EUROPEAN CO-ORDINATION NB-MED NOTIFIED BODIES	**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/2.13/Rec1**

Title:	**CE-Marking of pre-MDD devices**
Chapter:	**2.13 Transitional provisions**

Text:	**"... take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or ..."**
Key words:	**pre-existing national law, pre-existing national regulations, pre-existing national administrative provisions, implementation, transitional provisions**

1 INTRODUCTION

This document applies to Medical Devices which are placed on the market under the Medical Device Directive but which were designed to comply with existing regulations in Member States before the Medical Device Directive came into force. Such devices were based on design / requirements which existed before the Medical Devices Directive and may therefore not meet its requirements.

Manufacturers frequently request clarification from Notified Bodies on what requirements exist for pre-MDD devices on cases where these manufacturers need to affix the CE mark on these devices. The purpose of this document is to provide guidance to Notified Bodies and manufacturers to ensure these devices meet the requirements of the Medical Devices Directive.

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD		
MDD	Article: 22-3; Annex: I, II, III, IV, V, VI, X	
IVDD		

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
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VdTÜV
Technical Secretariat NB-MED
PO Box 10 38 34
D-45038 Essen

G. Hinrich Schaub (- 178)
Jörg Höppner (- 138)
Kurfürstenstraße 56
D-45138 Essen

Phone: ++49/201/8987- 0
Fax: ++49/201/8987- 120
eMail: vdtuev.hoeppner@t-online.de

2 REQUIREMENTS OF THE DIRECTIVE

The placing of a CE mark on a device demonstrates conformity to the requirements of the Medical Devices Directive. The directive requires Notified Bodies to take into account any pre-MDD device and system approvals held by a manufacturer for his device or quality system prior to the directive coming into force.

3 EVALUATION OF EXISTING PROVISIONS

Manufacturers will have technical documentation which describes the medical device and how it is manufactured: the Device History File. The amount and detail of this documentation will depend on the device and the age of the design. This device history file will be a description of the device and contain all the information used to demonstrate compliance with member states' regulatory requirements which existed at the time of design. It will also document any changes and modifications made to the design of the device. The manufacturer must assess this documentation and decide if the device and manufacturing processes meets the requirements of the directive.

Any differences between the existing documentation and the requirements of the directive need to be addressed by the manufacturer and assessed by the Notified Bodies.

4 CE CONFORMITY

The manufacturer must demonstrate and document compliance to the Essential Requirements and the absence of unacceptable adverse effects. This may be based on existing data and recorded through the use of checklists and documents cross referencing information contained in the device history file, quality system documentation or specific publications, reports and dossiers. Appendix 1 provides a decision tree which describes the process of demonstrating compliance to the Essential Requirements. Compliance may be based on information gained in the field or on similar devices. Such information should include an evaluation of the data together with a reasoned conclusion as to how the manufacturer feels the data demonstrates compliance with the requirements of the directive.

Possible methods of demonstrating compliance to the essential requirements includes:

(1) The Device History File

This is any documentation and data relating to the product. It should contain a description of the device and any variants, the product specification and the data which may have been submitted to a competent body or regulatory body for product approval. For quality system based approvals this documentation may be in the form of a device master file.

The device history file may be a document or a file referring to the location of this information.

(2) Risk Analysis

Using prEN 1441 as a guide, the manufacturer should identify any potential hazards which may exist with the device design and demonstrate how that risk has been minimised or eliminated. Information from the market (see also NB-MED recommendation *Post-Marketing Surveillance (PMS) post market/production*) could be used to demonstrate that a device is safe. Where this is base on experience, the manufacturer should indicate how long the device has been in use, the number of units sold and the number and classification of complaints. A critical appraisal of scientific literature may also be useful.

(3) Clinical evaluation

The manufacturer should, where applicable, taking into account the results of risk analysis, provide clinical evidence to demonstrate that the device conforms to the requirements referred to in annex X. For pre-MDD devices this may be evidence acquired from user experience. This may be a critical evaluation of published scientific literature.

For some devices, clinical evidence is difficult to be demonstrated only through experience (device with no negative side effect, biological safety of devices with a low rate of incident).

Notified Bodies should take into account the fact that information on clinical experience may be gained from clinical investigations performed in the past according to rules that may differ from the present rules defined for clinical investigations.

Guidance on clinical evidence is given in NB-MED recommendation *Guidance on clinicals*.

(4) Experience gained in the post-production phase

This may be used in order to estimate the risks associated with the device and its use.

5 DEVICES WHICH DO NOT MEET THE ESSENTIAL REQUIREMENTS

If the essential requirements are not met redesign action should be performed. This must include a risk analysis and the assessment of possible adverse effects.

Redesign action may include additional tests, verification activities, collection of additional data and information.

6 EVALUATION PROCEDURES

6.1 Annex II:

This evaluation procedure can be followed even when the device has not been developed under a quality system which include design and production aspects. At the time of the initial design, devices were generally not designed taking into account the "Essential requirements" as input data. It is therefore assumed that the assessment procedure described in annex II may not be fully applied.

In this case, the manufacturer shall set up a procedure in order to perform an "a posteriori" risk analysis and a procedure related to the verification that the device fulfils the essential requirements.

This verification procedure should be based on the general principles previously described (see § 3 & 4). Taking into account data from the Quality Assurance history file, the device history file, from the risk analysis and other available sources, it shall be demonstrated that each essential requirement is met. When an essential requirement is not met or when it can not be proved that a risk is acceptable, additional data should be collected. If these additional data are insufficient or indicate that an essential requirement is not met, then an redesign action shall be taken. This redesign action may be a modification of the design, a modification of the manufacturing process or additional information in the labelling or in the instructions for use.

Modifications, any further corrective action, and the manufacturing stage shall be performed under a quality assurance system which fulfils the requirements of annex II section 3.2.

The Notified Body must assess the procedures for risk analysis and verification of compliance to the essential requirements. The Notified Body must verify the availability of records resulting from those procedures. The Notified Body shall also assess whether the present quality system complies to the provisions of annex II section 3.2. The Notified Body shall have access to the information from the quality assurance history and device history files.

Class III devices: design examination:

The Notified Body shall assess the results of the risk analysis and of the verification of compliance to the essential requirements which shall be added to the design dossier. It shall also evaluate the redesign actions, if any.

6.2 Annex III:

Due to a design performed many years ago, some parts of the documentation to be submitted by the manufacturer to the Notified Body, as described in annex III section 3, may be not available, in particular information about design calculation or risk analysis at the time of the design. In addition, the manufacturer may have available test reports, certificates,... assessing the conformity to pre-existing national regulations.

In these conditions, the manufacturer must assess the available data and demonstrate that the device fulfils the essential requirements by means based on the general principles previously described (see § 3 & 4). This shall be documented and shall include an "a posteriori" risk analysis.

The manufacturer must make available to the Notified Body the results of risk analysis, the documents which demonstrate that the essential requirements fulfilment has been verified, the documents on which this verification was based, and the whole set of available documents as described in annex III section 3.

The Notified Body must assess this documentation and shall take into account that the demonstration of conformity may be based on non-harmonized standards or rules, according to the state of art at the time of the design, insofar as no unacceptable risk or unacceptable adverse effect has been detected and essential

requirements are met. In this case, tests and inspections carried out or arranged by the Notified Body should be based on such documents.

(Note: referring to the lifetime - 5 years)

6.3 Annex IV:

When type examination or the declaration of conformity of the manufacturer (annex VII) is based on standards or technical documents corresponding to the state of art at the time of the design or to pre-existing national regulations, the Notified Body should carry out the verification on the basis of these documents for the relevant technical aspects and taking into consideration the provisions of Annex IV.

6.4 Annex V:

This annex does not concern the design of the device. No distinction should appear between pre-MDD marketed devices and MDD devices.

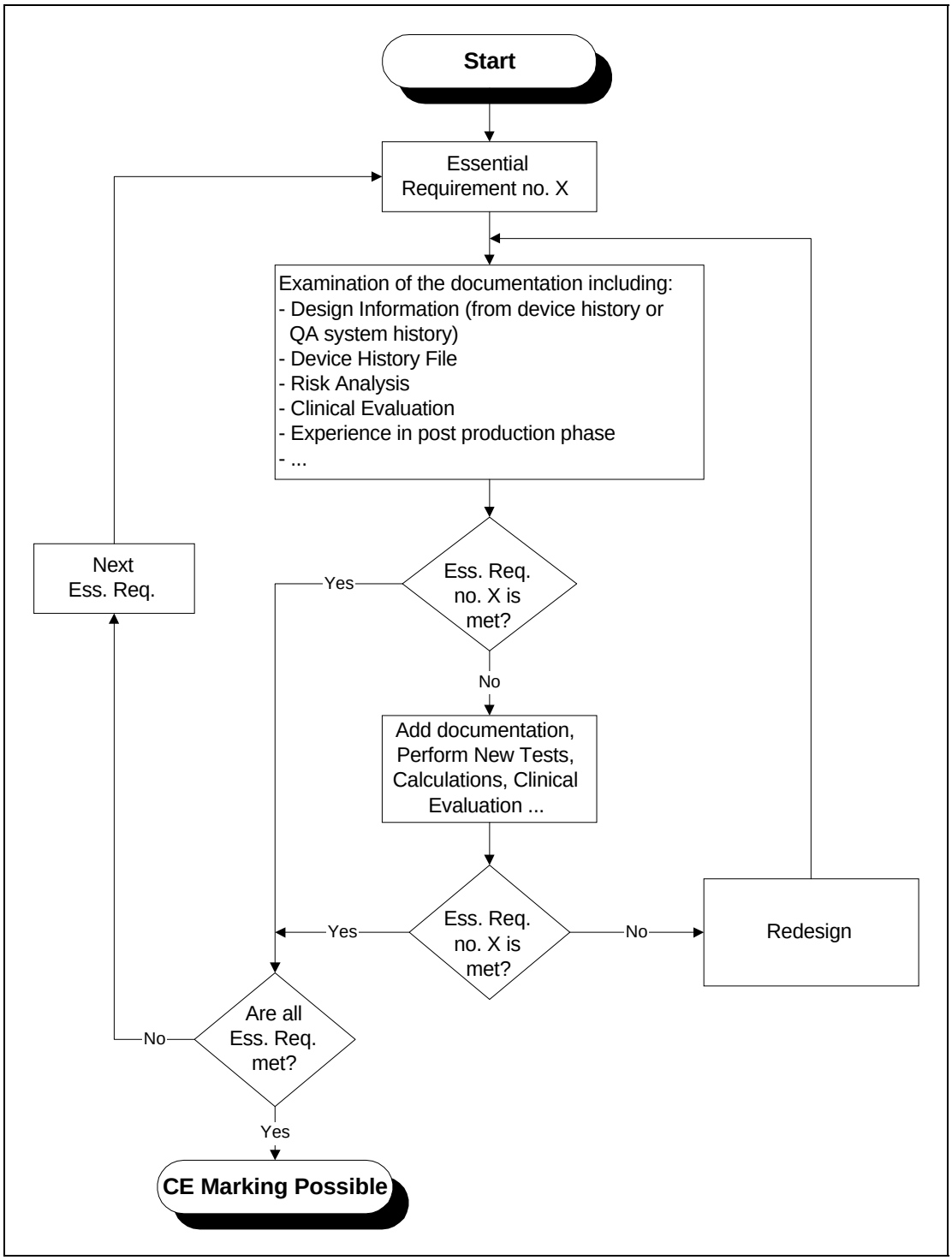
6.5 Annex VI:

This annex does not concern the design of the device. No distinction should appear between pre-MDD marketed devices and MDD devices.

6.6 Annex VII:

This annex does not imply the intervention by a Notified Body.

APPENDIX 1


Start
Essential Requirement no. X
Examination of the documentation including:
- Design Information (from device history or QA system history)
- Device History File
- Risk Analysis
- Clinical Evaluation
- Experience in post production phase
- ...
Ess. Req. no. X is met?
Yes
No
Next Ess. Req.
Add documentation, Perform New Tests, Calculations, Clinical Evaluation ...
Ess. Req. no. X is met?
Yes
No
Redesign
Are all Ess. Req. met?
No
Yes
CE Marking Possible

EUROPEAN CO-ORDINATION NB-MED NOTIFIED BODIES	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Rationale and history sheet to NB-MED/2.13/Rec1**
Title:	**CE-Marking of pre-MDD devices**	

Rev. 2: Notified Body Meeting, Brussels, Feb. 04. & 05. 1997:
Mr Binard (convenor of NB-MED Task Force "Existing products" explained the draft of the document "CE marking of pre-MDD devices" (NBM/26/96, rev. 4). Dr. Lehmann/COCIR and the representatives of the Notified Bodies proposed a number of amendments to the document. Mr Binard was asked to incorporate the amendments in the document, which the NBGR was asked to prepare for subsequent discussion at the next (14th) meeting of the NB-MED.

Meeting of NBR Group, Essen, April 03. & 04. 1997:
A new proposal was tabled by the Technical Secretariat. The footnotes was discussed and it was decided to delete some footnotes and to do some minor additions.
The proposal of Dr. Lehmann to change the term "device history file" to "device master file" (reason: to harmonize the term with EN 46001/EN ISO 9001 like "Device Master File", "Device History File", "Device History Record") was not finally discussed. The written remark from Mr Binard was: *"Device Master File", "Device History File", "Device History Record" are not defined in EN 46001/EN ISO 9001. "Design History File", "Device History Record" and "Device Master File" are defined in the FDA/C-GMP. The "Product history file" mentioned in this document is defined in Chapter 4 "CE Conformity", item (1) "The device history file". This is something which approach the definition of a "Device master file" including the "Design history file" if available, but also information about approval or assessment in one or many Member States, or information from the post production phase for devices of the same type which are already on the market. Due to the fact that a lot of manufacturer have not performed the design of the device under a quality system, the use of "device master file" may introduce some confusion with its meaning in the C-GMP where the content of this file is defined. For pre-MDD devices, a lot of manufacturer are not able to provide a complete device master file as defined in the C-GMP. Therefore Mr Binard proposes to use the term "Device history file", but he is open to other more suitable proposals.*
In a meeting (Ms O'Connell, Dr. Holland and Mr Höppner) on 17.04.97 it was decided to use the term "device history file" because this term is the most proper term. Also it was decided 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.
Revision no: 2
Confirmed to be at Stage: 2

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

G. Hinrich Schaub (- 178)
Jörg Höppner (- 138)
Kurfürstenstraße 56
D-45138 Essen

Phone: ++49/201/8987- 0
Fax: ++49/201/8987- 120
eMail: vdtuev.hoeppner@t-online.de

Rev. 3: Notified Body Meeting, Brussels, June 24. & 25. 1997:
Mr Binard (convenor of NB-MED Task Force "Existing products") explained the draft of the document concerning the use of „Device History File".
It was decided to do some minor additions/changes.
Confirmed to be at Stage: 3

Meeting of NBR Group, Brussels, June 26. & 27. 1997:
Respectively the results of the NB-MED plenary meeting the recommendation was revised by NBRG.
New revision no: 3
Confirmed to be at Stage: 3

Meeting of NBR Group, Essen, September 29 & 30 1997:
It was decided to fit the document in the new *recommendations nomenclature system* (chapter 2.13 *Transitional provisions*). Therefore the recommendation gets the number **NB-MED/2.13/R1**.

Medical Devices Expert Group Meeting, Brussels, February 9 & 10, 1998:
The stage 3 document was presented to the Medical Devices Experts Group and accepted without changes:
Confirmed at stage 4.