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/2.1/Rec1**

Title:	**Representative Sample**
Chapter:	**2.1 Scope, field of application, explanation of terms**

Text:	**---**
Key words:	**sample**

A "representative sample" of production for EC type examination is any one product manufactured according to the documentation delivered.

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 3-1	
MDD	Annex: III-1	
IVDD	Annex: V-1, VI-1, VI-4	prENxxx *"Sampling procedures used for acceptance testing of in vitro diagnostic medical devices"*

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3		4	03.02.2000	06.06.2000			1/1

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

Hermann Dinkler (-187)
Kurfürstenstraße 56
D-45138 Essen

Phone: ++49/201/8987- 0
Fax: ++49/201/8987- 120
eMail: hermann.dinkler@ vdtuev.de

Rev. 2: Notified Body Meeting, Brussels, September. 24 & 25. 1996:
The document was approved by the NB-MED plenary.
Confirmed at stage 3.
New revision no: 2

Rev. 3: Meeting of NBR Group, Brussels, November 7, 1996:
The NBRG has brought the document into the format of a NB-MED recommendation and issued it among their „stage 3"-recommendations. Some minor changes were done.
Confirmed at stage 3.
New revision no: 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. 4: Notified Body Meeting, Brussels, November, 2 & 3, 1999:
The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive.

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:
Dr. Holland reported that the current and valid/accepted stage 4 document (see NBM/123/99) was in the meanwhile revised by the NBRG/IVD task force (see NBM/35/00). Changes were made in light of the IVDD. Some comments have arrived and there is a need for incorporation those. The NB-MED agreed that further development on this Recommendation will be made within **NBRG**. A revised draft document should be presented at the next plenary (IVDD) meeting in June. Up to there the already accepted stage 3 document will be kept still valid.
Revision no: 4
stage 2

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

Hermann Dinkler (-187)
Kurfürstenstraße 56
D-45138 Essen

Phone: ++49/201/8987- 0
Fax: ++49/201/8987- 120
eMail: hermann.dinkler@ vdtuev.de

Meeting of NBR Group, Brussels, April 10 &11, 2000:
The document was once again accepted by NBRG in the same form as already presented to the last plenary meeting in March. NBRG agreed that the document, should be presented for adoption at the June NB-MED Plenary meeting.
Revision no: 4
stage 2

Notified Body Meeting, Brussels, June 6 & 7, 2000:
The document (NBM/56/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 4