Recommendations

of Notified Bodies Medical Devices

(NB-MED)

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

Issue 12/2001

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

vdtuev-file: ...\hoeppner\mp\nb\rec_vdt2\RECOMM_12_2001.DOC

Table of contents

Introduction

The aim of this recommendation document is to clarify certain matters and procedures referred to in Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC on the harmonization of the laws of Member States relating to medical devices.

This document comprises a series of recommendations accepted by the Forum of Notified Bodies Medical Devices (NB-MED). Recommendations with higher level content will be passed on to the EC Medical Device Expert Group, consisting of representatives of the authorities of the member states, and to the European Commission for adoption. After adoption they will be included in the EC Guide to the Medical Devices Directives as MedDev documents.

The recommendations contained in this document are not mandatory. Although they set out information on matters relating to the directives this is for guidance only, to help you to meet your obligations, whether you are a manufacturer, notified body or other interested party.

The formal document remains the text of directives 90/385/EEC, 93/42/EEC and 98/79/EC together with any officially published supporting or amending documents.

This document comprises also documents (e.g. the text of the directives or references to standards) which allow to give the interesting reader a overview about the most relevant documents concerning the subject “Medical Devices“.

Comments or other proposals to this tabled recommendation document may be sent directly to the Technical Secretariat of Notified Bodies Medical Devices (for the address, see below).

(Dr. Roy Holland)

Chairperson of the Notified Bodies Group Medical Devices (NB-MED)

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

User's guide

On the following pages in chapter *Recommendation documents* you will find all recommendations of the NB-MED in relation to relevant subjects of MDD, AIMD and IVDD which are accepted by the Forum of Notified Bodies Medical Devices (NB-MED). The acronym **NB-MED** encompasses all activities of the **N**otified **B**odies for **Med**ical devices.

The annex 1 *NB-MED procedure No 1 „Development of Notified Body Recommendations"* of this user's guide gives an overview about the procedure of developing of Notified Body Recommendations.

The annex 2 *NB-MED procedure No 2 „Layout, Numbering and Revisions of NBR´s"*of this user's guide gives the explanation for the system of layout, numbering and revisions of Notified Body Recommendations.

The chapter *List of recommendations on directive 93/42/ECC (related to the articles)* gives an overview of which article of the MDD is covered by which recommendation(s). The table is obtained from the references given on the front page of every recommendation.

The chapter *List of recommendations on directive 90/385/ECC (related to the articles)* gives the same for the articles from AIMD.

The chapter *List of recommendations on directive 98/79/EC (related to the articles)* gives the same for the articles from AIMD.

The chapter *Keywords* gives the list of key words with regard to the recommendations.

NB-MED procedure No 1 „Development of Notified Body Recommendations"

Purpose: To develop Notified Body Recommendations (NBR´s)

Scope: The development of NBR´s by the NB-MED taskforce on NBR´s (NBRG) for presentation to and approval by the NB-MED plenary

Definition: A NBR is a document developed to assist NB´s, manufacturers and interested parties in applying a common approach to the application of the Medical Device Directives.

Process: NBR´s are developed in the following stages:

Stage 0: A document submitted to and registered by the NB-MED as a proposal for a NBR.

Stage 1: A document accepted or returned by the NB-MED to be further developed as a NBR by the NBRG or an ad-hoc group assigned by the NB-MED. Before presenting the document to the NB-MED plenary, the document shall be circulated with a request for comments to all members of the NB-MED plenary.

Stage 2: A document developed or received for editing by the NBRG for presentation to and approval by the NB-MED plenary.

Stage 3: A document accepted by the NB-MED plenary for presentation to and approval by the Medical Device Expert group.

Stage 4: A document on proposal of the Commission accepted by the Medical Device Expert group for issuance as a MedDev document by the Commission.

Stage 5: A document issued by the Commission as a MedDev document.

Note: All NBR´s should be routed through the NBRG for consistency and format.

The responsibility for bringing the documents to the various stages is as follows:

Stage 1: NB-MED
Stage 2: NBRG or assigned ad-hoc group
Stage 3: NB-MED
Stage 4: Medical Device Expert Group on proposal of the Commission
Stage 5: European Commission

The technical secretariat is responsibility for:

- Editing the documents
- Sending the documents to the involved parties
- Collate the comments for further consideration, etc.

Approval of documents by the NB-MED plenary:

Approval will be, in general, on consensus of the meeting. If this is not possible due to fundamental disagreement the chairman has to note these and to decide if the document are to be referred back to the NBRG or if it has to go to a voting procedure as follows:

- The Notified Bodies and Associations of manufactures vote separately. Within these groups each Notified Body and each Association has one vote.

- Approval of the document is achieved by simple majority in favor in both groups.

  If the majorities of the groups differ, the document will be referred to the Commission for decision.

- The representative of Commission has the right to veto, due to political or regulatory reasons, the approval of any document.

NB-MED procedure No 2 „Layout, Numbering and Revisions of NBR´s"

Purpose: Layout, Numbering and Revision System for Notified Body Recommendations.

Scope: Through all stages of development Notified Body Recommendations have a document number.

Layout of NB-MED Recommendation:

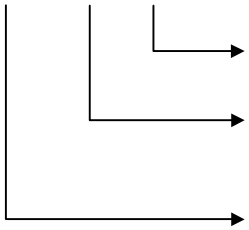
The layout of
- NB-MED Recommendations and
- Rationale & history sheet

will be as attachment to this procedure.

In the layout of NB-MED Recommendations the following subject will be mentioned:
- number of recommendation

  Explanation of the nomenclature system (example):

  NB-MED/2.1/Rec1

  Rec1 means: **Rec**ommendation number **1** in the current chapter of the recommendations collection

  Current chapter of the recommendations collection, here chapter **2.1** „Scope, field of application, explanation of terms"

  NB-MED is an acronym covering all activities of the **N**otified **B**odies for **Med**ical devices

- title (of the recommendation)
- chapter (in the table of contents)
- text (most a quote of the relevant part of the directives)
- key words
- note on the existence of „rationale and history sheet"
- references to Articles or Annexes of the AIMD, MDD and IVDD
- references to Standards (if appropriate)
- stage
- proposed by (gives an indication to the party making the first inquiry; only used for stage 0 or revision 0)
- Revision No. (means revision number after editing etc.):

  Revision 0:

  New documents will, after registration, start as a revision 0 document.

  Higher revisions:

  During the editing and commenting phases a higher revision number will be given at every change in the document.

- Revision date (means revision date after editing etc.)
- accepted (means date of approval by NB-MED; then document passes to stage 3 and becomes a stage of recommendation)
- amended (means date of changes, document stays at stage 3)
- withdrawn (means date of cancellation of the document)

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/_._._/Rec_**

Title:	
Chapter:	

Text:	
Key words:	

Note: - *in case of stage 0 - 2: a rational and history sheet is attached (or is not attached)*
- *in case of stage 3: a rational and history sheet is available, contact technical secretariat (or is not available)*

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD		
MDD		
IVD		

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page

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

vdtuev-file: ...\hoeppner\mp\nb\rec_vdt2*name*.doc

	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/_._._/Rec_**
Title:		

Rev.-Nr.	Rev. date	accepted	amended	withdrawn

Page

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

3 List of recommendations on directive 90/385/ECC (related to the articles)

Article/Annexes	Document No: NB-MED/...
Article 2	.../2.1/Rec3;
Article 11.7	.../2.15/Rec1;
Annex 1	.../2.2/Rec4; .../2.7/Rec3;
Annex 1-8	.../2.2/Rec1;
Annex 1-14	.../2.2/Rec3;
Annex 2	.../2.2/Rec2; .../2.5.1/Rec5; .../2.5.2/Rec1; .../2.5.2/Rec3;
Annex 2-3	.../2.5.1/Rec4;
Annex 2-3.1	.../2.1/Rec2;
Annex 2-3.1v	.../2.12/Rec1;
Annex 2-3.2	.../2.1/Rec2;
Annex 2-3.3	.../2.1/Rec2;
Annex 2-3.4	.../2.1/Rec2; .../2.5.2/Rec2;
Annex 2-4	.../2.5.1/Rec4; .../2.5.1/Rec6
Annex 2-4.4	.../2.5.2/Rec2;
Annex 3	.../2.5.1/Rec4; .../2.5.1/Rec5; .../2.5.1/Rec6
Annex 3-1	.../2.1/Rec1;
Annex 3-6	.../2.5.2/Rec2;
Annex 4	.../2.5.1/Rec4; .../2.5.1/Rec5; .../2.5.2/Rec3;
Annex 4-2	.../2.5.4/Rec1;
Annex 4-3	.../2.12/Rec1;
Annex 5	.../2.5.1/Rec4; .../2.5.1/Rec5; .../2.5.2/Rec3;
Annex 5-3iv	.../2.5.2/Rec2;
Annex 5-3vi	.../2.12/Rec1;
Annex 7	.../2.7/Rec1; .../2.7/Rec3;

4 List of recommendations on directive 93/42/ECC (related to the articles)

Article/Annexes	Document No: NB-MED/...
Article 1.2(f)	.../2.1/Rec5;
Article 1.2(h)	.../2.1/Rec5;
Article 11	.../2.5.5/Rec2;
Article 11.7	.../2.15/Rec1;
Article 12	.../2.5.5/Rec2;
Article 22-3	.../2.5.5/Rec2; .../2.13/Rec1;
Annex I	.../~~2.1/Rec4~~; .../2.13/Rec1; .../2.7/Rec3
Annex I-9.2	.../2.2/Rec1;
Annex I-12.5	.../2.2/Rec1;
Annex I-13.3	.../2.2/Rec3;
Annex II	.../2.5.1/Rec5; .../2.5.2/Rec3; .../~~2.5.5/Rec1~~; .../2.13/Rec1;
Annex II-3	.../2.1/Rec2; .../2.5.1/Rec4;
Annex II-3.1	.../2.1/Rec2;
Annex II-3.1vii	.../2.12/Rec1;
Annex II-3.2	.../2.1/Rec2;
Annex II-3.3	.../2.1/Rec2; .../2.5.2/Rec1
Annex II-3.4	.../2.1/Rec2; .../2.5.2/Rec2;
Annex II-4	.../2.5.1/Rec4; ...2.5.1/Rec6
Annex II-4.4	.../2.5.2/Rec2;
Annex III	.../2.5.1/Rec4; .../2.5.1/Rec5; ...2.5.1/Rec6; .../~~2.5.5/Rec1~~; .../2.13/Rec1;
Annex III-1	.../2.1/Rec1;
Annex III-6	.../2.5.2/Rec2;
Annex IV	.../2.5.4/Rec1; .../~~2.1/Rec4~~; .../2.5.2/Rec3; .../2.13/Rec1; .../2.5.1/Rec4; .../2.5.1/Rec5;
Annex IV-3.1viii	.../2.12/Rec1;
Annex V	.../~~2.1/Rec4~~; .../2.5.2/Rec3; .../2.13/Rec1; .../2.5.1/Rec4; .../2.5.1/Rec5;
Annex V-3.1	.../2.12/Rec1;
Annex V-3.3	.../2.5.2/Rec1;
Annex V-3.4	.../2.5.2/Rec2;
Annex VI	.../~~2.1/Rec4~~; .../2.5.2/Rec3; .../2.13/Rec1; .../2.5.1/Rec4; .../2.5.1/Rec5;
Annex VI-3.1viii	.../2.12/Rec1;
Annex VI-3.3	.../2.5.2/Rec1;
Annex VI-3.4	.../2.5.2/Rec2;
Annex VII	.../~~2.1/Rec4~~; .../2.5.1/Rec5;
Annex VII-4	.../2.12/Rec1;
Annex X	.../2.13/Rec1; .../2.7/Rec3
Annex IX (II)	.../2.4/Rec4 ;
Annex X-1.1	.../2.7/Rec1;

5 List of recommendations on directive 98/79/ECC (related to the articles)

Article/Annexes	Document No: NB-MED/...
Article 1.2(f)	.../2.1/Rec5;
Article 1.2(i)	.../2.1/Rec5;
Article 3	.../2.5.1/Rec5;
Article 5.3	.../2.5.5/Rec3;
Article 9	.../2.5.4/Rec2;
Article 22.4	.../2.5.5/Rec3; …/2.13/Rec2
Annex I	.../2.2/Rec4; .../2.5.5/Rec4 ; .../2.13/Rec2;
Annex I part B, 8.4	.../2.2/Rec3;
Annex I-3-3	.../2.2/Rec1;
Annex II	.../2.2/Rec4; .../2.5.4/Rec2; .../2.5.5/Rec3;
Annex III-5	.../2.12/Rec1;
Annex III-6.3	.../2.5.2/Rec2; …/2.13/Rec2
Annex IV	.../2.5.2/Rec3; …/2.13/Rec2
Annex IV-3.1	…/2.1/Rec2; .../2.12/Rec1;
Annex IV-3.2	…/2.1/Rec2
Annex IV-3.3	…/2.1/Rec2; .../2.5.2/Rec1; .../2.5.2/Rec2;
Annex IV-3.4	…/2.1/Rec2
Annex IV-4.4	.../2.5.2/Rec2;
Annex IV-6	.../2.5.4/Rec2;
Annex V	.../2.13/Rec2;
Annex V-1	.../2.1/Rec1;
Annex V-6.1	.../2..5.2/Rec2;
Annex VI	.../2.13/Rec2;
Annex VI-1	.../2.1/Rec1;
Annex VI-4	.../2.1/Rec1;
Annex VI-2.1	.../2.5.4/Rec1;
Annex VI-3.1	.../2.12/Rec1;
Annex VI-3.4	.../2.5.2/Rec2;
Annex VI-6.1	.../2.5.4/Rec1;
Annex VII	.../2.5.2/Rec3;
Annex VII-3.1	…/2.1/Rec2; .../2.12/Rec1;
Annex VII-3.3	.../2.5.2/Rec1;
Annex VII-5	.../2.5.4/Rec2;

6 Keywords

	Document No: NB-MED/...

L

labelling	.../2.1/Rec3 .../2.5.2/Rec3

M

manufacturer	.../2.1/Rec5
measuring	.../~~2.1/Rec4~~
measuring function	.../~~2.1/Rec4~~

N

no-CE-marked medical devices	.../2.5.5/Rec2
no-medical devices	.../2.5.5/Rec2

P

placing on the market	.../2.1/Rec5
pre-existing national administrative provisions	.../2.13/Rec1 .../2.13/Rec2
pre-existing national law	.../2.13/Rec1 .../2.13/Rec2
pre-existing national regulations	.../2.13/Rec1 .../2.13/Rec2
product	.../2.1/Rec2
programmes	.../2.2/Rec2

Q

quality assurance	.../2.15/Rec1
quality system	.../2.5.2/Rec2

	Document No: NB-MED/...

R

range	.../2.1/Rec2
registration card	.../2.12/Rec1
renewal	.../2.5.1/Rec6

S

sample(s)	.../2.1/Rec1 .../2.5.4/Rec1
sensitivity	.../2.5.5/Rec4
seroconversion panels	.../2.5.5/Rec4
software	.../2.2/Rec4
spare parts	.../2.1/Rec3
statement of competence	.../2.15/Rec1
statistical control	.../2.5.4/Rec1
subcontractors	.../2.5.2/Rec1
supplier	.../2.5.2/Rec1 .../2.15/Rec1
surveillance	.../2.12/Rec1
systems and procedure packs	.../2.5.5/Rec2

T

technical assessment	.../2.15/Rec1
technical documentation	.../2.5.1/Rec5
technical file	.../2.5.1/Rec5
transitional provisions	.../2.13/Rec1 .../2.13/Rec2
translation	.../2.5.2/Rec3

Document No:
NB-MED/...

U

V

W