	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/2.5.5/Rec2**

Title:	**Combination of CE-marked and non-CE-marked medical devices and non-medical devices**
Chapter:	**2.5.5 Conformity assessment for particular product groups**

Text:	**„If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.“**
Key words:	**systems and procedure packs, non-CE-marked medical devices, non-medical devices, combination of medical devices, labelling of combinations**

1. Purpose

The purpose of this recommendation is to provide guidance to the Notified Body and the manufacturer on the MDD regulatory requirements which apply to the placing on the market and putting into service of various combinations of CE-marked medical devices, non CE-marked medical devices and non medical devices. This includes guidance on the content of the technical file and information for the user in situations where medical devices are to be used in combination with other devices for a purpose within the scope of MDD. Those other devices may be CE-marked medical devices, non CE-marked medical devices or non-medical devices.

This recommendation does not address spare parts of medical devices. Spare parts in general are not subject to separate conformity assessments and therefore are not subject to CE marking.

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD		
MDD	Article: 11, 12, 22-3	
IVDD		

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	9	12.01.2001	06.03.2001			1/4

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2. Criteria for combinations

A combination is a configuration of two or more devices intended to be used together. The combination may be performed by the manufacturer or assembler or user. Refer to the matrix opposite for examples, which are not exclusive.

The manufacturer may act as an original device manufacturer or a second source manufacturer, when he wishes to use an alternative product. Finally, he may be a manufacturer whose sole objective is to produce combinations of devices placed on the market on its own from one or more manufacturers.

The intended purpose of the combination has to be within the definition of article 1, section 2a of the MDD.

The devices or accessories to be combined may be produced by one or more manufacturers.

The combination between a medical device and a medicinal product is not covered.

In each case it, should be established who creates the combination: the manufacturer, the assembler or the user. Where the user creates the combination for his own use, that combination is not placed on the market and therefore additional CE marking is not required.

Non CE-marked medical devices are medical devices which do not bear the CE mark to denote compliance with the MDD. Such devices may be placed on the market under national regulations before June 14, 1998 and put into service until June 30, 2001 but not after then.

A non-medical device is a device not covered by the MDD or AIMD or IVDD. It may be covered by other directives.

3. Guidance on the application of the regulatory requirements

Guidance for requirements for combinations is summarised in the following matrix.

In cases where the intended purpose of the device requires combinations, the requirements can be found in annex I, section 9.1 of the MDD with respect to construction and in section 13.6c with respect to labelling.

Procedures for monitoring and verifying the design of the products can be found in MDD, annex II, section 3.2c, 4th indent.

NB-MED (European Co-ordination of 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/2.5.5/Rec2**
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Combinations of devices and accessories after 13.06.98:

No.	Who combines	Device D1 or accessory A1			Device D2 or accessory A2			conform. assessment MDD		particular procedure
		CE/ non CE-MD	placed on the market	put into service	CE/non CE-MD or non-MD	placed on the market	put into service	D1 or A1	D2 or A2	Systems/ procedure packs
1	manufact.	CE-MD	yes	yes	non MD	no	no	Art. 11 done	not applicable	D1/A1 Art. 11 update[1]
2	manufact.	CE-MD	no	no	non MD	yes	yes	Art. 11	not applicable	D1/A1 Art. 11
3	manufact./ assembler	CE-MD	no	no	CE-MD	no	no	Art. 11	Art. 11	Art. 12
4	manufact./ assembler	CE-MD	no	no	non CE-MD	yes	yes	Art. 11	not applicable	Art. 12 ER 9.1
5	manufact./ assembler	CE-MD	yes	no	non CE-MD	yes	yes	Art. 11	not applicable	ER 9.1[2]
6	manufact./ assembler	CE-MD	no	no	non MD	no	no	Art. 11	not applicable	Art. 11
7	assembler	CE-MD	yes	yes	non CE-MD [until 30.6.2001]	yes	[no] [until 30.6.2001]	Art. 11 done	not applicable	Art. 11
8	assembler	non CE-MD [until 30.6.2001]	yes	[no]	non CE-MD [until 30.6.2001]	yes	[no] [until 30.6.2001]	not applicable	not applicable	Art 11
9	assembler	non CE-MD [until 30.6.2001]	yes	no	non CE-MD	yes	yes	Art. 11 done	not applicable	Done or Art 11
10	user	CE-MD	yes	yes	non CE-MD [until 30.6.2001]	yes	[no] [until 30.6.2001]	Art. 11 done	not applicable	voluntary manufact. declarat.[3]
11	user	non CE-MD [until 30.6.2001]	yes	[no]	non CE-MD [until 30.6.2001]	yes	[no] [until 30.6.2001]	not applicable	not applicable	voluntary manufact. declarat.

[1] That update via the article 11 procedure

[2] Emergency requirements 9.1

[3] A voluntary manufacturer's declaration would follow the same principle as in MDD article 12.2, but would be outside regulatory requirements

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Note: Systems and procedure packs subject to Article 12 are also required to conform to requirements of Annex I.13 with regard to information and labelling of such combination.

4. Content of technical file

4.1 Where CE-marked medical devices are combined under article 12 within the original manufacturer(s) intended use and limits of use, the manufacturer of the combination should include relevant items with respect to the proposed combination:

- intended use (of the combination),
- instruction for use (of the combination),
- risk analysis (of the combination),
- if relevant: additional clinical data relation to the combination,
- documentation of the fullfilment of all relevant essential requirements of the combination,
- declaration with respect to article 12 of the MDD, if applicable.

4.2 In all other circumstances where one or more of the devices are combined outside the original manufacturer(s) intended uses or limits of use the requirements of article 11 apply.

5. Information for the user

In additional to the usual requirements, the manufacturer of the combination may select for example to give the following information for the combination:

- description of relevant characteristics of the individual devices of the combination, if applicable, which assure that the combination meets the intended purpose;
- parameters of the devices in the combination which may have an impact on the safety and performance of the combination, if appropriate;

	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/2.5.5/Rec2**
Title:	**Combination of CE-marked and non-CE-marked medical devices and non-medical devices**	

Rev 1: Meeting of ad-hoc group „Combination of CE-marked/non-CE-marked medical devices“, Lübeck, January 9, 1998:
A NB-MED recommendation for the combination of CE-marked and non-CE-marked medical devices with regard to regulatory requirements of the Medical Device Directive content of the technical file and information to the user was drafted based on an earlier EUROM VI resolution.
New revision no: 1
Confirmed to be at Stage: 0

Rev 2: Meeting of ad-hoc group „Combination of CE-marked/non-CE-marked medical devices“, Lübeck, April 15, 1998:
The tabled rev 1 was redrafted.
New revision no: 2
Confirmed to be at Stage: 1

Rev 3: Meeting of NBR Group, Brussels, April 20 & 21, 1998:
Discussion concerning the tabled stage 0 document. Some minor changes were proposed and adopted by NBRG.
It was decided to fit the document in the *recommendations nomenclature system* (chapter 2.5.5 *Conformity assessment for particular product groups*). Therefore the recommendation gets the number **NB-MED/2.5.5/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 June 1998.
Confirmed at stage 2
Revision 3

Notified Body Meeting, Brussels, June 9 & 10, 1998:
NB-MED agreed the tabled draft recommendation but the representative of the Commission was concerned about the wording which seems to give this recommendation a mandatory character. It was agreed to accept this recommendations as stage 3 document with the condition that the NBR-group shall make some word editing on their meeting on 11./12.06.98.

Rev 4: Meeting of NBR Group, Brussels, June 11 & 12, 1998:
Following the recommendation made by NB-MED (plenary meeting on 9./10.06.98) it was rendered more precisely that the requirements result out of the directives. Additional the reference to the term „pre MDD devices“ was deleted, it was clarified which parts of this recommendation relate to the draft

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IVD and the chapter concerning the technical file received more clarification about scenarios of combination (article 11/article 12).
NBRG agreed to send the document, with its "Rationale and history" sheet to all member of NB-MED with the request to fit the document in the current booklet of NB-MED recommendations.
Confirmed at stage 3
Revision 4

Rev 5: Notified Body Meeting, Brussels, March 2 & 3, 1999:
Once again it was clarified that the main purpose of this recommendation is to demonstrate the possible *combinations of devices and accessories*. Therefore it was agreed to rearrange the table. Also two further cases (case 10 and 11) - as presented by Dr. Wallroth – shall be included. It was also agreed to accept this recommendations with these proposed changes as stage 3 document.
The revised document, with its "Rationale and history" sheet will be disseminated to all member of NB-MED a.s.a.p. with the request to fit the document in the current booklet of NB-MED recommendations.
Confirmed at stage 3
Revision 5

Rev 6: Meeting of NBR Group, Copenhagen, May 10 & 11, 1999:
NBRG agreed to make further clarification concerning the consideration of “spare parts”; a sentence was added: “This recommendation does not address spare parts of medical devices. Spare parts in general are not subject to separate conformity assessments and therefore are not subject to CE marking.” This change reflexes an extensive debate within the Medical Devices Experts Group were some German Authorities ask for decommissioning medical devices because the x-ray tubes does not have a CE-mark.
It was agreed that the document, as revised, should be presented for adoption at the June 8-9, 1999 NB-MED Plenary meeting.
Confirmed at stage 2
Revision 6

Notified Body Meeting, Brussels, June 8 & 9, 1999:
The revised draft document (NBM/85/99) was presented. Some members of NB-MED mentioned that this complicated and not easy readable recommendation needs clarification, especially concerning the use of the matrix. NB-MED adopted the revised document with this presented change as stage 3 document. But **NBRG** was asked to improve this recommendation with regard to its clarity; this will be considered in a later revision and shall be presented to the next meeting in November.
Confirmed at stage 3
Revision 6

Rev 7: Meeting of NBR Group, Brussels, June 10, 1999:
A proposal for a revised document - in light of the discussion made within the NB-MED plenary on 08./09.06.99 - was prepared by Mr. Tillotson and tabled to Dr. Wallroth and to the Technical Secretariat. It was agreed to distribute this draft document before the Nuremberg meeting in September and before presentation to the plenary in November.
Confirmed at stage 2
Revision 7

Meeting of NBR Group, Nuremberg, September 27 & 28, 1999:
The revised NB-MED Recommendation was tabled and discussed (see document NBRG/144/99).
It was agreed to accept this recommendations without any changes changes as stage 3 document.
The revised document, with its "Rationale and history" sheet will be disseminated to all member of NB-MED a.s.a.p. with the request to fit the document in the current booklet of NB-MED recommendations.
Confirmed at stage 3
Revision 7

Rev 8: Notified Body Meeting, Brussels, June 8 & 9, 1999:
Mr. Ruys/KEMA introduced document NBM/134/99. This inquiry with regard to "Labelling - Systems and procedure packs" (please look to NBM/134/99) describes - in spite of the NB-MED Recommendation on "No 2.5.5/Rec2 "Combination of CE-marked and non-CE-marked medical devices and non-medical devices" - some problems with the labelling of such combinations of devices. In the inquiry four possible product combinations were indicated, which may or may not be handled according Article 12, MDD. Due to the very complicated subject and the different described cases Mr. Ruys was asked to bring all within the discussion made answers/opinions (see minutes of that meeting NBM/82/99) together in a document prepared in the format of a matrix - supported by the **NBRG** - for presentation to one of the next NB-MED meetings.

Notified Body Meeting, Brussels, November 7 & 8, 2000:
Mr. Ruys explained that he has elaborated together with Mr. Roelofs-Heyrmans a draft document what will be discussed during the meeting of the NBRG this week (see document NBRG/226/00). Mr. Virefléau recommended to consider in this context the already existing NB-MED Recommendation 2.5.5/Rec2 „Combination of CE-marked and non-CE-marked medical devices and non-medical devices".

Meeting of NBR Group, Brussels, November 9, 2000:
The tabled document NBRG/226/00 made by Mr. Ruys and Mr. Roelofs-Heyrmans was discussed. This document explained that all four possible product combinations - as indicated in the above mentioned inquiry NBM/134/99 - have to be handled as described in Article 12, MDD. Therefore NBRG agreed to consider these toughts also within the already existing NB-MED Recommendation 2.5.5/Rec2. A small group (Dalgetty, Dr. Holland and

Dr. Wallroth) discussed only to add the following note under the matrix within this Recommendation: "*Systems and procedure packs subject to Article 12 are also required to conform to requirements of Annex I.13 with regard to information and labelling of such combination.*" The revised NB-MED Recommendation should be sent a.s.a.p. to the members of **NBRG asking for written approval**. Then the document, as revised, should be presented for adoption at the March 2001 NB-MED Plenary meeting.
Confirmed at stage 1
Revision 8

Rev 9: Consideration of comments made by the NBRG/Technical Secretariat (deadline January 12th, 2001):
With letter sent to NBRG - dated on 14.12.2000 - the members of NBRG were asked to give written approval or comments to the revised draft Recommendation (see document NBRG/236/00). The approval was given and one editorial comment was made to add in the list of keywors "labelling of combinations".
The document will be sent to NB-MED for adoption at the March 2001 Plenary meeting.
Confirmed at stage 1
Revision 9

Notified Body Meeting, Brussels, March 6 & 7, 2001:
Dr. Holland reported that the current and valid/accepted stage 4 document (see NBM/95/00 and NBM/95/00 rev. 1) was in the meanwhile revised by the NBRG (see EOTC–letter M1 Mail 02). Dr. Wallroth/EUROM VI explained that on page 4 a note was added ("Systems and procedure packs subject to Article 12 are also required to conform to requirements of Annex I.13 with regard to information and labelling of such combination"). This note was added in response to the older inquiry NBM/134/99 „Labelling – Systems and procedure packs" (see rationale and history sheet).
The revised document, with its "Rationale and history" sheet will be disseminated to all member of NB-MED a.s.a.p. with the request to fit the document in the current booklet of NB-MED recommendations.
Confirmed at stage 3

Members of ad-hoc group „Combination of CE-marked/non-CE-marked medical devices“

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Prof. Horst Frankenberger/EUROM VI (FH Lübeck)
Dr. Peter Gebhardt/EUROM VI (Dräger)
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Dr. Bernhard Lehmann/COCIR (Philips)
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Dr. Arne Hensten-Petterson/NIOM
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