	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/2.5.2/Rec3**

Title:	**Translation procedure**
Chapter:	**2.5.2** Conformity assessment procedures; **Quality assurance**

Text:	**"Translation of information provided by the manufacturer."**
Key words:	**translation, labelling, instructions for use**

Translation procedures

As part of the quality system or of the documents defining the manufacturing process, the manufacturer should have procedures for ensuring accurate translation of e.g. labelling, instructions for use and product claims in marketing material.

These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation.

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 2, 4, 5	
MDD	Annex: II, IV, V, VI	
IVDD	Annex: IV, VII	

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3		9	03.02.2000	29.02.2000			1/1

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Rev. 7: Notified Body Meeting, Brussels, September 24 & 25. 1996:
It was decided to give back this document (rev 6) to the task force for drafting a new proposal. The following points will be considered:
- to change the word "advisable" into "necessary".
- The last sentence should be clearer or deleted.
- The sentence "The manufacturer ... procedures for ensuring accurate translations" was contested by the industrial federations since the requirement of translation is part of a national law and is not a requirement from the notified bodies. Norbert Anselmann should favorise an approach where the manufacturer takes on board sufficient responsibility with regard to other languages. Johann Rader stated that the manufacturer who wishes to bring the product on the market with relevant community languages should have appropriate measures to verify that those languages are correct.

Revision no: 7

Rev. 8: Meeting of NBR Group, Essen, September 29 & 30 1997:
The above mentioned thoughts were considered and a easily changed text was elaborated. The words "it is necessary" were deleted.
It was decided to fit the document in the new *recommendations nomenclature system* (chapter **2.5.2** *Conformity assessment procedures;* ***Quality assurance***). Therefore the recommendation gets the new number **NB-MED/2.5.2/R3**. The old number will be retained for a transitional period. 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 November 1997.
Revision no: 8
Confirmed to be at stage: 2

Notified Body Meeting, Brussels, November 18 & 19, 1997:
Confirmed to be at Stage: 3

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.

Rev. 9: Notified Body Meeting, Brussels, November, 2 & 3, 1999:
The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive.

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Meeting of NBR Group, Cologne, February 3, 2000:
The work results of a small task force (task: reworking the Recommendations) were presented to that NBRG-meeting.
The tabled revised Recommendation was discussed and NBRG agreed that the document, as discussed and revised, should be presented for adoption at the February/March NB-MED Plenary meeting. Only some editorial changes were made.
Revision no: 4
stage 2

Notified Body Meeting, Brussels, February 29 & March 1, 2000:
The document (NBM/38/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 9