



# Form

## Application for Extension of EC-Certificates

In accordance with Council Directives 93/42/EEC (MDD), or 90/385/EEC (AIMDD), or 98/79/EC (IVDD)

### General (to be filled out for all certificates to be extended):

EC-Certificate needing Extension	
Certificate No.'s with expiration date which need(s) to be extended	Certificate ID-Number(s):
Copies of the certificates shall be attached.	

Manufacturer Data	
<b>Applicant</b> * (complete name/address)  * If european representative: please attach power of attorney from manufacturer.	
<b>Company Representative</b>	
<b>EC-Representative</b> (complete name/address)	
<b>Manufacturer</b> (complete name/address)	
<b>Design Facility(ies)</b> (complete name/address)  If necessary, please use a separate attachment.	
<b>Manufacturing Facility(ies)</b> (complete name/address)  If necessary, please use a separate attachment.	



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Products/Product Families	
<p>List of actual <b>Products/Product Families</b> including type, name, classification, rule, UMDNS code (for all according to MDD/AIMDD), EDMS code (IVDD), additionally (MDD):</p> <p>for class IIa devices: for each device subcategory scope expression by NBOG BPG 2009-3</p> <p>for class IIb devices: generic device group(s) referenced by GMDN preferred term(s)</p> <p>Indicate with the product identification if the following is relevant:</p> <ul style="list-style-type: none"><li>• Animal origin (TSE relevant/non TSE relevant)</li><li>• Blood derivatives</li><li>• Drug/device combination</li></ul> <p>If necessary, please use a separate attachment.</p>	
Are OEM products used?	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>If YES, please indicate the original product identification with the name of the Original Equipment Manufacturer (OEM) 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>	
Have products which need extension been <b>CE-marked</b> and have been <b>actually put into service</b> ?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> NO
If NO, which products are not put into service?	
If necessary, please use a separate attachment.	





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**Next three boxes have to filled out for Product related certificate(s)  
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 list all vigilance notifications, recalls and field actions for the last five years initiated for the products on the certificate. If necessary, please use a separate attachment.	
Please provide incident history data including amount of items sold for the products on the certificate. If necessary, please use a separate attachment.	
Please information about product related complaints about products covered by certificate(s) and related assessment(s).	





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**Please send this application to your contact person of Medical Health Services of the TÜV SÜD Group.**

**If not agreed in a different way, the application for extension to notified body should be made 6 months in front of the certificate(s) expiration date(s).**

The application will be processed by notified body with number 0123:

TÜV SÜD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 MÜNCHEN. Country: Germany.  
Tel.: +49 (89) 5008-40; Email: [medical\\_devices@tuev-sued.de](mailto:medical_devices@tuev-sued.de); Website: <http://www.tuev-sued.de/ps>

### Manufacturers Declaration

**The undersigned confirms,**

- that this application has not been made in parallel to any other notified body.
- to notify the competent authorities of the reportable 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 labeling and instructions for use which might lead to or might have led directly or indirectly to the death or to a serious deterioration in the state of health of a patient, user, or any other person;
  - (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.
- to send copies of reports of Field Safety Corrective Actions (recalls) and Field Safety Notices (FSN) to the Notified Body TÜV SÜD Product Service GmbH.
- that the business relations are based on the Standard Terms and Conditions as well as the Testing and Certification Regulations of TÜV SÜD Product Service in its currently valid version. This version can be obtained under [www.tuev-sued.com/ps](http://www.tuev-sued.com/ps). In the event of extension of the certificates the applicant will automatically become a member of the certification system of TÜV SÜD Product Service GmbH - if this is not already the case.
- that the circumstances which have been basis for original certification have not changed.
- that the above mentioned product(s) have not been significantly changed since initial issuance or latest extension of the EC-Certificate(s) or changes to the product(s) have been reported and are approved.
- that significant changes to the QM-Systems / Products have been reported to and are approved by the Notified Body TÜV SÜD Product Service GmbH which issued the EC-Certificates.
- 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.
- that the QM-Systems / Product(s) are still in compliance with all the details, requirements and provisions of the Directive 93/42/EEC (MDD), and/or 90/385/EEC (AIMDD), and/or 98/79/EC (IVDD). All initially made undertakings remain effective and to fulfill the obligations arising from the approved quality system.
- that the product(s) / the Quality Management System is still in compliance with the applicable provisions of the Directive 93/42/EEC (MDD), and/or 90/385/EEC (AIMDD), and/or 98/79/EC (IVDD) and fulfill, based on continuous assessments of complaints, the manufacturing specifications in relation to the usability.



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- 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.

If legal manufacturer signs this application please use this left column ↓	If EC-Representative signs this application please use this right column ↓
<b>Name of company representative:</b>	<b>Name of EC-Representative:</b> (In case CE-Application is submitted by EC-Representative)
<b>Signature:</b>	<b>Signature:</b>
<b>Date:</b>	<b>Date:</b>
<b>Company seal:</b>	<b>Company seal:</b>