applicable for ☒ AIMDD, ☒ MDD, and ☒ IVDD **2014-1**

Renewal of EC Design-Examination and Type-Examination Certificates: Conformity assessment procedures and general rules

1 Legal bases

In the three directives on medical devices, there are different formulations on the renewal of EC design-examination and type-examination certificates. These formulations read as follows:

90/385/EEC (**AIMD**) Article 9 (8) "Decisions taken by the Notified bodies in accordance with Annexes 2, 3 and 5 shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both Parties, for further periods of a maximum length of five years."

See also Annexes 2 (4) and 3.

93/42/EEC (**MDD**) Article 11 (11) "Decisions taken by the Notified bodies in accordance with Annexes II, III, V and VI shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of a maximum length of five years."

See also Annexes II (4) and III.

98/79/EC (**IVDD**) Article 9 (10) "Decisions taken by the Notified bodies in accordance with Annexes III, IV, and V shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of up to five years."

See also Annexes III (6), IV (4) and V.

2 Purpose

The common idea of these formulations is that the devices have to be re-assessed in accordance with the applicable conformity assessment procedures. The Directives do not specify which elements of the procedures can be omitted to avoid useless duplication and which elements of the procedures must be repeated. This document lists the elements which have to be repeated, so as to avoid the following extremes:

- automatic renewal
- repeating a complete product assessment

3 Scope

The renewal of

a) EC Design-Examination Certificates (Annex 2 (4) AIMD / Annex II (4) MDD, Annex III (6) and IV (4) IVDD) / and
b) EC Type-Examination Certificates (Annex 3 AIMD / Annex III MDD, Annex V IVDD)

The guidance covers the cases in which:

- The design-examination performed in accordance with Annex 2 (4) AIMD, II (4) MDD or IV (4) IVDD is an integral part of the Notified Body conformity assessment in the course of cer-

tifications according to the full quality assurance system module, where the same Notified Body shall assess compliance with all requirements of the relevant Annex;

- Design-examinations take place without an approval of the quality system at all (Annex III (6) of the IVDD)
- Type-examinations are undertaken (e.g. according to Annex III of the MDD) by a Notified Body that may or may not be the Notified Body involved for the production phase (e.g. according to Annex V or VI of the MDD).

4 General

According to the Directives EC Design-Examination and Type-Examination Certificates shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract between manufacturer and Notified Body for further periods of up to five years maximum.

The renewal of EC Design-Examination and Type-Examination Certificates shall be based on the updated documentation and is to be done according to the current state of the art. E.g. Notified bodies shall take into account relevant MEDDEV Guidelines for all aspects of the assessment, since these documents reflect the common opinion of the regulators on the subject.

Notified bodies shall have a documented procedure that specifies the activities for the renewal of certificates with due consideration to the change in the state of the art.

5 Renewal procedure

5.1 Activities by the manufacturer

In due time prior to the expiry date of the existing certificate the manufacturer shall make a formal application for the renewal of the certificate to their chosen Notified Body (see e.g. MDD Art. 11 (11)).

The application should be accompanied by a report containing data about changes of the product related to the conformity assessment criteria after the previous certification.

The application shall be signed by the manufacturer. Except in the case of Article 11 (8) of the MDD, the application can also be signed by the authorised representative on behalf of the manufacturer if the manufacturer has mandated the authorised representative.

The manufacturer's application to the Notified Body shall contain:

(a) the manufacturer's full name and address and, if applicable, the name and the address of the Authorised Representative;

(b) copies of the existing certificate(s);

(c) all relevant identification of all the device(s) and accessories(s) for which a certificate renewal is required (with clarification if the list is different to the earlier certification);

(d) updated list of harmonised standards applied;

(e) the manufacturing site(s) location(s) and a statement on any relevant EC Quality System Certificate(s);

(f) the identity of any other Notified Body(ies) involved in the conformity assessment for the device(s) involved, together with copies of any supplementary certificate(s) according to other (non medical device) Directives;

(g) a report of all the changes to the approved design or type made since the previous submission to the Notified Body;

(h) reference document of the key data submitted for the renewal process, including any cross references to any previously submitted data held by the Notified Body;

(i) a report demonstrating the compliance with the requirements of the Directives for the devices involved, taking into consideration the current state of the art including:
   - experience gained from the devices in the post-production phase including comparable products in the market (manufacturer's post-market surveillance)
   - change of suppliers, subcontractors
   - modifications of production or test methods
   - new experience regarding materials, components etc. used, including biocompatibility
   - results of the risk-management process (updated risk analysis)
   - risk assessment in relation to new medical treatments and medical technology (risk benefit ratio for the patient)
   - experience from changes of the updating of the essential requirements
   - results of new clinical investigations and/or the post marketing clinical follow up including results of comparable products in the market (updated clinical evaluation)
   - modifications according to regulatory changes

(j) if the device contains a medicinal product, or it is a device utilising materials of animal origin or a device assisted by human blood derivatives the manufacturer shall provide an updated statement on the rationale and justification for the use of the medicinal product, the material of animal origin or the human blood derivatives for each of their product types.

5.2 Activities by the Notified Body

The Notified Body shall assess the on-going compliance of the device(s) concerned, with the relevant Directive(s) in accordance with the conformity assessment procedure selected and taking into consideration the current state of the art for the specific medical devices.

The Notified Body shall thoroughly scrutinize the manufacturer's documentation especially for

- consideration if the adopted solutions still comply with the essential requirements in Annex I
- experience gained in post-production phase, e.g. justification for the acceptance of undesirable side effects weighed against the performance of other solutions
- results of testing
- latest relevant update of risk analysis
- latest relevant evaluation of clinical data
- latest regulatory developments
- etc.

If applicable, these procedures shall include the requirements for devices containing medicinal products, devices utilising materials of animal origin or devices assisted by human blood derivatives (i.e. Directive 2001/83/EC, Commission Regulation (EU) No 722/2012).

In this case the Notified Body shall for the renewal process review an updated statement on the rationale and justification for the use of the medicinal product, the material of animal origin or the human blood derivatives for each of their product types.

The NB shall evaluate the manufacturers extended risk analysis, including records relating to the control and/or audit on sources of raw materials, finished products, subcontractors and third party suppliers, etc.

In case of devices containing medicinal products, devices utilising materials of animal origin or devices assisted by human blood derivatives (covered by Directive 2001/83/EC or by Commission Regulation (EU) No 722/2012) the Notified Body has to consult the Competent Authority

previously involved (or, if previously involved or exclusively responsible: of the EMA[1]) in order to verify if new aspects will result in deviating opinions.

In case of devices utilising materials of animal origin, the aspects listed in Annex I, Point 2.2. of Commission Regulation (EU) No 722/2012 shall be reviewed. If the overall TSE risk is increased, the procedure set out in Article 5 of that Regulation shall be followed.

The Notified Body shall require any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure (e.g. Article 11 (10) MDD).

The Notified Body shall prepare a report that identifies the documentation assessed for the renewal process with a clear result of the assessment and a statement whether certification is recommended or not.

If the Notified Body has an application for a renewal of a certificate based on a certificate of another Notifed Body, the Notified Body is obliged assess the validity of this certificate e.g. by reviewing the underlying assessment report.

The information presented above and the final review process will form the basis upon which the validity period of the EC Design Examination and EC Type Examination Certificates can be extended for a period of up to five (5) years.

Based on this information the Notified Body has to make the final decision on the renewal application. The decision making process is the same as the one made during the first certification.

Each step of the decision making process needs to be justified and documented. Records shall be kept at the disposal of the designating authorities for a period ending at least five years, and in the case of implantable devices at least 15 years, after the expiry date of the certificates issued.

References	90/385/EEC[2] Article 9 (8) and Annexes 2 (4), 3
	93/42/EEC[3] Article 11 (11) and Annexes II (4), 3
	98/79/EC[4] Article 11 (11) and Annexes III (6), IV (4) and V
	Commission Regulation (EU) No 722/2012[5]
Sources	[1] NB-MED/2.5.1/Rec6/rev Renewal of EC Design-Examination and Type-Examination Certificates, 07.11.2000
Keywords	Conformity assessment, EC Design-dossier examination certificates, EC Type-examination certificates, Notified Body, renewal
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[1] European Medicines Agency; www.ema.europa.eu

[2] Directive 90/385/EEC on Active Implantable Medical Devices, O.J. L 189, 20.7.1990, p. 17, as amended

[3] Directive 93/42/EEC on Medical Devices, O.J. L 169, 12.7.1993, p. 1, as amended

[4] Directive 98/79/EC on *in vitro* diagnostic Medical Devices, O.J. L 331, 7.12.1998, p. 1, as amended

[5] Commission Regulation (EU) No 722/2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin, O.J. L 212, 9.8.2012, p. 3