1. **General Manufacturer Information**

Please fill in this application and transfer it into a pdf-format and send it signed 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.tuev-sued.com/ps](http://www.tuev-sued.com/ps)

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| **Application Identification:** | Please enter unique identification including revision index. It will be automatically transferred to the header |

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| **Legal Manufacturer:** | |
| Company name (incl. legal form): | Klicken oder tippen Sie hier, um Text einzugeben. It will be automatically transferred to the header |
| Address: | Please enter Address including Street, Street Number, Zip-Code, City and Country. |
| Contact Person at the Company: | Please enter the Name to contact at the Company. |
| Telephone Number: | Please enter the Telephone Number of the contact. |
| Email: | Please enter the Email address of the contact. |

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| **Authorised Representative:**  ***applicant[[1]](#footnote-3)*** | |
| Company name (incl. legal form): | Please enter Company Name of the AR. |
| Address: | Please enter Address including Street, Street Number, Zip-Code, City and Country. |
| Contact: | Please enter the Name to contact at the Company. |
| Telephone Number: | Please enter the Telephone Number of the contact. |
| Email: | Please enter the Email address of the contact. |

1. **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 2017/746 (IVDR) Article 110, please refer to MDCG 2022-6. Significant changes to the design and intended purpose cannot be processed under EU Regulation 2017/746 (IVDR) Article 110 and require an application for an EU Regulation 2017/746 (IVDR) conformity assessment.

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| **The change will affect the following Certificate(s) under the Directive(s):** |
| Please enter the affected certificate numbers (e.g. V1 for QMS and V7 for Product etc.) without revision index. |

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| **Change category:** | | | |
| **Change to** | **Type of change** | **Example** | **Minimum documentation to be submitted** |
|  | New name / new address | Change of certificate holder | Appendix A/B/C - sheet B; transition plan for product labelling |
|  | Site-related changes | Relocation or new site; closure of site | Appendix A/B/C - sheet 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/B/C – sheet A; audit report (product category); Design Dossier (product) |
|  | Change in product identification | Name of product / model | Appendix A/B/C – sheet 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 A/B/C - sheet B; where appropriate sheet 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 A/B/C - sheet C; action list for supplier control; EC Certificate and contract with OEM supplier |
|  | Change of authorised representative | Change or relocation of authorised representative | Appendix A/B/C - sheet 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 2022-6 Chart A | Appendix A/B/C – sheet A; verification report; clinical data |
|  | Changes of design or performance specification | See MDCG 2022-6 Chart B & D | Verification report |
|  | Software changes | See MDCG 2022-6 Chart C | Verification / validation report |
|  | Other (please categorize the change) | please categorise 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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| **Information on change covered by the application are provided in a separate document (e.g. Appendix F - Additional information) containing the following minimum information:**   * **Description of the plans for Changes (old/new comparison)** * **Reason for Change** |
| Please enter text or reference (via document code/reference) to a different document within your application submission.. |
| **The change covered by the application is complemented by the following appendices:** |
| Appendix A/B/C - Details on product groups and categories:  Please select. |
| Appendix F - Additional information:  Please select. |

1. **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.

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| **Conformity assessment in accordance with Directive 98/79/EC Annex:** | **IV.3** | **VII** | **IV.4** | **III.6** | **V** | **VI** |
| Relevant Type of certificate at TÜV SÜD Product Service GmbH | V1 | V2 | V7 | V9 | V5 | V8 |
| The undersigned declares that there are no significant changes in the design and intended purpose of those devices. | Yes | Yes | Yes | Yes | Yes | Yes |
| The undersigned declares that it has adjusted its quality management system according to the requirements of Article 110(3) IVDR concerning significant changes according to  (MDCG 2022-6 endorsed guidance for clarification). | Yes | Yes | - | - | - | - |
| The undersigned undertakes to fulfil the obligation of Article 110(3) of Regulation (EU) 2017/746 regarding the adjustment of quality management system on post-market surveillance, vigilance, registration of economic operators and of devices. | Yes | Yes | - | - | - | - |
| The undersigned declares that all appropriate processes relating to post-market surveillance including risk management and performance data feed into the post-market surveillance plan. | Yes | Yes | Yes | Yes | Yes | Yes |

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 certi ficate issue.

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

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| Name and Function of the undersigned: | Please enter full name and function of the undersigned. |
| Signature: |  |
| Place: please enter Place | Date: Please select a date. |

1. A copy of the power of attorney shall be enclosed if the authorized representative lodges the application [↑](#footnote-ref-3)