

Form



Product Service

Application for Extension of EC-Certificates

In accordance with EC-Directives 93/42/EEC, 90/385/EEC or 98/79/EC

General

EC-Certificate which needs Extension	
Certificate No.'s with expiration date which needs to be extended If necessary, please use a separate attachment. (copies of the certificates shall be attached)	Cert. No.:

Manufacturer Data	
Applicant * (complete name/address) * Please attach power of attorney from manufacturer.	
Company Representative	
European Representative (complete name/address)	
Manufacturer (complete name/address)	
Design Facilities (complete name/address) If necessary, please use a separate attachment.	
Production Facilities (complete name/address) If necessary, please use a separate attachment.	

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Products/Product Families	
<p>List of actual Products/Product Families including type, name, classification, rule, UMDNS code (MDD/AIMDD) or EDMS code (IVDD). Indicate with the product identification if the following is relevant:</p> <ul style="list-style-type: none"> • Animal origin (TSE relevant/non TSE relevant) • Blood derivatives • Drug/device combination <p>If necessary, please use a separate attachment.</p>	
<p>Are OEM products used?</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>If YES, please indicate the original product identification with the name of the OEM manufacturer in relation to the product identification on your certificate(s).</p> <p>If necessary, please use a separate attachment.</p> <p>Please provide also copies of the relevant OEM certificates.</p>	
<p>Have products which need extension been CE-marked and have been actually put into service?</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>If NO, which products are not put into service?</p> <p>If necessary, please use a separate attachment.</p>	

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Next three boxes have to be filled out for Product related certificates: I5, I7 (AIMDD) G5, G5A, G7, G7A (MDD) V5, V7, V9 (IVDD).

Reporting concerning product usage and performance	
Have there been insubstantial changes to the product?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, please provide a list of insubstantial changes including short description of the change If necessary, please use separate attachment.	
In case of certificates according to AIMDD Annex 3 (I5) or MDD Annex III (G5) are there certificates according to AIMDD Annex 5 or MDD Annex V or VI from another NB?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
If YES, please provide copies of current certificates from other NB.	
Have there been change notifications since issuance / last extension of the certificate(s)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, please list all change notifications. If necessary, please use a separate attachment.	
Please provide complaint history data. If necessary, please use a separate attachment.	

Documents that have to be provided
Please provide the following documents: <ol style="list-style-type: none">1. Risk Management2. ER-Checklist with indication of relevant updates3. Clinical data incl. risk-benefit ratio and post market experiences4. Instructions for use (IFU)/ Labeling5. Current version of the Design Dossier if not already updated with the last Change Notification Please submit a further Change Notification, if changes have occurred in the following fields after the last approved Change Notification: Biocompatibility, Sterilization/ Packaging/ Shelf life, Manufacturing, Performance, Functional Safety, Electrical Safety, Application of Software/Firmware, Electromagnetic Compatibility EMC, other product relevant changes (e.g. supplier etc.), formal changes (e.g. EC-representative address, etc.).

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Number of certificates to be re-issued per language	
Certificates to be issued:	_____ / _____ Number Language
Remarks:	_____ _____

Attachments

<input type="checkbox"/>	List of Certificates for Extension
<input type="checkbox"/>	Copies of Certificates for Extension
<input type="checkbox"/>	Power of Attorney
<input type="checkbox"/>	List of Design Facilities/Production Facilities
<input type="checkbox"/>	List of Products/Product Families
<input type="checkbox"/>	List of OEM Products
<input type="checkbox"/>	Copies of OEM Certificates
<input type="checkbox"/>	List of products not put into service
<input type="checkbox"/>	List of incidents/recalls/field actions and incident history data
<input type="checkbox"/>	List of Surveillance Audits
<input type="checkbox"/>	List of insubstantial changes to the product
<input type="checkbox"/>	Copies of certificates from other NB
<input type="checkbox"/>	List of Change Notifications
<input type="checkbox"/>	List of Complaint History Data
<input type="checkbox"/>	_____

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Manufacturers Declaration

The undersigned declares:

- that this application has not been made to any other Notified Body.
- herewith that the circumstances which have been basis for original certification have not changed.
- to notify the Competent Authorities of the following incidents immediately on learning of them:
 - I. any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
 - II. any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (I) to systematic recall of devices of the same type by the manufacturer.

TÜV PS is to be informed if the incident possibly occurred in connection with the design and/or production of the affected product.

- that the business relations are based on the Standard Terms and Conditions as well as the Testing and Certification Regulations of TÜV Product Service. In the event of extension of the certificates the applicant will automatically become a member of the certification system of TÜV Product Service - if this is not already the case.
- to the best of his knowledge, that all data and information related to this application are true and accurate and no material fact has been omitted.
- that the above mentioned QM-Systems have not been significant changed since initial issuance or latest extension of the EC-Certificates or last change notification and have been periodically surveyed.
- that significant changes to the QM-Systems/Products have been reported to and are approved by the Notified Body which issued the EC-Certificates.
- that the QM-Systems / Product(s) are still in compliance with all the elements, requirements and provisions of the Directive 93/42/EEC (MDD), 90/385/EEC (AIMDD) or 98/79/EC (IVDD). All initially made undertakings to fulfill the obligations arising from the quality system as approved remain effective.
- that the above mentioned product(s) have not been significant changed since initial issuance or latest extension of the EC-Certificate(s) or changes to the product(s) that have been reported and are approved.
- that in accordance with the implemented Corrective Action system and as result of the Vigilance system, the Essential Requirements are still met. If necessary for the safety and performance of the product(s) methods to meet these requirements have been updated.
- the are still in compliance with the applicable provisions of the Directive 90/385/EEC (AIMDD), 93/42/EEC (MDD) or 98/79/EC (IVDD) and meet, based on periodically performed complaint assessments, our manufacturer specification(s) for field performance.

Location / Date

Company seal / signature