Application for performance/change/extension of a conformity assessment procedure in accordance with Council Directive 93/42/EEC (MDD)

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, Ridlerstraße 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:	
Manufacturer Code: (DIMDI code only applicable to manufacturers headquartered in Germany)	
Competent Authority: (applicable to manufacturers headquartered in Europe)	

Authorized EU Representative: ☐ Applicant*

Company name:	
Address:	
Contact:	
Tel:	
Email:	
Competent Authority:	

* A copy of the power of attorney is enclosed if the authorized representative lodges the application ☐ Yes ☐ n/a

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Product Service

Manufacturer:

Application identification:

☐ **Initial application**

☐ **Change** – please enclose at least Appendix D

☐ **Extension** – please enclose Appendices A, B, C (if applicable) and E

Conformity assessment procedure:

Quality Management System (QMS) – please enclose Appendices A, B, and C

Annex II without (4) ☐ Full QMS without design examination
Annex V ☐ Production quality assurance
Annex VI ☐ Product quality assurance

Affected certificates/certificate numbers:

Product/Design – please enclose Appendix A

Annex II.4 ☐ EC design examination
Annex III ☐ EC type examination
Annex IV.5 ☐ EC verification (100% verification)
Annex IV.6 ☐ EC verification (statistical verification)

Affected certificates/certificate numbers:

The following Appendix/Appendices form(s) part of this application:

Appendix A – Details on product groups and categories:
☐ Yes, ☐ pages ☐ n/a
Appendix B – Details on all manufacturing sites covered by the quality system:
☐ Yes, ☐ pages ☐ n/a
Appendix C – Details on critical suppliers/Original Equipment Manufacturers (OEM):
☐ Yes, ☐ pages ☐ n/a
Appendix D – Details on plans for substantial change(s) to the quality system/product:
☐ Yes ☐ n/a
Appendix E – Extension of EC certificates
☐ Yes ☐ n/a
Appendix F – Additional information
☐ Yes, ☐ pages ☐ n/a
Appendix G – Change of Notified Body/Certification Body
☐ Yes, ☐ pages ☐ n/a

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Product Service

Manufacturer:

Application identification:

Details on new certificates and requested European languages:

Certificates to be prepared:

Quantity		Quantity		Quantity		Quantity	
Language		Language		Language		Language	

Proposed scope for product/product category:

The proposed scope can be changed based on the results of the conformity assessment procedure and the evaluation of the certification body.

☐ In case of space is not sufficient: please use Appendix F.

Translation(s) of the proposed scope:

☐ In case of space is not sufficient: please use Appendix F.

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Product Service

Manufacturer:

Application identification:

	Conformity assessment in accordance with Annex:					
	II w/o (4)	II.4	III	IV	V	VI
The undersigned declares that no application – related to this/these Medical Device(s) – has been lodged with any other Notified Body for the same product-related quality system.	Yes	Yes	–	–	–	–
The undersigned declares that no application has been lodged with any other Notified Body for the same devices.	–	–	–	–	Yes	Yes
The undersigned declares that no application has been lodged with any other Notified Body for the same type.	–	–	Yes	–	–	–
The undersigned undertakes to fulfil the obligations imposed by the quality system approved.	Yes	–	–	–	Yes	Yes
The undersigned undertakes to keep the approved quality system adequate and efficacious.	Yes	–	–	–	Yes	Yes
The undersigned undertakes to notify TÜV SÜD Product Service GmbH of any plans for substantial changes to the quality system or the product range covered.	Yes	–	–	–	Yes	Yes
The undersigned undertakes to inform TÜV SÜD Product Service GmbH, as Notified Body, of all substantial changes implemented in the approved device.	–	Yes	Yes	–	–	–
The undersigned undertakes to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action.	Yes	Yes	–	Yes	Yes	Yes
The undersigned undertakes to notify the competent authority/-ies of any reportable incidents immediately on learning of them.	Yes	Yes	–	Yes	Yes	Yes
The undersigned shall notify TÜV SÜD Product Service GmbH without undue delay of vigilance information (referred to in Art.10(1) MDD and NBOG 2009-2): - incidents - field safety corrective actions (FSCA) including field safety notice (FSN) - periodic summary reports (PSR) - trend reports The information shall be reported directly to TÜV SÜD Product Service GmbH. The information shall be done immediately but not later than referred to in MEDDEV 2.12-1 Rev.8, Point 5.1.7. Every FSCA or FSN shall be reported to TÜV SÜD Product Service GmbH, as Notified Body, immediately but not later than with starting of the corrective action. All reporting shall be done using the formal templates and forms which have been made available by the Commission. Every vigilance information or related documents must be submitted in English or in German.	Yes	Yes	Yes	Yes	Yes	Yes

The undersigned further undertakes to comply with all other requirements following from the Medical Devices Directives (EC Directives) and their transposition into the national law of the EU Member States.

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:** _____