	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/2.5.4/Rec1**

Title:	**Homogeneous batches**
Chapter:	**2.5.4** Conformity assessment procedures; **Verification of manufactured products**

Text:	**„Homogeneity of production batches“**
Key words:	**samples, statistical control**

„Homogeneity of production batches“

Certain statistical verification procedures are only meaningful when batches, (lots), are homogeneous.

A batch is considered homogeneous when equivalent parts or materials are manufactured and/or tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person, or with the same machine/equipment set-up and fulfil the same specifications.

For IVD's the following complementary definition shall apply: Mixtures of substances such as reagents aliquoted from the same bulk mixture are considered homogeneous if the mixing and aliquoting processes are validated.

Note: In ISO 2859, „lot“ is defined similar to „homogeneous batch“ of this paper.

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 4-2	
MDD	Annex: IV	
IVDD	Annex: VI-2.1, 6.1	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 date	accepted	amended	withdrawn	Page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	29.02.2000			1/1

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

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

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

	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/2.5.4/Rec1**
Title:	**Homogeneous batches**	

Rev. 2: Meeting of NBR Group, Brussels, June 21, 1996:
Changes agreed:
Add definition of batch from EN 1041 per reference.
Add: stage of IVD directive - on all NBM recommendation under references: 'IVD draft + date"
Add: stage 1 - change to stage 2 via mail ballot
New revision no: 2

Rev. 3: Meeting of NBR Group, Brussels, Sept. 4. 1996:
Confirmed at stage 2.

Notified Body Meeting, Brussels, Sept. 24 & 25. 1996:
It was decided **to give back this document to the ad-hoc group** to check with definitions of standards ISO 2859 and EN 1041. It was considered also that electro-medical devices which are not mass- produced can be included. This chapter should be shifted to "definitions" instead of "products". Suggestions and comments could be provided to Mr. Holland with a copy to the Secretariat before 15. October 1996 for circulation to the plenary to be ready for the next ad-hoc meeting on 7. November.

Meeting of NBR Group, Brussels, Nov. 7.1996:
Mr. Ian Dalgetty volunteered to provide information about EN 1041, ISO 2859 and a British standard about this issue, BS 6001.
RV proposed to reword recommendation to show criteria rather than definition. To be re-addressed in the January 1997 meeting including the NBM Plenary proposal to move the recommendation to definitions.

Meeting of NBR Group, Jan. 20. & 21. 1997:
No comments, apart from the information from Mr. Dalgetty, had been received since the NBM in September 1996.
Mr. Dalgetty informed that none of the standards mentioned above includes the term "homogeneous", and that the paragraphs dealing with "lots" or "batches" of EN 1041 and ISO 2859 are closely matched. It was therefore decided to disregard EN 1041, and insert a note regarding ISO 2859. In the text, the word "typically" was moved to underline the point that the production shall be without interruption.
It was noted that the comment on this document from the German Notified Bodies Group EK-Med (see NBM-document NBM/027/95) has been incorporated in the document.
It was agreed that the document are to be send to the NBM Plenary for approval.
New revision no: 3

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

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

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

Notified Body Meeting, Brussels, Febr. 4. & 5. 1997:
Confirmed 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 **2.5.4** *Conformity assessment procedures;* ***Verification of manufactured products***). Therefore the recommendation gets the new number **NB-MED/2.5.4/R1**. 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.

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:
The document (NBM/39/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 4