Application for performance of a conformity assessment in accordance with Council Directive 98/79/EC (IVDD)

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: (please enter the code for the competent authority; applicable to applicants headquartered in Europe)	

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

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Manufacturer:

Application identification:

Performance of conformity assessment:

Please complete a separate application plus the relevant Appendices for each type of conformity assessment

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

Annex IV without (4)	☐ Full quality assurance system without product design examination	Initial application: ☐
Annex VII	☐ Production quality assurance	

Product/Design – Please enclose Appendix A

Annex III.6	☐ EC design examination	Initial application: ☐
Annex IV.4	☐ EC design examination	
Annex V	☐ EC type examination	
Annex VI	☐ EC verification	

☐ **Change** – Please enclose Appendix D

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

☐ **Termination date**

Existing certificates / certificate number

Appendix/Appendices (only to be enclosed with initial applications and extensions):

Appendix A – Details of product groups, product categories and conformity assessment procedures:
☐ Yes ☐ n/a

Appendix B – Details of all sites covered by the same quality management system :
☐ Yes ☐ n/a

Appendix C – Details on critical suppliers:
☐ Yes, ☐ pages ☐ n/a

Appendix D – Plans for substantial change(s) to the quality management 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:

	Conformity assessment in accordance with Annex:					
	IV.3	VII	IV.4	III.6	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 approved quality system.	Yes	Yes	–	–	–	–
The undersigned undertakes to maintain the adequacy and effectiveness of the approved quality system.	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 implemented in the approved device.	–	–	Yes	Yes	Yes	–
The undersigned undertakes to inform TÜV SÜD Product Service GmbH, as Notified Body, without delay if it has obtained information about changes to the pathogens and markers of infections to be tested, in particular as a consequence of biological complexity and variability.	–	–	Yes	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 provisions referred to in Annex III.5, and to implement appropriate means to apply any necessary corrective action.	Yes	Yes	–	Yes	Yes	Yes
The undersigned undertakes to notify the competent authority/authorities 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.11(1) IVD 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 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 and to make all necessary assurances to TÜV SÜD Product Service GmbH, the Notified Body.

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