED discussed that the use of a harmonised standard is not mandatory, but in some cases it is very difficult - for the Notified Body who has to judge something - to find an other equivalent solution. With regard to EN 285 it was said that this harmonised standard could be applied to sterilizers to demonstrate compliance with the essential requirements, but voluntary.

NB-MED agreed with this proposed solution. The use of a harmonised standard is not mandatory.

21. Meeting NB-MED on 02./03.11.99, Item 3.4(12)

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**S/01/00            Colors/dyes needed for restoration of pigmentation  
(e.g.: restoration after mastectomy); Classification**

Mr. M. introduced document NBM/21/00. The question relates to the classification: Are those medical devices to consider as a) class IIb (rule 8, as implantable device and long term use) or as b) class III (rule 8, 3<sup>rd</sup> hyphen: implantable device, long term use and mainly adsorbed)? Mr. M. proposed “class IIb” because it is not meant to be mainly absorbed, it should remain in the skin.

Mr. V. explained that the main intention is to avoid metabolisation or absorption (therefore IIb).

NB-MED agreed with this proposed solution. Those medical devices should be considered as class IIb devices. A discussion on whether it could be a cosmetic product was not appropriate since the products have a medical purpose.

22. Meeting NB-MED on 29.02./01.03.2000, Item 3.4(9)

**S/02/00            Watermains connected eyewash equipment; Classification**

Mrs. A. introduced document NBM/27/00. The question was whether eyewash equipments connected to watermains should be classified as medical devices. Mrs. A. proposed to consider these as class I medical devices.

NB-MED discussed that the classification depends very strong from the intended purpose given by the manufacturer. Only if there is a clear medical intended use given it is a medical device. But also some opposite estimation was made. As first aid device this device does not fall under the PPE-Directive because it used after somebody has been hurt by an e.g. acid (and as such it could be considered as a medical device) plus the fact that this equipment is not worn by the user.

NB-MED took note of that discussion; the classification in that particular case depends from the intended purpose etc. claimed by the manufacturer.


22. Meeting NB-MED on 29.02./01.03.2000, Item 3.4(10)

**S/03/00            RTTE – New Directive relating radio equipment and  
telecommunication terminal equipment and the mutual recognition of  
their conformity**

Dr. H. highlighted the tabled document NBM/96/99 showing the mentioned new directive (RTD). As informed last time DG III was not fully informed on the work to this directive.

The main questions were “How to CE-mark such devices?”, “Two CE-marks for these products?” and “Which NB number should be affixed if several NB are involved?”.

Mr. H. mentioned that it is quite clear that this new directive covers certain medical devices. There has been contact to the unit responsible for this directive but a solution for the mentioned main questions has not yet been reached. With regard to the CE-marking he stated that one CE-marking is necessary and enough. According to the current issue

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of New approach guide the numbers of all involved Notified Bodies shall be stated adjacent to the CE-marking (2 bodies = 2 numbers). Mr. V. mentioned that these problems are addressed in Certif 98/1 "Guide to the implementation of Directives based on New Approach and Global Approach" on page 22 and in the directive 93/68. One CE mark means that all directives which apply are complied with. Further Mr. V. explained that for some of the New Approach Directives there is the necessity to add the NB number to the CE mark; for that case the mentioned guide is saying that that NB number has to be affixed to the CE mark who is involved of the most specific directive. In addition it could be said that the most specific directive apply and other directives apply with their applicable requirements. Mrs. L. mentioned that the RTD is applicable on April 8<sup>th</sup> 2000 and asked for some urgent consideration within the Commission; Mr. H. added that the transitional period will end in March 2001.

NB-MED asked the Commission to address this subject also within the discussion of the Medical Devices Experts Group.

22. Meeting NB-MED on 29.02./01.03.2000, Item 7.3

### **S/01/03            Recording paper for medical equipment**

Dr. Gianoglio gave an introduction to document NBM/161/98. The question is: Is recording paper for medical equipment a class I medical devices with measuring function?


*Within the NB-MED there was an intense discussion about the "measuring function in context of recording/printing paper". The relevant MedDev-document shows three criteria for the measuring function and where they are meet. Sometimes the recording paper comes together with the intended use – like pre-printed scale – for a medical device. In this special case the problem is not the intended use but to meet the measuring function. The printed lines on the paper are the scale that are used for the measuring. On the other side the paper itself does not measure.*

NB-MED made no final conclusion.

18. Meeting NB-MED, 03./04.11.98, item 3.4 (9)

Dr. Holland reminded that also this subject was tabled on occasion of the November '98 meeting as an inquiry (see NBM/161/98); a decision was not taken but the **representatives of the Commission** were asked to bring this subjects to the agenda of the **classification group**. The main background of that inquiry was whether the recording paper is a medical device with measuring function or not.

*Mr. Putzeys stated that he could not imagine that recording paper has some measuring function. Prof. Leitgeb/PMG explained that a manufacturer could claim such recording paper as an accessory to a medical device and therefore it become a medical product (class I) but - with regard to the scale on the recording paper - the „measuring result“ is not made by the paper but by the device. The measuring item is not related to the paper, it is*

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*just recording what the device is doing. Mr. Putzeys agreed that recording paper is - as an accessory to a medical device - a medical device but without a measuring function.*

NB-MED agreed with the proposed answer; recording paper is - as an accessory to a medical device - a medical device (class I) but not a „class I product with measuring function”.

24. Meeting NB-MED, 07./08.11.2000, item 3.3 (2)

Mr. Virefléau took up once again the discussion made last time on that matter: for every case supported by the relevant MedDev–document 2.1/5 "Medical devices with a measuring function" it has to be decided whether (or not) the three criteria described there are met. The summary made last time – that recording paper is (as an accessory to a medical device) a medical device but without a measuring function – has not taken into account that MedDev–document.

*Mr. Jepson explained that if recording paper (for an ECG) is calibrated in legal units then it is probably a class I accessory with a measuring function. Mr. Virefléau proposed the following clarification: when recording paper is placed on the market as an accessory to a medical device then it has to be considered as a medical device and if that recording paper is scaled by legal units – fulfilling the criteria given in the mentioned MedDev 2.1/5 – then it is a medical device (class I) with a measuring function.*

NB-MED agreed with the proposed answer; the minutes should reflect this answer very accurately and should be precise – if necessary – the discussion made last time.

25. Meeting NB-MED, 06./07.03.01 item 3.4 (4)


Dr. Holland took up once again the discussion made in November 2000 on that matter: for every case supported by the relevant MedDev–document 2.1/5 "Medical devices with a measuring function" it has to be decided whether (or not) the three criteria described there are met. The summary made at that time – that recording paper is (as an accessory to a medical device) a medical device but without a measuring function – has not taken into account that MedDev–document.


26. Meeting NB-MED, 06./07.11.01, item 3.4 (3)

Mr. Seitsonen reported that there is no new answer from the Commission than the known. According to this answer the recording paper is a class 1 accessory with measuring function. Dr. Holland concluded that this would be a pragmatic solution for this type of product but that this answer has no general inclusions.

27. Meeting NB-MED on 12./13.11.02, item 3.4.3




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	<b>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</b>	<b>List of keywords for Consensus statements of NB-MED</b>
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#### 4. Keywords


	Consensus Statement No:		Consensus Statement No:
Arms rests	S/18/97		S/21/99
Accessories, demarcation	S/01/98 S/20/99	Class IIb products in combination of Annexes II and V of the MDD	S/12/97
Artificial liver	S/17/99	Cleaning devices	S/07/96
Active electrical laboratory equipment	S/07/99	Coatings of implants	S/07/97
Aqueous eosin solution	S/06/99	Coloration	S/12/99 S/01/00
Auditing of internal audits performed by a manufacturer within his QS	S/10/98	Comfort devices	S/05/97
Auditors	S/25/97	Complex salt solution for irrigation	S/24/97 S/36/97
Authorized representative	S/03/96	Computer	S/02/99 S/08/99
Beautician equipment	S/09/96	Conformity assessment procedures	S/09/99
Bicarbonate solution during dialysis	S/14/98	Contact lenses	S/07/96 S/12/99 S/15/99
Blood bags with preservation solution	S/04/98 S/12/98	Containers	S/16/99
Blood bank refrigerators	S/13/99	Cosmetic devices	S/05/97
Breast implants	S/09/99	Custom-made mouth guards	S/02/97
Brushers with disinfectants	S/19/97	Custom-made products	S/22/99
Carotid shunt	S/05/99	Data Exchange	S/22/97
CE marking	S/04/96 S/05/96 S/11/96 S/11/99 S/19/99 S/03/00	Data Management	S/22/97
Certificates	S/05/96 S/13/96 S/08/97 S/03/98 S/19/99 S/21/99	Declaration of conformity	S/01/99 S/07/99
		Decoupling of certificates	S/05/98
		Demarcation Medical Devices, Accessories and Production or Laboratory Devices	S/01/98
Class I devices	S/05/96 S/19/99	Demarcation Medical Laboratory Equipment	S/02/95 S/01/98

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Consensus Statement No:

Consensus Statement No:

<b>Dental filling material</b>	<b>S/38/97</b>	<b>Hospitals</b>	<b>S/04/97 S/06/98</b>
<b>Dental laboratories</b>	<b>S/12/96</b>	<b>Humidifying solutions</b>	<b>S/01/97</b>
<b>Device intended for special purpose</b>	<b>S/04/99</b>	<b>Hydrating devices</b>	<b>S/07/96</b>
<b>Diagnostic device for determining woman's fertile and infertile period</b>	<b>S/15/97</b>	<b>Hydrating liquid for contact lenses</b>	<b>S/15/99</b>
<b>Dialysis concentrates</b>	<b>S/09/97</b>	<b>Implants</b>	<b>S/07/97</b>
<b>Disabled persons</b>	<b>S/10/96 S/18/97 S/03/99</b>	<b>Independence</b>	<b>S/25/97</b>
<b>Disinfecting devices</b>	<b>S/07/96</b>	<b>Labelling</b>	<b>S/03/95 S/11/97 S/39/97 S/13/98</b>
<b>Distribution chain</b>	<b>S/26/97</b>	<b>Laboratory Devices, Demarcation</b>	<b>S/01/98</b>
<b>Documentation</b>	<b>S/01/96</b>	<b>Laboratory equipment</b>	<b>S/07/99</b>
<b>Documents; retention periods</b>	<b>S/07/98</b>	<b>Laser equipment</b>	<b>S/03/97</b>
<b>Ear thermometers</b>	<b>S/02/96</b>	<b>Laser for skin treatment</b>	<b>S/02/98</b>
<b>Eyewash equipment</b>	<b>S/02/00</b>	<b>Latex</b>	<b>S/21/97 S/39/97</b>
<b>Expiration date</b>	<b>S/04/95</b>	<b>Low level laser</b>	<b>S/02/98</b>
<b>Free movement</b>	<b>S/04/99</b>	<b>Low pressure regulators</b>	<b>S/17/98</b>
<b>Gas distribution networks</b>	<b>S/04/97 S/06/98</b>	<b>Manufacture declaration concerning application to any other NB</b>	<b>S/28/97</b>
<b>Gases for driving medical tools</b>	<b>S/11/98</b>	<b>Manufacturers representative</b>	<b>S/03/95</b>
<b>Gloves</b>	<b>S/32/97</b>	<b>Medical gas pipeline systems</b>	<b>S/04/97 S/06/98</b>
<b>Handicapped persons</b>	<b>S/10/96 S/18/97 S/03/99</b>	<b>Medical Laboratory Equipment</b>	<b>S/02/95 S/01/98</b>
<b>Harmonised standards</b>	<b>S/25/99</b>	<b>Mercury</b>	<b>S/18/99</b>
<b>Hearing aids</b>	<b>S/13/97 S/08/99 S/22/99</b>	<b>Misuse of NB Number</b>	<b>S/10/99 S/03/00</b>
<b>Heart surgery</b>	<b>S/31/97</b>	<b>Mouth guards</b>	<b>S/02/97</b>
<b>Home training devices</b>	<b>S/05/97</b>		

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Consensus Statement No:		Consensus Statement No:	
Nasal rinsing	S/01/97	Quality systems	S/08/96
Nebulizers	S/33/97	Refillable glass capsule	S/14/98
Notified Body	S/15/99	Refrigerators	S/13/99
Notified Body Identification Number	S/10/99 S/03/00	Refurbished devices	S/04/96
OEM Products	S/11/97	Refusal of certificates	S/08/97
Other marks	S/11/99	Resuscitation masks	S/16/97
Otoplastics	S/22/99	Restoration after mastectomy	S/01/00
Own brand labelling	S/11/97 S/13/98	Restoration of pigmentation	S/01/00
Oven	S/12/96	Reusable devices	S/16/98 S/18/98 S/19/98
Oximeter	S/09/98	Re-use	S/19/98
Packaging for instruments sterilized by the user	S/05/95	Reversed osmotic systems	S/06/96
Packaging for sterile products	S/04/95	Rigid containers	S/16/99
Pools for training disabled persons	S/03/99	Rinsing devices	S/07/96 S/34/97
Preparation of solution bags	S/27/97	Road motor vehicle	S/10/96
Preservation solution	S/04/98	Role of Notified Body	S/15/99
Pressure vessels Directive	S/06/98 S/23/98	RTTE Directive	S/03/00
Production Devices, Demarcation	S/01/98	Salt solution for irrigation	S/24/97
Product testing	S/06/95	Separate sold devices	S/11/96
Programmable electrical Medical Systems	S/14/97	Single products	S/10/97
Programming hearing aids	S/08/99	Single use devices	S/19/98
Proteins produced by genetic means used with devices for bone repairing	S/37/97	Sodium-hydrogen carbonate	S/14/98
Quality certificates	S/10/97	Software (programmes)	S/20/97 S/21/98
Quality records; retention periods	S/07/98	Standards	S/25/99
		Sterile patient drapes	S/08/98

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Consensus Statement No:

Consensus Statement No:

<b>Sterilisation</b>	S/05/95 S/16/98 S/18/98 S/16/99	<b>Visits, unannounced</b>	S/15/98
		<b>Washing machine for instruments</b>	S/20/99
		<b>Watermains connected eyewash equipment</b>	S/02/00
<b>Sterilized instruments</b>	S/05/95	<b>Weight monitoring</b>	S/24/99
<b>Sterilizer</b>	S/18/98	<b>Wigs</b>	S/17/97
<b>Storage of blood determined to be returned to the human body</b>	S/30/97	<b>Withdrawal of certificates</b>	S/08/97
<b>Storage of human cells determined to be returned to the human body</b>	S/30/97		
<b>Storage of sperm determined to be returned to the human body</b>	S/30/97		
<b>Storage solutions for organs</b>	S/23/97 S/35/97		
<b>Subcontracting</b>	S/08/96 S/14/96		
<b>Subcontracting of design</b>	S/01/95		
<b>Subcontracting of production</b>	S/01/95		
<b>Surgical instruments</b>	S/06/97		
<b>Surveillance</b>	S/03/95 S/06/95 S/01/96 S/10/98 S/15/98		
<b>Technical documentation</b>	S/01/96		
<b>Thermometers</b>	S/18/99		
<b>Thermosealing machine</b>	S/29/97		
<b>Time limits</b>	S/13/96		
<b>Transition period</b>	S/26/97		
<b>Toupees</b>	S/17/97		
<b>Use of NB Number</b>	S/03/00		
<b>Validation</b>	S/01/96		

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Consensus Statement No:

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