

FORMS AND REQUIREMENTS FOR THE EXTENSION OF EC CERTIFICATES ACCORDING TO AIMDD, MDD, IVD

Due to a consensus reached between Notified Bodies and requirements defined by the competent authorities, TÜV SÜD Product Service has implemented a harmonized process for the extension of the validity of EC certificates.

Goal/purpose/modification

The goal of the extension process is to move from a formalistic approach to a process taking more into account the changes in laws and the state of the art as well as the field experiences with the certified product(s).

All this has led to the current evaluation process. The application form contains all items important for a decision based on the field experiences with the products.

Relation between Directives, their Annexes and the type of certificates

a) Product-related

Directive	Annex	Combined with	Class	Type
AIMDD 90/385/EEC	3	Annex 4 or 5		I5
AIMDD 90/385/EEC	2.4	Annex 2.3		I7
MDD 93/42/EEC	III	Annex IV, V or VI	IIb, III	G5
MDD 93/42/EEC	II.4	Annex II.3	III	G7
IVDD 98/79/EC	V.4	Annex IV, VI.5/6 or VII	Self-testing, List A, B	V5
IVDD 98/79/EC	IV.4	Annex IV.3	List A	V7
IVDD 98/79/EC	III.6	Annex III	Self-testing	V9

b) QM-related

Directive	Annex	Combined with	Class	Type
AIMDD 90/385/EEC	2.3			I1
AIMDD 90/385/EEC	5			I2
MDD 93/42/EEC	II.3		IIa, IIb, III	G1
MDD 93/42/EEC	V	Annex III/ VII	IIb, III/ IIa	G2
MDD 93/42/EEC	V	Annex VII	I, measuring function	G2M
MDD 93/42/EEC	V	Annex VII	I, sterile	G2S
MDD 93/42/EEC	VI	Annex III/ VII	IIb/ IIa	G3
MDD 93/42/EEC	VI	Annex VII	I, measuring function	G3M
IVDD 98/79/EC	IV.3	Annex IV.4 for List A	Self-testing, List A, B	V1
IVDD 98/79/EC	VII.3	Annex V.4	Self-testing, List A, B	V2

For the extension of the EC certificates, the company has to present the enclosed application document MED_F_03.10, duly completed and accompanied by the following documentation.

Documents to be provided for the extension of QM Certificates:

- list of audits performed during the certification period;
- list of vigilance notifications for the product(s) on the certificate (except MDD class III, IVDD List A and AIMDD products);
- list of recalls/field actions initiated by the manufacturer of the product(s) on the certificate (except MDD class III, IVDD List A and AIMDD products);
- complaint history data including amount of products sold (except MDD class III, IVDD List A and AIMDD products);
- list of products covered by the scope of the certificate with all relevant data such as type and name of the medical product, catalog no., rule applied, classification, UMDNS/GMDN code.
For OEM products the list should also indicate original product identification and name of OEM manufacturer.
- In case of OEM products copies of the relevant certificates from the other Notified Bodies.

Documents to be provided for the extension of product certificates:

- list of change notifications submitted to TÜV SÜD Product Service;
- list of vigilance notifications for the product(s) on the certificate;
- list of recalls/field actions initiated by the manufacturer for the product(s) on the certificate;
- complaint history data including amount of products sold;
- list of insubstantial changes to the product(s) (NB-MED/2.5.1/Rec.6);
- list of products covered by the scope of the certificate with all relevant data such as type and name of the medical product, catalogue no. etc., rule applied, classification, UMDNS/GMDN code. Products containing human blood derivatives or drugs should be marked as such.
For OEM products, the list should also indicate the original product identification and the name of OEM manufacturer.
- In case of OEM products, copies of the relevant certificates from the other Notified Bodies;
- copies of certificates according to Annex V.5 or Annex VI.6 from another Notified Body in case we have released the Annex III.3 MDD/AIMDD certificate;
- current version of the design dossier or technical file respectively for review.

In order to ensure the extension on time, the company has to present the documentation between **four and six** months before the expiration date.

Scope of the new EC certificate

The scope of the certificates to be extended also has to be re-evaluated to ensure the validity and acceptance of the EC certificate for all regulatory bodies.

Current regulations require that the scope of EC certificates is specific to the medical product certified:

- The scope should not contain terms like „accessories“ as accessories are part of the

medical product and therefore not necessary to be mentioned in the certificate. If it is an accessory sold independently from the medical product and a separate medical product, it has to be mentioned on the certificate as a medical device.

- The term for a medical product should be selected as close as possible to the terms related to in the UMDNS/GMDN code.

Service provided to customers

TÜV SÜD Product Service will inform the manufacturer on a regular basis regarding the expiration date of the EC certificates, e.g. during the regular audits, when sending the yearly licence fee invoice, or through regular contact with the client coordinator.

Future changes in processes and new revisions of forms will be communicated to our customers prior to their enforcement, and appropriate implementation times will be established for a smooth implementation.



www.tuev-sued.com/mhs

Please also visit our website www.tuev-sued.com/mhs for further information from your Notified Body.

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