**Thank you for your interest in TÜV SÜD Medical & Health Services.**

**We kindly ask you to complete this questionnaire to provide us with data for the generation of an individual quotation. In case further information is necessary, we will contact you.**

**Please send your request to medicaldevice@tuvsud.com.**

**The questionnaire is divided into the following sections:**

1. General information
2. Quality Management System (EN ISO 13485, EN ISO 9001, MDSAP and other Quality Management Certifications)

**Note on language:**

Available languages for the complete audit documentation are either exclusively German or English. This includes that your responses related to the audit (e.g. responses to nonconformities) shall be exclusively in the respective language.

Please choose a language:

[ ]  English [ ]  German

**SUMMARY** **AND** **APPLICATION** **FORMS**

A list of all our questionnaires and appendices can be found [here](https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/questionnaires-and-application-forms-for-medical-devices).

1. GENERAL InFORMATION
2. **COMPANY INFORMATION:**
3. **Applicant**

|  |  |
| --- | --- |
| **Applicant/Company:**(incl. legal form) |       |
| **Type of company:** | [ ]  business unit of      [ ]  also trades under the name of      [ ]  subsidiary of      [ ]  independent company |
| **Street, №:**  |       |
| **Postal Code:**  |       |
| **City:** |       |
| **Province / State:** |       |
| **Country:** |       |
| **Contact incl. function:** |       |
| **Telephone:** |       |
| **E-Mail:** |       |
| **Website:** |       |

1. **Facilities/Buildings**

Please complete the following table and attach organizational charts as well as a description of responsibilities relevant for the requested certification (e.g. EN ISO 13485).

 (Please reproduce the table in case of more than three facilities)

|  | **Facility/Build. 1** | **Facility/Build. 2** | **Facility/Build. 3** |
| --- | --- | --- | --- |
| Address: |       |       |       |
| Product(s) and product-related process(es): |       |       |       |
| Function of site within organization\* (headquarters, central function, or permanent site): |       |       |       |
| **Quality Management Process:** | **Number of employees per site per process****(as applicable):** |
| Management/Administration: |       |       |       |
| Regulatory Affairs: |       |       |       |
| Design/Development: |       |       |       |
| Production: |       |       |       |
| Final inspection and testing: |       |       |       |
| Further activities: |       |       |       |
| **Information about employees:** | **Number of employees per site (as applicable):** |
| Total number of employees: |       |       |       |
| Number of employees relevant for the EN ISO 13485 certification: |       |       |       |
| Number of employees working in 1st shift or single shift only: |       |       |       |
| Number of employees working in 2nd shift: |       |       |       |
| Number of employees working in 3rd shift: |       |       |       |
| If applicable: Alternative shift model |       |       |       |

\* Headquarters: Applicant

 Central Function: Centrally controls the Quality Management System

 Permanent site: Physical location where product-related processes are continuously performed

If there are several locations with the same QMS, please complete Appendix B and send it to us:

Appendix A/B/C – Sheet B: Details on sites covered by the same QMS

1. **Subcontracting / critical suppliers:**

For the term 'critical supplier' see [NBOG\_BPG\_2010\_1\_Supplier\_E](http://www.doks.nbog.eu/Doks/NBOG_BPG_2010_1.pdf)
For further information on control of products and suppliers, please see [309\_0410\_B17 (zlg.de)](https://www.zlg.de/index.php?eID=dumpFile&t=f&f=238&token=068a7a140ea30692d3b3396bb109b93d436eee92).

Are there any outsourced processes (e.g. design or manufacturing) which may affect regulatory compliance of the devices and are these processes not covered by the applicant’s quality management system? If yes, please complete the Appendix C and send it also to us:

Appendix A/B/C – Sheet C: Details on critical suppliers not covered by the same QMS

In case the supplier is certified valid certificate(s) need to be enclosed.

# Quality Management System (EN ISO 13485, EN ISO 9001, MDSAP and other Quality Management Certifications)

**Requested STANDARD(s) / Countries:**

[ ]  **EN ISO 13485**

[ ]  **EN ISO 9001:2015**

[ ]  **TAIWAN**

[ ]  **MDSAP** [ ]  **USA**

[ ]  **CANADA**

[ ]  **JAPAN**

[ ]  **AUSTRALIA**

[ ]  **BRAZIL**

[ ]  **other Quality Management Certification, please specify:**

**Requested service:**

[ ]  Initial certification

[ ]  Voluntary change of Certification Body (Transfer) - please submit a copy of the valid certificate

[ ]  Enforced change of Certification Body (Transfer) - please submit a copy of the certificate

**In case of more than one facility, please specify:**

[ ]  Campus all buildings and grounds are contiguous OR every building is within an approximately 3 km radius from the central office;
Definition under MDSAP: a group of sites (buildings) within a maximum range of 1 km or within a 60 minute car drive in which their activities are correlated to the manufacturing processes of the same or complementary finished medical devices

[ ]  Multi-site buildings and grounds NEITHER contiguous NOR within the 3 km radius from central office

**PROPOSED CERTIFICATE SCOPE:**

[ ] Design and development of:

[ ]  Distribution of:

[ ] Service of:

[ ] Production of:

[ ] Other (please specify):

**Desired Audit Date(s):**

|  |  |  |
| --- | --- | --- |
|  |  | **Date (YYYY/MM/DD)** |
| **Initial certification:** | Stage 1 Audit: |       |
|  | Stage 2 Audit: |       |
| **Change of Certification Body:** | Transfer Audit: |       |

Please add further documents to the questionnaire:

* [EN ISO 13485 Application certification](https://www.tuvsud.com/en/-/media/global/pdf-files/brochures-and-infosheets/healthcare-and-medical-devices-application-forms/en-iso-13485/en-iso-13485-application.pdf?la=en&hash=4C0CFB4ED5C9348D8E82D8AF87E18C7D)
* Appendix A/B/C for EN ISO 13485
* A company description which makes the relationship to the medical device area comprehensible
* A precise description of the activities that entitles you to a certification according to EN ISO 13485
* If applicable, a copy of the existing certificates
* An organizational chart of the organization
* If applicable, a copy of the valid supplier certificates

Submitted by: Function: Date:

                /    /