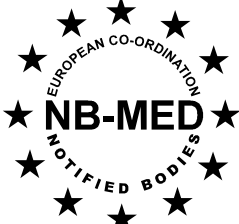


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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
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|-----------------|--|
| Title: | Reporting of design changes and changes of the quality system |
| Chapter: | 2.5.2 Conformity assessment procedures; Quality assurance |

| | |
|-------------------|--|
| Text: | Reporting of changes to the Notified Body According to the Directives the following changes must be reported : <ul style="list-style-type: none"> ▪ Any plan of substantial/significant changes in the quality system ▪ Any plan of substantial/significant changes to the product-range covered by the quality system ▪ Any changes to the approved design that could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product |
| Key words: | changes, quality system, product range, design |

1 Rationale

The Medical Devices Directives variously require in different Annexes that where a Notified Body has been involved in the approval of the quality system or the device design / type, the manufacturer must inform the Notified Body of any plan of “substantial” changes to :


- the quality system and/or
- the product-range covered by the quality system and/or
- the device which could affect compliance with the essential requirements or the intended use.

Note : In the different directives, the terminology uses “substantial” or “significant”. For editorial reasons, and because the purpose of the requirements attached to these two words is the same, in the following text, the term that is used in “substantial”.

It is not practicable to specify in general terms what types of change are or are not “substantial”. For instance, a change in colour may be purely cosmetic in some cases, yet be “substantial” in other cases e.g. where it is the means for drawing attention to warnings, functions etc. –The manufacturer should establish, maintain and apply a procedure for categorising documenting and implementing changes and informing the Notified Body as appropriate, (see table below).

| Reference to Directives: | Article/ Annex: | Reference to standards: |
|--------------------------|---|-------------------------|
| AIMD | Annex: 2-3.4, 2-4.4, 3-6, 5-3.4 | EN ISO 13485 |
| MDD | Annex: II-3.4, II-4.4, III-6, V-3.4, VI-3.4 | EN ISO 13485 |
| IVDD | Annex: III-6.3, IV-3.4, IV-4.4, V-6.1, VI-3.4 | EN ISO 13485 |


| Stage | proposed by | Rev.-Nr. | Rev. date | accepted | amended | withdrawn | Page |
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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

When must the manufacturer inform the notified body?

| | NB assessment of the quality system | | |
|---|---|--|--|
| | Full quality assurance system | Production quality assurance | Product quality assurance |
| 93/42/CEE 90/385/CEE 98/79/CE | Class Im – Is - IIa – IIb –III - AIMD Lists A and B | Classe Im – Is - IIa – IIb – III - AIMD Lists A and B | Classe Im - IIa – IIb / |
| Substantial change to the quality system | yes | yes | yes |
| Substantial change to the product-range covered by the quality system | Yes | The manufacturer may need to inform a substantial change to the product range under all quality system routes – although not stated in MDD annex V or VII if the change to product range is not within the scope of the current annex V or VI certificate the manufacturer needs to inform the Notified Body in order to get their certificate updated. I dependent on the type of change, this may require an audit if, for instance the product technology is not covered by the existing scope. | The manufacturer may need to inform a substantial change to the product range under all quality system routes – although not stated in MDD annex V or VII if the change to product range is not within the scope of the current annex V or VI certificate the manufacturer needs to inform the Notified Body in order to get their certificate updated. I dependent on the type of change, this may require an audit if, for instance the product technology is not covered by the existing scope. |

| | NB assessment of the product | |
|--|--|--|
| | Design examination | Type examination Included annex III for IVD |
| 93/42/CEE 90/385/CEE 98/79/CE | Classe III AIMD Lists A Self test devices | Classe IIb – III AIMD Lists A and B Self test devices |
| Substantial change to the product-range covered by the quality system | A modification of the product-range requires an assessment as a new device | A modification of the product-range requires an assessment as a new device |
| Change to the device which could affect compliance with the essential requirements or the intended use | yes | yes |

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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

In some cases, the nature of the modification that must be reported is described in the regulation

- MD incorporating
 - product of animal origin (covered by 2003/32/EC) : Any change in relation to processes of sourcing, collection, handling and inactivation/elimination and that could modify the result of the manufacturer's risk management dossier must be transmitted to the notified body for the purpose of an additional approval prior to its implementation.
 - medicinal product or human blood derivative : change, in particular related to the manufacturing process of the substance.
- IVDD (98/79/EEC) : The manufacturer shall inform the notified body without delay if it has obtained information about changes to the pathogen and markers of infections to be tested, in particular as a consequence of biological complexity and variability. In this connection, the manufacturer shall inform the notified body whether any such change is likely to affect the performance of the *in vitro* diagnostic medical device concerned.


The following steps are typical of the change assessment process :

1. The detection by the manufacturer of the need/desire to change the product, the product range or the quality system
2. The verification and validation performed by the manufacturer to take the decision to effectively modify the product or the product range or the quality system related to its risk management process
3. The determination as to whether the change is substantial or not (referring to the definition given hereafter)
4. The decision to implement the change taken by the manufacturer and the timing of implementation (dependent on the need for NB review).
5. The information given by the manufacturer to a notified body about any substantial change
6. The appropriate assessment process defined by the notified body (complete/partial – on desk/on site...)
7. Final implementation of the change

Manufacturers are encouraged to contact and discuss with their notified bodies about any question related to the substantial or not substantial characteristic of the change.

2 Complementary elements on the terminology “ substantial”

Changes are “substantial“ where :

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|---|---|---|
|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

2.1 For product changes, the change would affect conformity with

- the essential requirements and/or
- the indications and/or contra-indications determined by the manufacturer to be appropriate to ensure safety and effectiveness for the intended use of the device.

When considering whether or not a particular product change is “substantial” the following considerations should be made:


- Does the change affect the performance specification of the MD?
- Does the change affect materials of the MD?
- Does the change introduce new hazards which have not been previously addressed?
- Does the change affect the risks associated with existing hazards?
- Does the change alter the details on compliance with the essential requirements given in the design / type approval dossier submitted to the Notified Body?
- Does the change alter the details on intended use given in the design / type approval dossier submitted to the Notified Body?
- Does the change mean that the device will have different end users or be used in a different manner?
- Does the change mean that the clinical data/performance evaluation data for the original device is not sufficient to confirm conformity of the changed device with the required characteristics and performance?
- Is the change a direct result of actions taken related to concerns arising from incidents/recalls/complaints?

2.2 For changes to the quality system, either

- the change affects compliance of the devices covered by the quality system with the essential requirements or the approved type / design, or
- the change affects the compliance of the quality system with its own regulatory requirements.

When deciding whether or not particular quality system change is “substantial” the following considerations should be made:

- Does the change affect the ownership of the manufacturer?
- Does the change affect the location of the manufacturer’s activity?
- Does the change affect the manufacturing technologies (processes and equipments)?
- Does the change affect product conformity with the essential requirements or the approved type / design (e.g. change of supplier)?

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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

- Does the change affect the arrangements implemented to achieve continued compliance of the quality system with the relevant harmonized standards and/or the requirements of the Directive (e.g. design verification, design validation, organizational structure, processes interaction, quality control procedures, addition or deletion or move of a facility)?
- Does the change affect the arrangements (e.g. verification, validation, organizational structure) for ensuring continued compliance with the requirements of the Directive?

2.3 For changes to the product-range covered by the quality system, the change affects the categories of MD designed and/or manufactured through the quality system.

When considering whether or not a particular product-range change is “substantial” the following considerations should be made:

- Are there any additional or deleted categories of MD that are designed and manufactured through the quality system?

In the relationship between a manufacturer and a notified body, any change related to the terms of the contract between the two parties or the EC certificates is a substantial change even it is not directly related to conformity or performance of the MD (e.g. : change of the MD identification, of business name, of the company’s owner, etc..).


Note 1 : The term “affect the compliance” has to be understood as a potentially positive as well as a potentially negative term in relation to conformity.

3 Manufacturer decision on whether or not particular changes are substantial

The manufacturer should establish, maintain and apply a procedure for categorising documenting and implementing any changes to the device design/type (including software) and/or quality system and/or product range as either “substantial” or not substantial. The reporting procedure to the notified body should be determined.

4 Manufacturer reporting of changes

The manufacturer should inform the Notified Body of planned substantial changes as soon as possible without delay that could not be justified.

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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

A notification of any substantial change in the design /device as well as in the quality system should include

- a brief description of the modifications compared to the approved design / device or the approved quality system and
- the reason for the changes / modifications and
- in the case of design / device changes, a statement on the relevance to the compliance with the essential requirements and
- the technical data and documentation supporting the above points.

5 Notified Body surveillance and certification

(see also “Global Harmonization Task Force *Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers*”, section *Special audits*)

The review by the notified body of the manufacturer’s procedures (documentation and implementation) to define a change (substantial or not) and to inform the notified body is a required part of the initial, surveillance and renewal audits of the quality system.


The Notified Body should also review (on a sampling basis) those changes considered by the manufacturer as non-substantial and which therefore have not been reported.

Where a “substantial” change is reported, the Notified Body should define the appropriate action including :

- Contract review,
- Update of the contract if needed,
- Document assessment related to the product or complete re-assessment of the design dossier or the type examination dossier,
- Document assessment related to the quality system, special audit or complete re-assessment of the quality system,
- Update of the EC certificate or addenda, if needed,
- List of elements for which implementation has to be checked during the next audit.

Manufacturers should maintain a current listing of devices covered by the certificate and update the Notified Body accordingly.

6 Some Examples

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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

6.1 Changes to EC-approved quality systems (MDD Annex II, V, VI; IVDD Annexes IV and VII respectively):

a) Reportable change:

- change of a critical material supplier, critical component/process subcontractor, OEM
- A change in the manufacturing process whereby a completely new technology is introduced writing a complete new set of design control procedures that replaces the existing approved one.
- Buying a product design from a subcontractor, that falls within the manufacturer's own approved product range, but which was not designed under the manufacturer's own design control system.
- Making substantial changes to the sterilization cycle that would necessitate a full new validation.
- Building a new clean room a major extension of the present clean room or a change in its classification.
- Making substantial changes to the environmental monitoring program or the environmental control systems.
- Going from EtO sterilization to gamma sterilization.
- Changing the sterilization contractor.
- Moving a production line from in-house to an outside facility (manufacturer's own or a contractor) ; introducing a new production line into your own facility or moving a complete production line within ones own facility.
- Making substantial changes to the structuring of the quality system.


b) Non-reportable change:

Addition of an electrical components supplier, e.g. for resistors, to the list of approved suppliers as

- selection and approval of suppliers is part of the quality system of the manufacturer
- the components to be supplied
 - meet the manufacturer's existing specifications
 - do not fall within the manufacturer's classification of a "substantial change".

6.2 Changes to EC-approved medical devices design/type (including software) (MDD Annexes II, 4.4 and III; IVDD Annexes VI-4.2 and V, respectively):

a) Reportable changes:


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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | Recommendation NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

- Changes to the medical device included computer software (e.g. new functionalities, new algorithms for computing) which will change the specifications and / or performances of the device (e.g. changes of those materials which have to be biocompatible or changes of main components like power source, Central Processing Unit (CPU), defibrillator-capacitors etc.)
- new operating systems
- Change in material supplier that potentially affects biocompatibility (ER 7)
- Change in the sterilization cycle that potentially affects sterilization validation and sterility (ER 8)
- Change in the diameter (French size) of a catheter that potentially affects the flow rate and thus performance (ER 7)
- Change in the packaging configuration that could potentially affect protection against transportation or maintenance of sterility during shelf life (ER 5, 8)
- Change in the design of the product, that leads to new specifications and that could potentially affect the essential requirements (ER 7, 11, 12).
- Change in intended use (Indications/Contraindications)
- ⊖ Other changes which may affect the design or performance / characteristics of the device (e.g. new sterilisation method, new welding method, or in the case of computer software, new functionalities, new algorithms for computing, new operating system) are considered to be substantial changes.


Note : In the case of IVD reagents substantial changes are those which could significantly influence the performance characteristics compared to those of the originally approved design. Where changes of the performance characteristics are due to changes of the manufacturing process, these may well be considered as substantial.

b) Non-reportable change:

- A change in the length of the proximal end of a central venous catheter does not necessarily affect performance (ER 7).
- A change in the design of the product that does not alter the design specifications, but is only made to get better tolerances for a certain specification does not necessarily affect performance (ER 7), so is not considered a significant change.
- A change in a manufacturing process that will need process validation, but does not affect the product specifications including tolerances, does not necessarily affect performance (ER 7), so is not considered a significant change.

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|  | <p style="text-align: center;">Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p> | <p style="text-align: center;">Recommendation NB-MED/2.5.2/Rec2</p> |
| <p>Title:</p> | <p style="text-align: center;">Reporting of design changes and changes of the quality system</p> | |

- A manufacturer is using a component which deviates from a component that he used before (e.g. electronic circuitry). However, he corrects this deviation with another component so that the finished product specification and performance are not changed and documents the actions taken. Upon review, the manufacturer determines and records that risks are not adversely affected and compliance with the essential requirements is maintained and so it is not considered to be a substantial change.

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|  | Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC | <u>Rationale and history sheet</u> to NB-MED/2.5.2/Rec2 |
| Title: | Reporting of design changes and changes of the quality system | |

Rev 1: Meeting of NBR Group, Cologne, Jan. 20 & 21. 1997:

It was decided that the previous text required major revision. An attempt was made to list which types of change did or did not need to be advised to the Notified Body. This proved to be impracticable since a particular type of change could be minor in one situation, yet "substantial" in another.

For instance, a change in colour may be purely cosmetic in some cases, yet be "substantial" in other cases where it is the means for drawing attention to warnings, functions etc.

Meeting of NBR Group, Essen, April 03. & 04. 1997:

It was decided to redraft the document to recommend that the manufacturer apply a systematic approach to evaluation and categorisation of changes. Lists are included of matters for the manufacturer to consider when categorising changes. In preparing the redraft, comments received in relation to the original text (from MDC and the German NB Group) were fully considered.

NBRG agreed to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in June 1997.

New revision no: 1

Confirmed to be at Stage: 2

Rev 2: Notified Body Meeting, Brussels, June. 24 & 25. 1997:

It was decided to accept this recommendation with some minor changes excluded the samples (chapter 5).

It was also decided **to give back this document to the NBRG** to rework the samples.

Meeting of NBR Group, Brussels, June 26. & 27. 1997:

The document (chapter 1 - 4) was reworked.


New revision no: 2

Confirmed to be at Stage: 3

The samples (chapter 5) was also reworked; new proposal (*in italics*, see next page):

| Rev.-Nr. | Rev. date | accepted | amended | withdrawn |
|----------|------------|----------|---------|-----------|
| | 06.06.2000 | | | |

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| 1/5 |

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|  | <p>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p> | <p><u>Rationale and history sheet</u> to NB-MED/2.5.2/Rec2</p> |
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5 Examples

5.1 Changes to EC-approved quality systems (Annex II, V, VI):

a) Reportable change:

Addition of a sterilisation subcontractor to the list of approved suppliers. Rationale: Sterilisation is a “special process” requiring validation, therefore this is a substantial change.

b) Non-reportable change:

Addition of an electrical components supplier, e.g. for resistors, to the list of approved suppliers as

- *selection and approval of suppliers is part of the quality system of the manufacturer*
- *the components to be supplied*
 - *meet the manufacturer’s existing specifications*
 - *do not fall within the manufacturer’s classification of a “substantial change”.*

The change is not reportable.


5.2 Changes to EC-approved medical devices design/type (Annex II, 4.2 and III):

a) Reportable change:

- *Changes to the medical device (included software) which will change the specifications and / or performances of the device (e.g. changes of those materials which have to be biocompatible or changes of main components like power source, Central Processing Unit (CPU), defibrillator-capacitors etc.) are substantial changes.*
- *Altering the intended use of the product (e.g. from Brady Implantable Pulse Generator (IPG) to Tachy IPG) or other changes which may affect the design or performance/characteristics of the device (e.g. new sterilisation method, new welding method) are considered to be substantial changes.*

b) Non-reportable change:

A manufacturer is using a component which deviates from a component that he used before (e.g. electronic circuitry). However, he corrects this deviation with another component so that the finished product specification and performance are not changed and documents the actions taken. Upon review, the manufacturer determines and records that risks are not adversely affected and compliance with the essential requirements is maintained and so it is not considered to be a substantial change.

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|  | <p style="text-align: center;">Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p> | <p style="text-align: center;"><u>Rationale and history sheet</u> to NB-MED/2.5.2/Rec2</p> |
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NBRG agreed

- to fit in this document in the bundle of „stage 3-documents“ and
- to send it - concerning the acceptance of the proposal for the chapter „samples“ - with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval (text plus samples) in the Plenary meeting in November 1997.

Rev 3: Meeting of NBR Group, Essen, September 29 & 30 1997:

It was decided to add the above mentioned proposal for examples into the recommendation and to fit the document in the new *recommendations nomenclature system* (chapter **2.5.2 Conformity assessment procedures; Quality assurance**). Therefore the recommendation gets the new number **NB-MED/2.5.2/R2**. NBRG agreed to send the document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1997.

Revision no: 3

Confirmed to be at stage: 2

Notified Body Meeting, Brussels, November 18 & 19, 1997:

Confirmed to be at Stage: 3

Rev. 4: Medical Devices Expert Group Meeting, Brussels, February 9/10, 1998:

The stage 3 document was presented to the Medical Devices Experts Group but not accepted because this document needs more clarification about „When exactly have changes to be indicated?“. The UK-representative will examine the document and will inform the NBR Group about the results.

Meeting of NBR Group, Brussels, April 20 & 21, 1998:

The NBRG reworked the document and made in light of above mentioned discussion in the MDEG some clarification:

„2 *Manufacturer decision on whether or not particular changes are substantial*
The manufacturer ... or not substantial.

Changes to the design of a device are relevant to conformity assessment under annex II, 4 (design examination) and annex III (type examination). Changes to the quality system are relevant to conformity assessment under annex II, 3 (full quality system), annex V (production quality assurance) and annex VI (product quality assurance).

Note: Changes to the intended use may constitute a new device or alter the classification, and so affect the conformity assessment procedure.


...

4 *Notified Body surveillance and certification*

...
The Notified Body should review ... to inform the Notified Body.

Where a „substantial“ change is reported and agreed either a new certificate or an addendum to an existing certificate can be issued or the existing certificate can remain valid.

...“

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|  | <p style="text-align: center;">Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p> | <p style="text-align: center;"><u>Rationale and history sheet</u> to NB-MED/2.5.2/Rec2</p> |
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On occasion of the next NB-MED meeting on June NB-MED will be informed about this changes; further consideration will be done by the Medical Devices Experts Group.

Confirmed at stage 3

New revision no: 4

Rev 5: Notified Body Meeting, Brussels, November 3 & 4, 1998:

The NB-MED agreed the recommendation with this changes; also some minor editorial hints were given and will be considered. This document will remain a stage 3 document. Further development will take place in the Medical Devices Experts Group.

Confirmed to be at Stage: 3

New revision no: 5

Rev 6: Notified Body Meeting, Brussels, March 2 & 3, 1999:

Mr. Reincke introduced the document NBM/37/99 which could be considered as a further aspect to be included in the existing NB-MED Recommendation 2.5.2/Rec2 "Changes ...". The document should give within a list an answer to "What could be regarded as major changes if – in case of an approved product – some software- or hardware-changes appear with the requirement for notification by a Notified Body?". NBRG was asked to take this proposal on board within the NBRG for consideration to the above mentioned NB-MED Recommendation 2.5.2/Rec2 e. g. as a sample. But due to the workload within the NBRG it was not yet reached the possibility to work on this document. In the meanwhile **Mr. Reincke** was asked by the Technical Secretariat to make a concrete proposal for a revised Recommendation 2.5.2/Rec2.

Notified Body Meeting, Brussels, February 29, & March 1, 2000:

A proposal was sent to TS for further presentation to the NBRG meeting on 10./11. April 2000.

New revision no: 6

Rev 7: Meeting of NBR Group, Brussels, April 10 & 11, 2000:

Proposed changes - made by Mr. Reincke - were accepted and modified with minor editorial changes. Dr. Dörr brought in verbal form his view of changes which should be made in light of IVDD; in parallel he referred to the comments made by Mr. Dalgetty (see NBRG/176/00). After the discussion it was agreed that all comments were considered in the new revised draft document.

NBRG agreed that the document, as discussed and revised, should be presented for adoption at the June NB-MED Plenary meeting.

Revision no: 7

stage 2


Notified Body Meeting, Brussels, June 6 & 7, 2000:

The document (NBM/59/00) was approved by the NB-MED plenary.

Confirmed at stage 3.

Revision no: 7

Rev 8 : Meeting of NBR Group, Brussels, April 10 & 11, 2000:

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|  | <p style="text-align: center;">Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC</p> | <p style="text-align: center;"><u>Rationale and history sheet</u> to NB-MED/2.5.2/Rec2</p> |
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- April 2007 : After an analysis of Eucomed Document (Design changes : what is a substantial change?) presented during November 2006 NBRG Meeting, NBRG decided to reconsider the NB rec taking into account the NBOG comments (February 2007).
- November 2007 : 1st presentation of a draft during NBRG meeting by Corinne Delorme.
- March 2008 : 2nd presentation of a draft during NBRG meeting by Corinne Delorme.
- September 2008 : T conf (Gert Bos, Ian Purdy, Sharon Williams, Corinne Delorme) – Analysis of all NBRG received comments.
- November 2008 : Final presentation of a draft during NBRG meeting by Corinne Delorme. NBRG agreed that the document 326-08, as discussed and revised, should be presented for adoption at the November NB-MED Plenary meeting.

Notified Body Meeting, Brussels, November 25&26, 2008 :

The document (NBM/59/00) was approved by the NB-MED plenary.

Confirmed at stage 3.

Revision no: 8