applicable for ☒ AIMDD, ☒ MDD, and ☒ IVDD

2010-3

Certificates issued by Notified Bodies with reference to Council Directives

- **93/42/EEC on medical devices (MDD)**
- **98/79/EC on in vitro diagnostic medical devices (IVDD)**
- **90/385/EEC on active implantable medical devices (AIMDD)**

Introduction

Certificates issued by Notified Bodies with reference to the Council Directives 93/42/EEC on medical devices (MDD), 90/385/EEC on active implantable medical devices (AIMDD), both amended by Directive 2007/47/EC, and 98/79/EC on *in vitro* diagnostic medical devices (IVDD) are important documents to all parties involved. The certificates shall clearly and unequivocally show the Directive and Annex against which the Notified Body (NB) assessed the manufacturer and that the manufacturer and/or the devices in question fulfil the requirements given in that Annex and Directive.

To simplify the interpretation and to avoid misunderstandings it is desirable that the certificates are formulated in a similar way.

This document contains recommendations for the following:

- Which certificates a Notified Body may issue.
- Names for the different certificates.
- General comments regarding the certificates.
- Detailed information concerning the contents in the different certificates.

For clarity, the certificates are indicated and arranged alongside the various modules used within the New Approach Directives [1, 2]. Only in special cases, Module A requires the intervention of a Notified Body. Modules C and G are not used within the medical devices directives.

Module A = Internal Control of Production. Covers internal design and production control. Does normally not require a Notified Body to take action. Within medical devices directives, Notified Body action is required for sterile devices and devices with measurement function (compare MDD Annex VII) or *in vitro* diagnostic medical devices for self-testing (compare Annex III (6) IVDD).

Module B = EC type-examination. Covers the design phase, and must be followed up by a module providing for assessment in the production phase. Within the medical devices directives Modules C and G are not applicable.

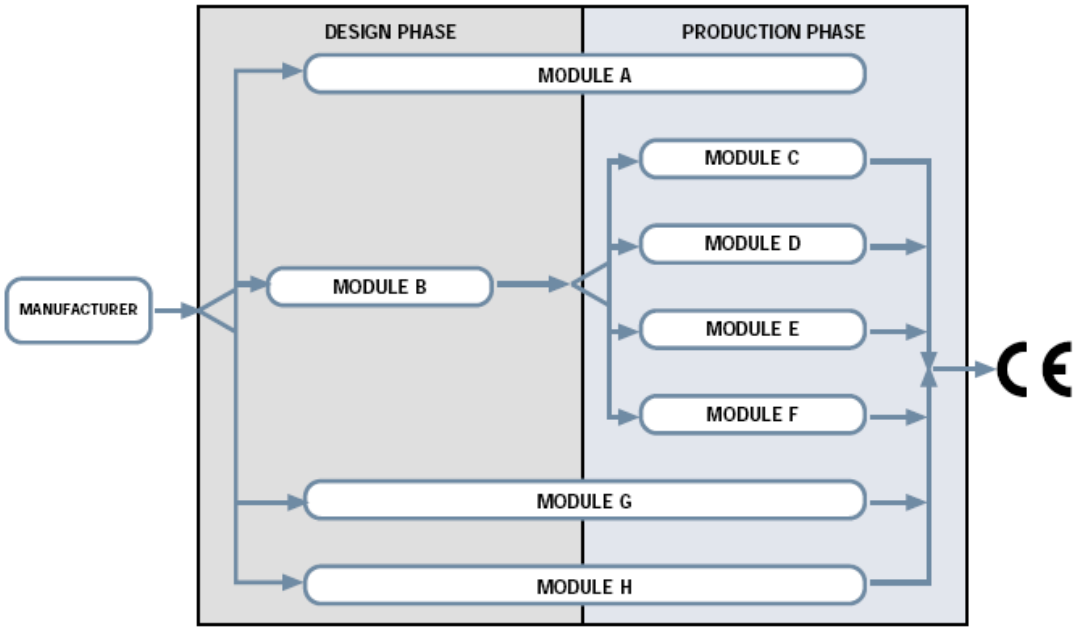

Table 1 Simplified flow chart of conformity assessment procedures (copy from "Guide to the Implementation of Directives Based on New Approach and Global Approach", page 32 [1]), not adapted to the medical device directives

Module D = Production quality assurance. Covers the production phase and is an approval of the quality system for production, final product inspection and testing set up by the manufacturer. Within IVDD also the verification of manufactured products is part of Module D.

Module E = Product quality assurance. Covers the production phase and is an approval of the quality system for final product inspection and testing set up by the manufacturer.

Module F = Product verification. Covers the production phase; verification by examination and testing of every product and also statistical verification are possible.

Module H = Full quality assurance. Covers the design and production phases. Within the medical device directives Module H consists of EC design examination and an approval of the quality system for design, manufacture, final product inspection and testing set up by the manufacturer. Within IVDD also the verification of manufactured products is part of Module H.

Tables 2-4 show all certificates Notified Bodies can issue under the medical devices directives. In the tables a separation is made between product certification activities and quality system assessment activities.

---------- Product certification ---------- ------ Quality system assessment -------

93/42/EEC Medical Devices (MDD)						
Type of certificate ⇨	EC Type-Examination Certificate	Certificate of Conformity	EC Design-Examination Certificate	EC Certificate Full Quality Assurance System	EC Certificate Production Quality Assurance	EC Certificate Product Quality Assurance
Module ⇨ Annex ⇨ **Class** ⇩	**Module B** III	**Module F** IV	**Module H** II (4)	**Module H** II excluding (4)	**Module D** V (3)	**Module E** VI (3)
Class I						
Class I Sterile		(F)		H3	D2	(E)
Class I measuring function (Annex VII, 5)		F3		H4	D3	E2
Class I measuring function, sterile		(F)		H5	D4	(E)
Class IIa		F2		H2	D1	E1
Class IIb	B1	F1		H2	D1	E1
Class III	B1	F1	H1	H2	D1	
Sterilised systems or procedure packs (Art. 12.3)				H3	D2	

Table 2 Possible certificates for NBs under Directive 93/42/EEC;
(F) and (E) = Possible certificates for a NB but not useful

---------- Product certification ---------- ---- Quality system assessment ----

98/79/EC In Vitro Diagnostic Medical Devices (IVDD)									
Type of certificate ⇨	EC Design-Examination Certificate	EC Type-Examination Certificate	Certificate of Conformity	EC Design-Examination Certificate		EC Certificate Full Quality Assurance System	EC Certificate Production Quality Assurance		EC Certificate Product Quality Assurance
Module ⇨ Annex ⇨ **Type of device ⇩**	**Module A** III (6)	**Module B** V	**Module F** VI	**Module H** IV (4) / IV (6)		**Module H** IV excluding (4, 6)	**Module D** VII (3) / VII (5)		**Module E** –
List A		B2		H6	V1	H7	D5	V2	
List B		B2	F4			H7	D5		
Devices for self-testing	A1	B2	F4			H7	D5		
Devices for performance evaluation									
General Devices (Art. 9.1)									

Table 3 Possible certificates for Notified Bodies under Directive 98/79/EC

---------- Product certification ---------- ----- Quality system assessment -----

90/385/EEC Active Implantable Medical Devices (AIMDD)						
Type of certificate ⇨	EC Type-Examination Certificate	Certificate of Conformity	EC Design-Examination Certificate	EC Certificate Full Quality Assurance System	EC Certificate Production Quality Assurance	EC Certificate Product Quality Assurance
Module ⇨ Annex ⇨	**Module B** 3	**Module F** 4	**Module H** 2 (4)	**Module H** 2 excluding (4)	**Module D** 5 (3)	**Module E** –
Type of device Other devices than custom-made or intended for clinical investigation	B3	F5	H8	H9	D6	

Table 4 Possible certificates for Notified Bodies under Directive 90/385/EEC

General comments about the certificates

1. A Notified Body (NB) may, under the medical devices directives, issue only those certificates listed in this document. Especially it is worth notice that certificates according to 93/42/EEC Annex VII (MDD), 98/79/EC Annex III (IVDD) except for self-test devices, are not to be issued by a NB.
2. However an organisation designated as an NB may issue other certificates e.g. to a specific standard in its position as an accredited certification body. Those certificates must not make any reference to the Notified Body status of the certification body.
3. Each certificate shall unambiguously refer to the relevant part of the directive (Annex, section). Certificates refer to the parent Directive only, i.e. they should not mention subsequent amendments [3]. A reference to harmonized standards or other documents may be accepted as supplementary information.
4. A certificate should not carry the CE mark. The CE mark is only intended to be used on devices and associated instructions for use.
5. The scope of product certification certificates must unambiguously describe the device(s) covered. In the case of Quality system approvals it is preferable that the scope of products covered by a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates and/or terms. Irrespective of the description used in/with the certificate the NB must set out a system that enables the determination of the devices, including their classification, covered by the certificate.
6. The Directives limit the maximum validity for certificates – except for certificates according to Module F "EC Verification" and within Directive 98/79/EC for certificates according to Annex VII "Quality assurance production" – generally to 5 years. However,

it is strongly recommended to limit the validity of all quality system related certificates to 5 years. Certificates according to Module F "EC Verification" and also the "Verification of manufactured products" under Directive 98/79/EC, Annexes IV and VII, are related to individual devices and/or batches and normally without limitation in time.

7. Certificates can only be issued to one manufacturer (natural or legal person). This does not allow the concept of "doing business as" (dba) certificates, i.e. different "names" of a manufacturer on one certificate.

Specific recommendations for the individual certificates

Certificates to be issued under MDD – overview see table 2

B1

EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex III

(Devices in Class IIb and III)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex III must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the approved type (mark and model) covered by the certificate, preferable including a description of the intended purpose, utilizing the GMDN code
8. Performed examinations and tests, e.g. reference to relevant test reports
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination in accordance with MDD Annex III (4) and found that the type conforms to the relevant provisions of MDD
10. A reference to relevant parts of the documentation

Comment: Supplements to an EC Type-Examination Certificate are part of the original certificate (MDD Annex III, (6)); they do not have any separate period of validity. Changes to the approved product must receive further approval (MDD III (6)).

F1

Certificate of Conformity

Directive 93/42/EEC on Medical Devices, Annex IV

(Certificate issued with reference to a specific EC Type-Examination Certificate, Devices in Class IIb and III)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex IV must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. A legally binding signature of the Notified Body according to the applicable national law
6. Data needed for identification of the verified devices (as stated in the corresponding type-examination certificate) and including batches/serial numbers
7. Performed examinations and tests, e.g. reference to relevant standards/test reports
8. Reference to the EC Type-examination Certificate (Annex III)
9. A statement that the Notified Body has performed examinations and tests in accordance with MDD Annex IV (4) and found that the device(s) or batches of devices conforms with the type described in the EC Type-Examination Certificate and meet the applicable requirements of MDD

F2

Certificate of Conformity

Directive 93/42/EEC on Medical devices, Annex IV

(Certificate issued with reference to a technical documentation. Devices in Class IIa)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex IV, must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. A legally binding signature of the Notified Body according to the applicable national law
6. Data needed for identification of the device(s) (mark and model, batches/serial numbers) covered by the certificate
7. Performed examinations and tests, e.g. reference to relevant standards/test reports
8. A statement that the Notified Body has performed examinations and tests in accordance with MDD Annex IV (4) and found that the device(s) or batches of devices conform(s) with the technical documentation

F3

Certificate of Conformity

Directive 93/42/EEC on Medical devices, Annex IV

(Certificate issued with reference to a technical documentation,
Devices in Class I with measuring function)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex IV must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. A legally binding signature of the Notified Body according to the applicable national law
6. Data needed for identification of the device (s) (mark and model, batches and serial numbers) covered by the certificate
7. Performed examinations and tests, e.g. reference to relevant standards/test reports
8. A statement that the Notified Body has performed examinations and tests in accordance with MDD Annex IV (4) and found that the device (s) or batches of devices conforms – restricted to the metrological requirements – with the technical documentation

H1

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II (4)

(Devices in Class III)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex II (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer (legally responsible)
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum) from the date of issue to the expiration date
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the approved design, devices (mark and model) covered by the certificate, preferable including a description of the intended purpose, utilizing the GMDN code
8. Performed examinations, e.g. reference to relevant report(s)
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination of the design dossier relating to the device in accordance with MDD Annex II (4) and found that the design of the device conforms to the requirements of MDD

Comment: Supplements to the EC Design-Examination Certificate are part of the original certificate (MDD Annex II, (4)); they do not have any separate period of validity.

H2

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex II excluding (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant audit report(s)
10. The conclusion of the inspection e.g. a statement that the Notified Body has audited the quality system in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II
11. If appropriate, a note that for the placing on the market of Class III devices covered by this certificate, an EC design-examination certificate according to MDD Annex II (4) is required
12. A note concerning the required surveillance as referred to in MDD Annex II (5)

H3

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Class I devices in sterile conditions and sterilised systems or procedure packs)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex II excluding (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant audit report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions – in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II
11. A note concerning the required surveillance as referred to in MDD Annex II (5)

H4

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class I with measuring function)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex II excluding (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant audit report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements – in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II
11. A note concerning the required surveillance as referred to in MDD Annex II (5)

H5

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class I with measuring function and in sterile condition)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex II excluding (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant audit report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions – in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II
11. A note concerning the required surveillance as referred to in MDD Annex II (5)

D1

EC Certificate – Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class IIa, IIb or III)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex V must at least contain the following additional information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned (e.g. as stated in the corresponding type-examination certificate) for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system in accordance with MDD Annex V and found that the quality system meets the requirements in MDD Annex V
11. If appropriate a note that for the placing on the market of Class IIb and Class III devices covered by this certificate an EC type-examination certificate according to MDD Annex III is required
12. A note concerning the required surveillance as referred to in MDD Annex V (4)

D2

EC Certificate – Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Class I devices in sterile conditions and sterilised systems or procedure packs)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex V must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions – in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V
11. A note concerning the required surveillance as referred to in MDD Annex V (4)

D3

EC Certificate – Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class I with measuring function)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex V must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements – in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V
11. A note concerning the required surveillance as referred to in MDD Annex V (4)

D4

EC Certificate – Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class I with measuring function and in sterile condition)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex V must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions – in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V
11. A note concerning the required surveillance as referred to in MDD Annex V (4)

E1

EC Certificate – Product Quality Assurance

Directive 93/42/EEC on Medical devices, Annex VI

(Devices in Class IIa or IIb)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex VI must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product groups concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system in accordance with MDD Annex VI and found that the quality system meets the requirements in MDD Annex VI
11. If appropriate a note that for the placing on the market of Class IIb devices covered by this certificate an EC type-examination certificate according to MDD Annex III is required
12. A note concerning the required surveillance as referred to in MDD Annex VI (4)

E2

EC Certificate – Product Quality Assurance

Directive 93/42/EEC on Medical devices, Annex VI

(Class I Devices with measuring function)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to MDD, Annex VI must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product groups concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system – restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements – in accordance with MDD Annex VI and found that the quality system meets the applicable requirements in MDD Annex VI
11. A note concerning the required surveillance as referred to in MDD Annex VI (4)

Certificates to be issued under IVDD – overview see table 3

A1

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)

(Devices for self-testing)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex III (6) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the approved design of the devices (mark and model) and, where appropriate, a description of the intended purpose of the devices, preferable utilizing the GMDN code
8. Performed examinations, e.g. reference to relevant report(s)
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination of the design dossier relating to the device in accordance with IVDD Annex III (6) and found that the design of the device(s) conforms to the requirements of IVDD.

Comment: Supplements to the EC Design-Examination Certificate are part of the original certificate; they do not have any separate period of validity.

B2

EC Type-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex V

(List A, B and devices for self-testing)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex V must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices (mark and model) covered by the certificate, preferable including a description of the intended purpose of the devices, preferable utilizing the GMDN code
8. Performed examinations and tests, e.g. reference to relevant test report(s)
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination in accordance with IVDD Annex V (5) and found that the type conforms to the relevant provisions of IVDD
10. A reference to relevant parts of the documentation

Comment: Supplements to an EC Type-Examination Certificate are part of the original certificate; they do not have any separate period of validity.

F4

Certificate of Conformity

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex VI

(List B and devices for self-testing)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex VI must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. A legally binding signature of the Notified Body according to the applicable national law
6. Data needed for identification of the verified device (as stated in the corresponding type-examination certificate) and batches
7. Performed examinations and tests, e.g. reference to relevant test report(s)
8. Reference to the EC Type-examination Certificate
9. A statement that the Notified Body has performed examinations and tests in accordance with IVDD Annex VI (4) and found that the device(s) or batches conform(s) with the type described in the EC Type-Examination Certificate and meet the applicable requirements of IVDD

H6

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)

(List A)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex IV (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the approved design, devices (mark and model) and, where appropriate, a description of the intended purpose of the devices, preferable utilizing the GMDN code
8. Performed examinations, e.g. reference to relevant report(s)
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination of the design dossier relating to the device in accordance with IVDD Annex IV (4) and found that the design of the device conforms to the requirements of IVDD.
10. A reference to relevant parts of the documentation

Comment: Supplements to the EC Design-Examination Certificate are part of the original certificate; they do not have any separate period of validity.

V1

Verification of manufactured products

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (6)

(List A)

Each decision/certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex IV (6) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. The date of issue
4. A legally binding signature of the Notified Body according to the applicable national law
5. Data needed for identification of the verified devices (mark and model, batches and serial numbers) covered by the certificate
6. Performed examinations and tests, e.g. reference to relevant test report(s)
7. The conclusions of the examination, e.g. a statement that the Notified Body has verified the manufactured products in accordance with IVDD Annex IV (6) and found that they conform to the requirements of IVDD

Comment: The Directive does not require issuing such a certificate. But if the Notified Body decides to issue one, at least the contents mentioned above should be given.

H7

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)

(List A and B and devices for self-testing)

Each certificate shall be identified through a title and a subtitle as specified above.

The certificate according to IVDD, Annex IV excluding (4, 6) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied (enclosure if needed). It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant audit report(s)
10. The conclusion of the inspection, e.g. a statement that the Notified Body has audited the quality system in accordance with IVDD Annex IV and found that quality system meets the requirements of IVDD Annex IV
11. If appropriate a note that for the placing on the market of List A devices covered by this certificate an EC design-examination certificate according to IVDD Annex IV (4) is required
12. A note concerning the required surveillance as referred to in IVDD, Annex IV (5)

D5

EC Certificate – Production Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex VII

(List A, B and devices for self-testing)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex VII must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum is recommended)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product groups concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant report(s)
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system in accordance with IVDD Annex VII and found that the quality systems meets the applicable requirements in IVDD Annex VII
11. A note that for the placing on the market of devices covered by this certificate an EC type-examination certificate according to IVDD Annex V is required
12. A note concerning the required surveillance as referred to in Annex VII (4)

V2

Verification of manufactured products

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex VII (5)

(List A)

Each decision/certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to IVDD, Annex VII (5) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. The date of issue
4. A legally binding signature of the Notified Body according to the applicable national law
5. Data needed for identification of the verified devices (mark and model, batches and serial numbers) covered by the certificate
6. Performed examinations and tests, e.g. reference to relevant test report(s)
7. The conclusions of the examination, e.g. a statement that the Notified Body has verified the manufactured products in accordance with IVDD Annex VII (5) and found that they conform to the requirements of IVDD

Comment: The Directive does not require the issue such a certificate. But if the Notified Body decides to issue one, at least the contents mentioned above should be given.

Certificates to be issued under AIMDD – overview see table 4

B3

EC Type-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 3

(Other devices than custom made or intended for clinical investigation)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to AIMDD, Annex 3 must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices (mark and model), preferable including a description of the intended purpose of the devices, utilizing the GMDN code
8. Performed examinations and tests, e.g. reference to relevant standards/test reports
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination in accordance with AIMDD Annex 3 (4) and found that the type conforms to the relevant provisions of AIMDD
10. A reference to relevant parts of the documentation

F5

Certificate of Conformity

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 4

(Other devices than custom made or intended for clinical investigation)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to AIMDD, Annex 4 must at least contain the following additional information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. A legally binding signature of the Notified Body according to the applicable national law
6. Data needed for identification of the approved device(s) (mark and model, batches and serial numbers) covered by the certificate
7. Performed examinations and tests, e.g. reference to relevant test reports
8. A statement that the Notified Body has performed examinations and tests in accordance with AIMDD Annex 4 (5) and found that the devices or batches of devices conforms with the technical documentation and with the applicable requirements of AIMDD

H8

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)

(Other devices than custom made or intended for clinical investigation)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to AIMDD, Annex 2 (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the approved design, devices (mark and model) and, a description of the intended purpose of the devices, preferable utilizing the GMDN code
8. Performed examinations and e.g. reference to relevant report(s)
9. The conclusions of the examination, e.g. a statement that the Notified Body has performed an examination of the design dossier relating to the device in accordance with AIMDD Annex 2 (4) and found that the design of the device conforms to the requirements of AIMDD

Comment: Supplements to the EC Design-Examination Certificate are part of the original certificate; they do not have any separate period of validity.

H9

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)

(Other devices than custom made or intended for clinical investigation)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to AIMDD, Annex 2 excluding (4) must at least contain the following information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Data needed for identification of the devices or product categories concerned for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
8. If appropriate, the facilities, covered by the certificate
9. Reference to relevant audit report(s)
10. The conclusion of the inspection, e.g. a statement that the Notified Body has audited the quality system in accordance with AIMDD Annex 2 and found that quality system meets the requirements of AIMDD Annex 2
11. A note that for the placing on the market of devices covered by this certificate an EC design-examination certificate according to AIMDD Annex 2 (4) is required
12. A note concerning the required surveillance as referred to in AIMDD Annex 2 (5)

D6

EC Certificate – Production Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5

(Other devices than custom made or intended for clinical investigation)

Each certificate shall be identified through a specified title and a subtitle as specified above.

The certificate according to AIMDD, Annex 5 must at least contain the following additional information:

1. The name, address and identification number of the Notified Body
2. The name and address of the manufacturer
3. A unique number identifying the certificate
4. The date of issue
5. The validity (5 years at maximum)
6. A legally binding signature of the Notified Body according to the applicable national law
7. Reference to relevant reports
8. Data needed for identification of the devices or product categories concerned (as stated in the corresponding type-examination certificate) for which the quality system is being applied. It is preferable that the scope of a certificate shall be stated through a list of GMDN categories, sub categories (when available), templates, terms and/or devices (mark and model). Irrespective of the description used in/with the certificate the NB must be able to demonstrate on request, which (individual) devices are covered by the certificate
9. If appropriate, the facilities, covered by the certificate
10. The conclusions of the inspection, e.g. a statement that the Notified Body has audited the quality system in accordance with AIMDD Annex 5 and found that the quality system meets the requirements in AIMDD Annex 5
11. A note that for the placing on the market of devices covered by this certificate an EC type-examination certificate according to AIMDD Annex 3 is required
12. A note concerning the required surveillance as referred to in AIMDD Annex 5 (4)

Reference	93/42/EEC* Article 11, Annexes II-VI 98/79/EC Article 9, Annexes III-VII 90/385/EEC* Article 9, Annexes 2-5 *as amended
Sources	[1] Guide to the Implementation of Directives Based on the New Approach and the Global Approach, European Commission 1999 [2] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [3] Interpretative document of the Commission's services: Implementation of Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC, 5 June 2009
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