

Application for certification in accordance with EN ISO 13485



Product Service

? **Manufacturer:**

? **Application identification:**

Please send this application to your local contact in Medical and Health Services at the TÜV SÜD Group.

The application will be processed by the Notified Body with identification number 0123:

TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 Munich, Tel: +49 89 5008-40,

Email: medical_devices@tuev-sued.de, Website: www.tuev-sued.com/ps

Legal Manufacturer:

Company name
(incl. legal form):

Address:

Contact:

Tel:

Email:

Initial application

Transfer of Notified Body/Certification body – please enclose Appendix G

EN ISO 13485

Please complete a separate application for each certificate to be issued. Please list the manufacturing sites which should be included in the certification using Appendix B.

Proposed scope:

The scope as proposed by customer can be changed based on audit results and the assessment of the certification body.

Design and development of:

Distribution of:

Service of:

Production of:

Other (please specify):

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Product Service

Manufacturer:

Application identification:

Details on new certificates and requested European languages:

Certificates to be issued:

Quantity <input type="text"/>	Quantity <input type="text"/>	Quantity <input type="text"/>	Quantity <input type="text"/>
Language <input type="text"/>	Language <input type="text"/>	Language <input type="text"/>	Language <input type="text"/>

Translation(s) of the proposed scope:

Change – please enclose Appendix D

Certificates/certificate numbers to be changed:

The undersigned further accepts the General Terms and Conditions of Business of TÜV SÜD Product Service GmbH and the Testing and Certification Regulation of the TÜV SÜD Group, which, in accordance with the submitted quotation, form the basis of this contract. Applicants that do not yet have the status of partners in the certification scheme of TÜV SÜD Product Service GmbH will automatically become partners in this scheme upon certificate issue.

The undersigned confirms that to its best knowledge all details provided in this application are correct and complete.

Name of the undersigned:

Function of the undersigned:

Signature: _____

Place: _____ **Date:** _____

