NB-MED (EUROPEAN CO-ORDINATION, 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/2.5.1/Rec4**

Title:	**Content of mandatory certificates**
Chapter:	**2.5.1** Conformity assessment procedures; **General rules**

Text:	**.....................................**
Key words:	**certificate, certificate of competence,**

Content of mandatory certificates

1. Purpose

The purpose of this recommendation is to provide guidance on the minimum content of mandatory certificates to be issued by the Notified Body (see table 1).

2. Types of certificates

EC certificates **covered** by the directives are the following types of certificates:

- **EC Design-Examination Certificate** (Annex II section 4 MDD; Annex 2 section 4 AIMD)
- **EC Type Examination Certificate** (Annex III MDD; Annex 3 AIMD)
- **Full Quality Assurance System Approval Certificate** (Annex II section 3 MDD; Annex 2 section 3 AIMD)
- **EC Verification Certificate** (Annex IV MDD; Annex 4 AIMD)
- **Production Quality Assurance System Approval Certificate** (Annex V MDD; Annex 5 AIMD)
- **Product Quality Assurance System Approval Certificate** (Annex VI MDD)

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

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	Annex: 2-3, 2-4, 3, 4, 5	
MDD	Annex: II-3, II-4, III, IV, V, VI	
IVDD		

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
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Certificates provided in connection with conformity assessment under the various Annexes of the Directives should have titles which reflect the relevant provisions of the Directives; for example, certificates under MDD, Annex II.4 should be titled „EC design-examination certificate“.

The titles of most of the certificates are regulated in the relevant annexes of the Directives. The titles of all certificates should include the words „EC CERTIFICATE“.

Table 1: Information about the minimum content of mandatory certificates

Content / Type of certificate	II, 4 / 2, 4 [1]	III / 3 [2]	II, 3 / 2, 3 [3]	IV / 4 [4,7]	V / 5 [5,7,8]	VI [6,7]
Number of certificate [9]	+	+	+	+	+	+
Date of issue [10]	+	+	+	+	+	+
Date of the end of validity [11]	+	+	+	o	o	o
Title [12]	+	+	+	+	+	+
Main text:						
- reference to national regulations [13]	o	o	o	o	o	o
- text [14]	+	+	+	+	+	+
Reference to NB file number [15]	+	+	+	+	+	+
Manufacturer:						
- Name	+	+	+	+	+	+
- Address	+	+	+	+	+	+
Representatives [16]:						
- Name	o	o	o	o	o	o
- Address	o	o	o	o	o	o
Device concerned [17]:						
a) - Name of product category [18]	+	+	+	+	+	+
- Nomenclature code [18]	o	o	o	o	o	o
b) - Name/Identification of the model/type	+	+	o[19]	+	o[19]	o[19]
c) - Series or batch number	-	-	-	+	-	-
Scope of quality system [20]	-	-	+	-	+	+
Specific conditions of validity if any	o	o	o	o	o	o
Notified Body:						
- Authorised signature	+	+	+	+	+	+
- notified to EC under number	+	+	+	+	+	+
- Name and address	o	o	o	o	o	o
- Tel./Fax-No.	o	o	o	o	o	o
Identification of change [21]: - issued - modified - refused - withdrawn - extended - renewal	o	o	o	o	o	o

explanation of footnotes see next page

+ required
o optional
- not required

Note: The matter of **interlinking of certificates** has been considered and is recognised to be an administrative responsibility of the NB and should be traceable through the file of the NB. Inclusion of an cross-reference on the certificates themselves, however, would lead to practical difficulties.

Explanation of footnotes:

1 **EC DESIGN-EXAMINATION CERTIFICATE** (Annex II section 4 of the Directive 93/42/EEC, MDD; Annex 2 section 4 of the Directive 90/385/EEC, AIMD)

2 **EC TYPE EXAMINATION CERTIFICATE** (Annex III MDD; Annex 3 AIMD)

3 **FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE** (Annex II section 3 MDD; Annex 2 section 3 AIMD)

4 **EC VERIFICATION CERTIFICATE** (Annex IV MDD; Annex 4 AIMD)

5 **PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE** (Annex V MDD; Annex 5 AIMD)

6 **PRODUCT QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE** (Annex VI MDD)

7 For products of class I with a measuring function, a certificate is required in accordance with annex IV, V or VI concerning the aspects of manufacture concerned with conformity with the metrological requirements

8 For products of class I, sterile, a certificate is required, which covers only the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with annex V (see annex VII, 5, first indent)

9 unique inside Notified Bodies

10 No format is prescribed for how the data is to appear on the certificate. To include the footnote: „*The validity of the certificate starts at the date of issue, unless an explicit statement is made to the contrary*.“ For later entering into Database EUDAMED (<u>Eu</u>ropean <u>Da</u>ta Exchange for <u>Me</u>dical <u>D</u>evices): a format will be prescribed

11 see: Date of issue; end is limited. Proposal for text*: „This certificate is valid for x years from the date of issue“.* For annex II and III maximum validity 5 years (comment/recommendation: required and desirable for all certificates)

12 necessary for identification of the type of certificate (i.e. conformity assessment procedure under which issued in the case of certificates covered by the Directive <u>or</u> purpose of certificates where supported by the Directives)

13 use text such as: „*MDD ... as transposed into national legislation*.“

14 text samples relating to the different certificates see on <u>table 2</u> (text is not prescribed)

15 any reference to underlying documents; does not go to EUDAMED

16 if applicable; could be e.g. authorised representative, responsible representative

17 either a) or b) ; c) limited to annex IV

18 UMDNS term when available

19 one of the following alternatives shall be taken: a) model numbers directly on the certificate or on an annex to the certificate; b) list of models in the files of the Notified Body with link via the NB file reference; c) all declarations of conformity in the hands of the Notified Body. Aim: to show clearly if a particular product is covered by the NB approval to which the certificate relates.

20 Scope of quality system in terms of , for example, facilities or activities covered

21 In case of change of the design the use of an **addendum** is an option, but not mandatory. Where issued, the addendum should (a) include the note: *„This addendum is only valid if attached to the certificate mentioned above.“* and (b) make clear the change to which it relates.

Table 2: Text samples relating to the different certificates which are covered by the MDD/AIMD (text is not prescribed)

Type of certificate	<u>**examples**</u> for: **Title / Main text**
II, 4 / 2, 4	**EC DESIGN-EXAMINATION CERTIFICATE** (Annex II section 4 of the Directive 93/42/EEC on Medical Devices) We hereby declare that a design examination has been carried out on the device(s) listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing annex II section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of annex II section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.
III / 3	**EC TYPE EXAMINATION CERTIFICATE** (Annex III of the Directive 93/42/EEC on Medical Devices) We hereby declare that a design examination has been carried out on the device(s) listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing annex III of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) conforms with the relevant provisions of the aforementioned directive.
II, 3 / 2, 3	**EC CERTIFICATE** **FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE** (Annex II of the Directive 93/42/EEC on Medical Devices) We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.
IV / 4	**EC VERIFICATION CERTIFICATE** (Annex IV of the Directive 93/42/EEC on Medical Devices) We hereby declare that a EC verification has been carried out on the series or batch of device(s) listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing annex IV of the Directive 93/42/EEC on medical devices. We certify that the device(s) hereafter referenced conform with the relevant provisions of the aforementioned legislation.
V / 5	**EC CERTIFICATE** **PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE** (Annex V of the Directive 93/42/EEC on Medical Devices) We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Continuation see next page

Table 2 (continuation)**:** **Text samples relating to the different certificates which are covered by the MDD/AIMD** **(text is not prescribed)**

Type of certificate	**examples** for: **Title** / **Main text**
VI	**EC CERTIFICATE** **PRODUCT QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE** (Annex VI of the Directive 93/42/EEC on Medical Devices) We hereby declare that an examination of the under mentioned product quality system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing annex VI of the Directive 93/42/EEC on medical devices. We certify that the product quality system conforms with the relevant provisions of the aforementioned legislation .

Rev. 1: Notified Body Meeting, Brussels, April 29 & 30, 1996:
EUROMCONTACT presented a proposal for a certificate of compliance with specific requirements of a contact lens manufacturer and evidence of conformity with the EN 46000 series in the case of a supplier of contact lens blanks. While not mandatory under Directive 93/42/EEC the proposal was accepted subject to modification to ensure purpose of the contact lens blanks, is included in the certificate.

Notified Body Meeting, Brussels, February 4 & 5, 1997:
The "certification" of subcontractors (sterilisation) was discussed. The question was also addressed in the document NBM/13/97. The MDD, Article 11, paragraph 7 provided the possibility for having to take account of qualification measures in an intermediate stage of production in the conformity assessment procedure. One possibility for qualification was certification to ISO 9001/2 or 46001/2. After a successful certification, a "certificate of competence" could be issued. Mr **Mestmacher**/RWTÜV agreed to send the Commission the certificate he used. The Commission declared its willingness to develop a uniform sample (see also item 8.2).

Notified Body Meeting, Brussels, November 18 & 19, 1997:
The Commission proposed and explained the draft document „samples of certificates“ (document NBM/108/97). This samples should harmonise the certificates which are made by the Notified Bodies because it was obvious that there are a lot of certificates with many different contents and it was not ever clear whether these contents were in full compliance with the requirements of the directives. The document should become the status of a MEDDEV-document or before of a NB-MED recommendation. NBRG should make further development of this document.

Meeting of NBR Group, Brussels, January 22 & 23, 1998:
The structure of a NB-MED recommendation „Contents of certificates“ was elaborated. Both types of certificates - those which covered by the Directives (as mandatory) and those which are supported by the directive (as optional) - should be considered in this recommendation. The Technical Secretariat was asked to carry together all thoughts and to bring this in an appropriate form; so this should be presented to the Medical Devices Experts Group on their meeting on 09./10.02.98.

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Notified Body Meeting, Brussels, March 3 & 4, 1998:
Mrs. O'Connell reported that the draft NB-MED recommendation „Contents of certificates“ (document NBM/17/98) was also presented to the Medical Devices Experts Group meeting in February. The Medical Devices Experts Group has received some comments of the member states concerning the Commission's proposal; most of them wish a harmonisation of the content of certificates, some see the need for consideration of the class of the device on the certificates. No consensus in the Medical Devices Experts Group has been achieved. The NB-MED agreed that the samples of certificates should define the minimum that should appear on the certificates; the legal is the basis for the given details but everybody is free to add more details. After consideration and discussion within NBRG **the Commission** should inform the Medical Devices Experts Group about the result of this discussion.

Meeting of NBR Group, Brussels, April 20 & 21, 1998:
The draft NB-MED recommendation was finalised. It was decided to fit the document in the *recommendations nomenclature system* (chapter **2.5.1** *Conformity assessment procedures;* ***General rules***). Therefore the recommendation gets the number **NB-MED/2.5.1/Rec4**. NBRG agreed to send the revised 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 June 1998.
Revision no: 1
Confirmed to be at Stage: 2

Rev. 2: Notified Body Meeting, Brussels, June 9 & 10, 1998:
NB-MED discussed the draft NB-MED recommendation NB-MED/2.5.1/Rec4 „Content of certificates“ (document NBM/95/98) especially the principle of the minimum content and the both kinds of certificates (required/only supported by the directives). Mr. Lally/BSI reported about a meeting within the UK Notified Bodies and it was the common position to reject this particular document in its current from. Some aspects are too prescribed and on the other hand the table 3 relating to voluntary certificates delivered at an intermediate stage of manufacture is not supported at all, because it is not an absolute part of the remit of the Notified Bodies to undertake certification of work outside the directive. They may do it but not by influence as part of the role as a Notified Body. This opinion covers also the opinion of the MDA. Mr. Lally, Mr. Jepson/SGS. and Mr. Ruys/KEMA promised to send their comments directly to the NBRG. NBRG was asked to finalise the draft recommendation on their meeting on 11./12.06.98.
Confirmed to be at Stage: 1

Meeting of NBR Group, Brussels, June 11 & 12, 1998:
NBRG discussed the results of the NB-MED plenary meeting on 09./10.06.98. Mr. Ruys, Mr. Lally and Mr. Jepson/ submitted written comments and suggestions to the effect that:
- the sample of a certificate at an intermediate stage of manufacturing should be separated from this recommendation as it is voluntary form of certification and not mandatory under the Directives.
- various editorial suggestions for improvement of the contents of the mandatory certificate.

NBRG considered these comments and suggestions, adopted the main points of principle and introduced **two separate NB-MED recommendations**:
- NB-MED/2.5.1/Rec4 „Content of mandatory certificates“
- NB-MED/2.15/Rec1 „Certification at an intermediate stage of manufacture“.

NBRG noted that while the MDD, Article 11 (7) [and IVD-Directive, Article 9 (5)] makes reference to such certification, this is not the case for the AIMD but manufacturers regulated by this Directive see a clear requirement for such certification in their case.
NBRG agreed to send **both** revised documents, with the belonging "Rationale and history" sheets to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1998.
Revision no: 2 (NB-MED/2.5.1/Rec4 „Content of mandatory certificates“)
(Revision no: 1 (NB-MED/2.15/Rec1 „Certification at an intermediate stage of manufacture“))
Confirmed to be at Stage: 2

Rev. 3: Meeting of NBR Group, Lübeck, August 31 & September 1, 1998:
NBRG made some minor editorial changes and agreed to delete the former sample for a design examination certificate.
NBRG agreed to send the revised document, with the belonging "Rationale and history" sheets to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1998.
Revision no: 3
Confirmed to be at Stage: 2

Rev. 4: Notified Body Meeting, Brussels, November 3 & 4, 1998:
NB-MED accepted the tabled document with a editorial change. The document was confirmed to be at stage 3, the rationale and history sheet will be changed subsequently. It will be incorporated in the booklet of NB-MED recommendations and will be also presented to the Medical Devices Experts Group.
Revision no: 4
Confirmed to be at Stage: 3