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| 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**<br><br>**NB-MED/2.1/Rec2** |

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| **Title:** | **Explanation of Terms** |
| **Chapter:** | **2.1 Scope, field of application, explanation of terms** |

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| **Text:** | **---** |
| **Key words:** | **product, device, range, category** |

**Explanation of Terms** (used in the directives)

1.0 Product / device (medical device and/or medical device accessory)

An article or articles manufactured to a defined specification and labelled for a specific intended use.

The definition of medical device is given in MDD, article 1.

In MDD “product“ is also used to indicate individual items instead of “type“ (as this term is used in MDD).

2.0 Product Category (medical device group)

Products or product and any accessories needed for their proper use which have common attributes of technology and application.

This term must be regarded as being the best equivalence to the terms “medical device group“ used in prENV 12611:1996 and “generic device group“ used in prEN 1874.

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

| **Reference to Directives:** | **Article/ Annex:** | **Reference to standards:** |
|---|---|---|
| AIMD | Annex: 2-3.1, 2-3.2, 2-3.3, 2-3.4 | |
| MDD | Annex: II-3.1, II-3.2, II-3.3, II-3.4 | prEN 1874; prENV 12611:1996 |
| IVD | Annex: 4-3.1, 4-3.2, 4-3.3, 4-3.4, 7-3.1 | |

| Stage | proposed by | Rev.-Nr. | Rev. date | accepted | amended | withdrawn | Page |
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| 4 | | 5 | 17.04.97 | 09.02.98 | | | 1/2 |

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3.0 Product Range

Different products or product categories, marketed by the same manufacturer under the directives.

This term is not equivalent with the term “device category“ used in prEN 1874.

The term “product range“ is not used in prEN 1874.

Note 1: The term “product family“ is sometimes used to describe products (above) which may differ in visible dimensions and/or have a number of intended end uses created by parameters set during manufacture. This term is not used in any of the directives.

Note 2: In MDD, the term “product“ is used equivalent with the term “device“.

See also: draft standard prEN 1874 on nomenclature, especially note 1 on page 7 and prENV 12611:1996 Medical informatics - Catagorical structure of systems of concepts - Medical Devices.

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| 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/2.1/Rec2** |

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| **Title:** | **Explanation of Terms** |

**Rationale**

This document is developed in order to explain terms used in the medical device directives.

**History**

**Rev 3:** Meeting of NBR Group, Brussels, June 21
Changes agreed:
Add: “prEN Nomenclature“ instead of “draft standard on nomenclature“
Add: stage 1 - change to stage 2 via mail ballot
New revision no: 3

**Rev 4:** Meeting of NBR Group, Brussels, Sept. 4, 1996:
Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, Sept. 24 & 25. 1996:
The Notified Bodies expressed the need of this paper until the time the nomenclature system is ready even if the aim is different (one is conformity assessment and the other is exchange of data). It was decided **to give back this document to the task force** and to bring it in line and make the connections with the definitions of the nomenclature system.

Meeting of NBR Group, Brussels, Nov. 7, 1996:
VD will revise wording by harmonizing it with prEN nomenclature including
2.0 product family: delete: "end"
3.0 product category: add: attributes of technologies **of application**

Meeting of NBR Group, Cologne, Jan. 20 & 21. 1997:
It was decided to concentrate on the terms used in the directives. i.e. product/device, product category an product range. The term "product family" is not used in the directives and was moved to a note. The text was revised in light of the written comments received. All the comments were regarded to have been properly addressed. NBRG agreed to send the revised document, with its "Rationale and history" sheet to all the member of NBM Plenary for commenting before presenting it for approval.
New revision no: 4

**Rev 5:** Meeting of NBR Group, Essen, April 03. & 04. 1997:
A proposal from EUCOMED with regard to the standards prENV 12611:1996 and prEN 1874 was tabled. It was decided to include this changes.
It was decided to change the title to “Explanation of Terms“ and to do some minor additions. NBRG agreed to send the revised document, with its "Rationale




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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: 5
Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, June. 24 & 25. 1997:
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 2.1 *Scope, field of application, explanation of terms*). Therefore the recommendation gets the new number **NB-MED/2.1/R2**. The old number will be retained for a transitional period.

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.