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|  | <p align="center"><b>Co-ordination of<br/>Notified Bodies Medical Devices<br/>(NB-MED)</b><br/>on Council Directives 90/385/EEC,<br/>93/42/EEC and 98/79/EC</p> | <p align="center"><b>Recommendation</b><br/><br/><b>NB-MED/2.1/Rec4</b></p> |
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|                 |                                                              |
|-----------------|--------------------------------------------------------------|
| <b>Title:</b>   | <b>Medical devices with a measuring function</b>             |
| <b>Chapter:</b> | <b>2.1 Scope, field of application, explanation of terms</b> |

|                   |                                      |
|-------------------|--------------------------------------|
| <b>Text:</b>      | “ ... ”                              |
| <b>Key words:</b> | <b>measuring, measuring function</b> |

### The NB-MED Recommendation

#### **NB-MED/2.1/Rec4 *Medical devices with a measuring function***

(stage 3, Rev.-Nr. 6, Rev. date 10.06.98)

**was superseded by**

**the MedDev-document**

#### **MedDev 2.1/5 *Medical devices with a measuring function***

(June 98,  
distributed to NB-MED as **NBM/39/99**)

(reasons see also attached *Rationale and history sheet*)

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

| <b>Reference to Directives:</b> | <b>Article/ Annex:</b>   | <b>Reference to standards:</b> |
|---------------------------------|--------------------------|--------------------------------|
| AIMD                            |                          |                                |
| MDD                             | Annex: I, IV, V, VI, VII |                                |
| IVD                             |                          |                                |

| <b>Stage</b> | <b>proposed by</b> | <b>Rev.-Nr.</b> | <b>Rev. date</b> | <b>accepted</b> | <b>amended</b> | <b>withdrawn</b> | <b>Page</b> |
|--------------|--------------------|-----------------|------------------|-----------------|----------------|------------------|-------------|
| <b>5</b>     |                    | <b>7</b>        | <b>10.06.98</b>  | <b>10.06.98</b> |                |                  | <b>1/1</b>  |

**VdTÜV**

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

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

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



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| <p><b>Title:</b></p>                                                              | <p><b>Medical devices with a measuring function</b></p>                                                                                                                      |                                                                                          |

## **Background**

~~Annex VII, paragraph 5 requires for class I devices with a measuring function that the manufacturer must also follow one of the procedures referred to in annex IV, V or VI, for “the aspects of manufacture concerned with the conformity of the products with the metrological requirements”.~~

~~It is therefore necessary to specify criteria for the existence of a “measuring function” in a medical device.~~

## **Criteria for devices with a measuring function**

~~The following criteria, if fulfilled together, indicate that a device has a measuring function:~~

### ~~a) The device is intended by the manufacturer to measure:~~

- ~~— quantitatively a physiological or anatomical parameter, or~~
- ~~— a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body.~~

### ~~b) The result of the measurement:~~

- ~~— is displayed in legal units or other acceptable units within the meaning of Directive 80/181/EEC<sup>1</sup> or~~
- ~~— is compared to at least one point of reference indicated in legal units or other acceptable units in compliance with the pre-mentioned directive.~~

### ~~c) The intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient’s health and safety.~~

~~**Note 1:** The expression “claimed implicitly” covers cases where the user, on the basis of the designation of the device or of its accompanying documents, or on the basis of the common use is entitled to expect accuracy where the accuracy of the measurement has an impact on the diagnosis or therapy of the patient.~~

<sup>1</sup> OJ n° L 39/40, 15.2.1980 as amended by Directive 89/617/EEC, OJ n° L 357/28, 7.12.1989

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| <p>Title:</p>                                                                     | <p><b>Medical devices with a measuring function</b></p>                                                                                                               |                                                                                          |

~~**Note 2:** Measuring activities during the manufacturing process including those for calibration purposes are not covered by this recommendation and do not imply a measuring function of the manufactured device.~~

### ~~**Examples for class I devices with a measuring function**~~

- ~~— device for measuring body temperature,~~
- ~~— pacifier which includes a temperature display including those with only a change of colour where criteria b) is met,~~
- ~~— device for indicating that a body temperature is above or below a specified value,~~
- ~~— non active non invasive device for measuring blood pressure,~~
- ~~— non active device for measuring intra ocular pressure,~~
- ~~— device for measuring volume or pressure or flow of liquid or gases delivered to or removed from the human body (included any container with a graduation scale or with a single point graduation, where criteria c) is met).~~

### ~~**Examples for class I devices without a measuring function**~~

- ~~— patch for indicating trends of body temperature (where criteria b) is not met),~~
- ~~— device for the delivery of liquid to the human body (e.g. medicine spoons, cups, droppers, without graduation or scale or display of measuring unit),~~
- ~~— device for displaying trends of physiological parameters (e.g. urine bags without graduation or scale, callipers for obesity),~~
- ~~— eye test chart.~~

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| <p><b>Title:</b></p>                                                              | <p><b>Medical devices with a measuring function</b></p>                                                                                                                      |                                                                                                             |

**Rev. 3:** Notified Body Meeting, Brussels, June. 24 & 25. 1997:

The draft document „Medical devices with a measuring function“ was revised on 09.04.97; the comments from the NB-MED plenary meeting on 04./05.02.97 and the comments from the Medical Device Experts Group have been discussed. This document was prepared by NB-MED **ad-hoc Group „MD with a measuring function“** (Convenor: Mr Robert Virefleau/EC; Members: Mr Freeman/CEN, Dr. Rader/TÜV Product Service, Dr. Wallroth/EUROM VI). The document was tabled on the Notified Body Meeting on 24./25.06.97. The document was approved by the NB-MED plenary.

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

The NBRG has brought the document into the format of a NB-MED recommendation and issued it among their „stage 3“-recommendations.  
Confirmed at stage 3.  
New revision no: 3

**Rev. 4:** Medical Devices Expert Group Meeting, Brussels, July 10, 1997:

The stage 3 document „Medical devices with a measuring function“ was presented to the Medical Devices Experts Group and accepted with minor changes:

- criteria a) read: “quantitatively a physiological or anatomical parameter, or“
- list of positive examples, read: “ ... non-active device for measuring intra-ocular pressure,“
- list of negative examples, read: “ ... (e.g. urine bags without graduation or scale, ...)

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

The NBRG reworked the document and considered the above mentioned changes. It was decided to fit the document in the new *recommendations nomenclature system* (chapter 2.1 *Scope, field of application, explanation of terms*). Therefore the recommendation gets the number **NB-MED/2.1/R4**. The document (with its "Rationale and history") sheet should be tabled on the Notified Body Meeting on 18./19.11.97.  
Confirmed at stage 4.  
New revision no: 4

| Rev.-Nr. | Rev. date | accepted | amended | withdrawn |
|----------|-----------|----------|---------|-----------|
|          | 10.06.98  |          |         |           |

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**Rev. 5:** Medical Devices Expert Group Meeting, Brussels, February 9/10, 1998:

The stage 4 document „Medical devices with a measuring function“ was presented to the Medical Devices Experts Group but was not fully accepted; the following comments were made (see NB-MED/2.1/R4):

page 1, 1st paragraph: delete „meteorological“, insert „metrological“  
French comment: would like to add positive examples for anatomical parameter  
page 2, last insert: „device for measuring volume or pressure or flow of liquid ...“  
paragraph:  
German comment: would like to send a proposal for modifying the expression „... without graduation or scale“ (see page 3)

After considering the French and German comments including a earlier statement made by EMIG the document will become a MEDDEV.

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

The NBRG reworked the document (above mentioned editorials) and made the clarification under c):

*„c) the intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in an significant adverse effect the patient's health and safety.“*

Also the note 2 was modified by deleting the example:

*„Note 1: The expression “claimed implicitly” covers cases where the user, on the basis of the designation of the device or of its accompanying documents, or on the basis of the common use is entitled to expect accuracy ~~(examples: a device designated with the use of the suffix “-meter” or a device~~ where the accuracy of the measurement has an impact on the diagnosis or therapy of the patient).“*

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: 5

**Rev. 6:** Notified Body Meeting, Brussels, June 09 & 10, 1998:

The document was tabled on the Notified Body Meeting on 09./10.06.98. One modification was made in the paragraph for *Examples for class I devices with a measuring function*:

- device for measuring volume or pressure or flow of liquid or gases delivered to or removed from the human body (included any container with a graduation scale or with a single point graduation, where criteria c) is met)

Confirmed at stage 3

New revision no: 6

**Rev. 7:** Notified Body Meeting, Brussels, November 3 & 4, 1998:

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**MedDev:** The new MedDev document was tabled to the NB-MED as NBM/148/98. Only slight editorial changes were made due to discussions within the Medical Devices Experts Group. NB-MED agreed to supersede the old NB-MED Recommendation NB-MED/2.1/Rec 4 by this MedDev document MedDev 2.1/5 (issued June 98).

Confirmed at stage 5 (NB-MED took note of this new stage)

New revision no: 7



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