Application for a conformity assessment procedure in accordance with Council Directives 93/42/EEC (MDD) or 90/385/EEC (AIMDD) and Article 120 of EU Regulation 2017/745 (MDR)

Product Service

Manufacturer:

Application identification:

1. General manufacturer information

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,
Website: www.tuvsud.com/ps

Legal manufacturer:

Company name (incl. legal form):	
Address:	
Contact person at the company:	
Telephone number:	
Email:	

Authorised representative: ☐ applicant*

Company name (incl. legal form):	
Address:	
Contact:	
Telephone number:	
Email:	
Competent authority:	

* A copy of the power of attorney shall be enclosed if the authorised representative lodges the application.

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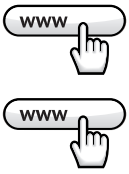
Product Service

Manufacturer:

Application identification:

2. Change(s) to the quality management system / product



For the definition of significant changes, please refer to NBOG-BPG 2014-3. For guidance on significant design changes and changes to the intended purpose regarding the transitional provision under EU Regulation 2017/745 (MDR) Article 120, please refer to MDCG 2020-3. Significant changes to the design and intended purpose cannot be processed under EU Regulation 2017/745 (MDR) Article 120 and require an application for an EU Regulation 2017/745 (MDR) conformity assessment.

The change will affect the following certificate(s) under the directive(s):

Please enter the affected certificate numbers.

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Product Service

Manufacturer:

Application identification:

Change category:			
Change to	**Type of change**	**Example**	**Minimum documentation to be submitted**
☐	New name / new address	Change of certificate holder	Appendix B; transition plan for product labelling
☐	Site-related changes	Relocation or new site; closure of site	Appendix B; audit report or site certificate; validation data in case of new production facilities
☐	Removal of product category / product variant	Product category: applicable to QMS product variant: applicable to product	Appendix A; audit report (product category); Design Dossier (product)
☐	Change in product identification	Name of product / model	Appendix A; labelling and declaration of conformity
☐	Transfer of processes to other site(s)	Transfer of development or production processes to another site; outsourcing of a production process to a (critical) supplier	Appendix B; where appropriate Appendix C; audit report or site certificate; validation data in case of transfer of production
☐	Changes in critical processes	Process changes which are critical to quality for the product (e.g. change in sterilisation process, drug coating, etc.)	Procedure / process description
☐	Changes of suppliers	Critical suppliers; OEM suppliers	Appendix C; action list for supplier control; EC Certificate and contract with OEM supplier
☐	Change of authorised representative	Change or relocation of authorised representative	Appendices B or C; excerpt from the register of companies; contract with new EC Representative; transition plan for product labelling
☐	Limitation of the Intended Purpose	See MDCG 2020-3 Chart A	Appendix A; verification report; clinical data
☐	Changes of design or performance specification	See MDCG 2020-3 Chart B & D	Verification report
☐	Software changes	See MDCG 2020-3 Chart C	Verification / validation report
☐	Other (please describe the change)		

For changes limited to (1) clarification of scope statements; (2) scope reductions or (3) changes to the manufacturer data confirmation statements may be issued by the Certification Board to clarify the scope / content of valid EC Certificates.

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Product Service

Manufacturer:

Application identification:

Information on change covered by the application shall contain the following minimum information:

- Description of the plans for change(s) (old / new comparison)
- Reason for change(s)

Information on change:

Please enter text or reference (via document code/revision) to a different document within your submission.

The change covered by the application is complemented by the following appendices:

Appendix A – Details on product groups and categories:

Please select

Appendix B – Details on all manufacturing sites covered by the quality system:

Please select

Appendix C – Details on critical suppliers / Original Equipment Manufacturers (OEM):

Please select

Appendix F – Additional information:

Please select

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Product Service

Manufacturer:

Application identification:

3. Application statement

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 and function of the undersigned:

Signature:

Place:

Date: