Application for performance/change/extension of a conformity assessment procedure in accordance with Council Directive 90/385/EEC (AIMD)

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

Manufacturer details:

Company name:	
Street/Number/Suite:	
Postal Code/City:	
Province/State/Country:	
Contact:	
Tel.:	
Email:	
Manufacturer: (DIMDI code; only applicable to manufacturers headquartered in Germany)	
Competent Authority: (applicable to applicants headquartered in Europe)	

Authorized EU Representative details: ☐ Applicant*1)

Company name:	
Street/Number/Suite:	
Postal Code/City:	
Province/State/Country:	
Contact:	
Tel.:	
Email:	
Competent Authority:	

*1) 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

Conformity assessment procedure:

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

Annex 2.3 ☐ Full QS without design examination

Annex 5 ☐ Quality system production

Product/Design – Please enclose Appendices A and B

Annex 2.4 ☐ EC design examination

Annex 3 ☐ EC type examination

Annex 4 ☐ EC verification

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

☐ **Extension** – Please enclose Appendices A, B, C and E

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:

☐ 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

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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:

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

Translation(s) of the proposed scope:

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

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Product Service

Manufacturer:

Application identification:

	Conformity assessment in accordance with Annex:				
	2.3	2.4	3	4	5
The undersigned declares that no application has been lodged with any other notified body for the same product-related quality system.	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 approved quality system.	Yes	–	–	–	Yes
The undersigned undertakes to maintain the approved quality system in such a way that it remains adequate and efficacious.	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
The undersigned undertakes to inform TÜV SÜD Product Service GmbH, as notified body, of all planned substantial changes for the approved product.	–	Yes	Yes	–	–
The undersigned undertakes to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7 and to implement appropriate means to apply corrective actions, if necessary.	Yes	–	–	Yes	Yes
The undersigned undertakes to notify the competent authorities of the following incidents immediately on learning of them.	Yes	–	–	Yes	Yes
The undersigned shall notify TÜV SÜD Product Service GmbH without undue delay of vigilance information (referred to in Art.8(1) AIMD 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

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:

Signature: _____

Place: _____ **Date:** _____

Company stamp:

TÜV SÜD Product Service GmbH