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/2.7/Rec1**

Title:	**Guidance on clinicals**
Chapter:	**2.7 Clinical investigations, clinical evaluation**

Key words:	**Guidance on when a clinical investigation is needed for CE marking**
Key words:	**Clinicals**

The purpose of clinical data is to provide **clinical evidence** of the compliance with the essential requirements.

I Definitions

Clinical investigations

Any specific study in human subjects undertaken to verify the safety and performance of a specific medial device under normal conditions of use (from EN 540).

Safety

Freedom of unacceptable risk of harm (from EN 1441 "Risk Analysis")

Also relevant is:

The devices which must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended by the manufacturer, they will not compromise the clinical condition or the safety of patients, or the safety an health of users or, where applicable, other persons, provided that any risks which my be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety (annex 1.1. MDD).

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 7	EN 540
MDD	Annex: X-1.1	EN 540
IVDD		

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Performance

The action of a specific medical device with reference to its use as intended by the manufacturer when correctly applied to appropriate subjects (from EN 540).

Clinical evidence

Clinical evidence is gained when a qualified expert is able to conclude that the examined medical device complies to the following requirements.

1. when, used under the conditions and for the purposes intended by the manufacturer, the performances of the device comply with those indicated in par. 2 of Annex 1 (AIMD Directive) or par. 3 of Annex 1 (MD Directive).

2. undesirable side effects, under normal conditions of use, are acceptable when weighed against the benefits to the patient.

II Need to perform clinical investigation.

The need to perform clinical investigation results from the following considerations:

- Clinical evidence shall be obtained in all cases.

- Clinical evidence can be demonstrated on the assessment of pertinent literature, relevant data the result of clinical investigation or any combination of these.

- Unless safety and performance can be adequately demonstrated in other ways (e.g. convincing experience from previous use), clinical investigation of a medical device is likely to be required in particular in the following circumstances:

  1. Where a completely new device is proposed for the market, whose components, features and / or method of action are previously unknown;

     or

  2. Where an existing device is modified and the modification might significantly affect the clinical safety and performance;

     or

  3. Where a previously established device is proposed for a new indication:

or

4. Where a device incorporates new materials, previously unknown, coming into contact with the human body or existing materials applied in a location not previously exposed so that material, and for which there is no convincing prior clinical experience, or that the device will be used for a significantly longer time.

	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/2.7/Rec1**
Title:	**Guidance on clinicals**	

Rev. 1: The subject has come up in the NB-MED meeting years ago, based on the "old" draft NB-MED recommendation 4.2.4b *Guidance on clinicals*. It was accepted at the NB-MED meeting on 17.01.96. Also the stage 3 was confirmed during the process of development NB-MED recommendations.

Rev. 2: Medical Devices Expert Group Meeting, Brussels, February 9/10, 1998:
The stage 3 document was presented to the Medical Devices Experts Group but not accepted. The NB-MED was asked to rework the document considering a wide range of proposed changes, especially the NB-MED task force on „Evaluation of clinical data". One document should represent all aspects of clinical investigation, clinical evaluation and clinical data.

Meeting of NBR Group, Brussels, April 20 & 21, 1998:
Under consideration that the NB-MED task force on „Evaluation of clinical data" will deal with this matter only one minor (editorial) change was agreed (instead prEN 1441: EN 1441).
On occasion of the next NB-MED meeting on June the NB-MED task force on „Evaluation of clinical data" will present the forthcoming work on this subject.
Confirmed at stage 3
New revision no: 2

Notified Body Meeting, Brussels, June 9 & 10, 1998:
The NB-MED agreed the minor above mentioned changes; this document will remain a stage 3 document. Further development will take place in the Medical Devices Experts Group. This document will be merged with the coming document with regard to „clinical data" (separate **Task Force „Evaluation of clinical data"**).
Confirmed at stage 3

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