Form

Request for Quotation Questionnaire EN ISO 13485, AIMDD, MDD, IVDD, AO-TSE

Product Service

Thank you for your interest in TÜV SÜD Medical & Health Services. We kindly ask you to fill in the applicable sections of this questionnaire so that we can prepare a quotation. In case further information is necessary, we will contact you.

Please send your request to contactmhs@tuv-sud.com.

The questionnaire is divided into sections:

- Please always use the pages 2-4 to provide general information
- In case of EN ISO 13485, EN ISO 9001 and MDSAP and other Quality Management Certifications, please use the relevant page 5
- In case of a conformity assessment according to MDD, AIMDD or IVDD please use pages 7-14

Please mark which of the following sections form part of your request:

☐ I: Quality Management System (EN ISO 13485, EN ISO 9001, MDSAP, and other Quality Management Certifications

☐ II: MDD (Council Directive “Medical Devices” 93/42/EEC)

☐ III: AIMDD (Council Directive “Active implantable medical Devices” 90/385/EEC)

☐ IV: IVDD (Council Directive “In-vitro-diagnostic medical Devices” 98/79/EC)

☐ V: Derivatives of Human Blood or Human Plasma (Regulation (EC) No 726/2004) Animal Origin (Regulation (EC) No 722/2012), Drug-Device Combination (Regulation (EC) No 726/2004, Directive 2001/83/EC)

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 language:
☐ English ☐ German

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Product Service

GENERAL

1. COMPANY INFORMATION:

a) 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:	

b) 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:			
Regulatory affairs:			
Quality Management:			
Design/Development:			
Production:			
Measurement/Analysis/Improvement:			
Communication:			
Purchasing:			
Monitoring and measurement of products:			
Further activities:			
Information about employees:	**Number of employees per site (as applicable):**		
Total number of employees:			
Total number of employees working in shifts:	☐ No shifts # of employees:	☐ No shifts # of employees:	☐ No shifts # of employees:
Number of employees working in 1st shift:			
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

c) Subcontracting / critical suppliers:

Definitions for the purpose of EN ISO 13485/AIMDD/MDD/IVDD/AO-TSE:
For the term 'critical supplier' see NBOG BPG 2010-1.
For further information on control of products and suppliers, please see GHTF/SG3/N17:2008.
For the definition of OEM see EK-MED 3.9 B 16 (German only).

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 fill in the following list:

(Please expand the table as necessary

Critical supplier (name, address, country)	Design/Development	Production	Product testing	OEM (only for directives)	Sterilization	Further activities of the critical supplier	Concerns the following product(s)
	☐	☐	☐	☐	☐		
	☐	☐	☐	☐	☐		
	☐	☐	☐	☐	☐		

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

For Directives only:
Please name OEM devices and the reference to the valid EC certificate:

Submitted by: Title: Date: / /

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I QUALITY MANAGEMENT SYSTEM (EN ISO 13485, EN ISO 9001, MDSAP, AND OTHER QUALITY MANAGEMENT CERTIFICATIONS)

REQUESTED STANDARD(S) / COUNTRIES:

☐ **EN ISO 13485:2016**

☐ **EN ISO 9001:2015**

☐ **MDSAP**
- ☐ **USA**
- ☐ **CANADA**
- ☐ **JAPAN**
- ☐ **AUSTRALIA**
- ☐ **BRAZIL**

☐ **TAIWAN**

☐ **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 60minute 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):

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Product Service

DESIRED AUDIT DATE(S):

Date
(YYYY/MM/DD)

Initial certification:

Stage 1 Audit:

Stage 2 Audit:

Change of Certification Body:

Transfer Audit:

II COUNCIL DIRECTIVE "MEDICAL DEVICES" 93/42/EEC (MDD)

Please complete this part for each product category (i.e. devices with the same description/ intended use/indication) and provide - if available - product literature, instructions for use, brochures, etc.

REQUESTED SERVICE:

☐ Initial certification

☐ Voluntary change of Notified Body (Transfer) – please submit existing certificates

☐ Enforced change of Notified Body (Transfer) – please submit existing certificates
An "enforced" change of NB is necessary if the notification of a NB expires i.e. if a NB ceases its activities due to withdrawal of designation by the Designating Authority (partly or completely) or voluntarily abandons its designation (partly or completely).

AUTHORIZED REPRESENTATIVE:
(mandatory in case legal manufacturer is located outside of the European Union)

Authorized Representative: (incl. legal form)	
Street, №:	
Postal Code:	
City:	
Province / State:	
Country:	
Contact:	
Telephone:	
E-Mail:	
Website:	

PRODUCT GROUPS AND CATEGORIES:

Product Category/NBOG Code (acc. to NBOG_F_2012-1)	
Intended Use and Indication:	
Class:	☐ MDD III ☐ MDD IIb ☐ MDD IIa ☐ MDD I* sterile ☐ MDD I** with measuring function
Classification Rule (acc. to Annex XI)**:**	

Sterilization	☐ non-sterile ☐ sterile Sterilization method:
MDS Code (if applicable): (acc. to NBOG_F_2012-1)	☐ **MDS 7001** Medical devices incorporating medicinal substances, according to Directive 2001/83/EC ☐ **MDS 7004** Medical devices referencing the Directive 2006/42/EC on machinery ☐ **MDS 7006** Medical devices in sterile condition ☐ **MDS 7007** Medical devices utilizing micromechanics ☐ **MDS 7008** Medical devices utilizing nanomaterials ☐ **MDS 7009** Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed ☐ **MDS 7010** Medical devices incorporating software/ utilizing software/controlled by software

REQUESTED TYPE OF CONFORMITY ASSESSMENT PROCEDURE:

Class	Annex
III	☐ Annex II including (4) (full quality assurance system + EC design examination) ☐ Annex III + Annex IV.5 (EC type examination + EC verification – 100%) ☐ Annex III + Annex IV.6 (EC type examination + EC verification – statistical) ☐ Annex III + Annex V (EC type examination + production quality assurance)
IIb	☐ Annex II without (4) (full quality assurance system + sample based technical documentation) ☐ Annex III + Annex IV.5 (EC type examination + EC verification – 100%) ☐ Annex III + Annex IV.6 (EC type examination + EC verification – statistical) ☐ Annex III + Annex V (EC type examination + production quality assurance) ☐ Annex III + Annex VI (EC type examination + product quality assurance)

IIa	☐ Annex II without (4) (full quality assurance system + sample based technical documentation) ☐ Annex VII + Annex IV.5 (EC declaration of Conformity + EC verification – 100%) ☐ Annex VII + Annex IV.6 (EC declaration of Conformity + EC verification – statistical) ☐ Annex VII + Annex V (EC declaration of Conformity + production quality assurance) ☐ Annex VII + Annex VI (EC declaration of Conformity + product quality assurance)
I with measuring function	☐ Annex II without (4) (full quality assurance system + sample based technical documentation) ☐ Annex VII + Annex IV.5 (EC verification – 100%) ☐ Annex VII + Annex IV.6 (EC verification - statistical) ☐ Annex VII + Annex V (EC declaration of Conformity + production quality assurance) ☐ Annex VII + Annex VI (EC declaration of Conformity + product quality assurance)
I sterile	☐ Annex II without (4) (full quality assurance system + sample based technical documentation) ☐ Annex VII + Annex V (EC declaration of Conformity + production quality assurance)

III COUNCIL DIRECTIVE "ACTIVE IMPLANTABLE MEDICAL DEVICES" 90/385/EEC (AIMDD)

Please complete this part for each product category (i.e. devices with the same description/ intended use/indications) and provide - if available - product literature, instructions for use, brochures, etc.

REQUESTED SERVICE:

☐ Initial certification

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(mandatory in case legal manufacturer is located outside of the European Union)

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PRODUCT GROUPS AND CATEGORIES:

Product Category/NBOG Code (acc. to NBOG_F_2012-2)	
Intended Use and Indication:	
MDS Code (if applicable): (acc. to NBOG_F_2012-2)	☐ **MDS 7001** Medical devices incorporating medicinal substances, according to Directive 2001/83/EC ☐ **MDS 7004** Medical devices referencing the Directive 2006/42/EC on machinery ☐ **MDS 7006** Medical devices in sterile condition ☐ **MDS 7007** Medical devices utilising micromechanics ☐ **MDS 7009** Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed ☐ **MDS 7010** Medical devices incorporating software/ utilising software/controlled by software

REQUESTED TYPE OF CONFORMITY ASSESSMENT:

☐ **Annex II.4** EC Design examination

☐ **Annex III + Annex IV** EC type examination + EC verification – statistical

☐ **Annex III + Annex V** EC type examination + production quality assurance

☐ **Annex II excluding (4)** Full quality assurance system

IV COUNCIL DIRECTIVE "IN-VITRO-DIAGNOSTIC MEDICAL DEVICES" 98/79/EC (IVDD)

REQUESTED SERVICE:

☐ Initial certification

☐ Voluntary change of Notified Body (Transfer) – please submit existing certificates

☐ Enforced change of Notified Body (Transfer) – please submit existing certificates
An "enforced" change of NB is necessary if the notification of a NB expires i.e. if a NB ceases its activities due to withdrawal of designation by the Designating Authority (partly or completely) or voluntarily abandons its designation (partly or completely).

AUTHORIZED REPRESENTATIVE:
(mandatory in case legal manufacturer is located outside of the European Union)

Authorized Representative: (incl. legal form)	
Street, №:	
Postal Code:	
City:	
Province / State:	
Country:	
Contact:	
Telephone:	
E-Mail:	
Website:	

PRODUCT GROUPS AND CATEGORIES:

Please provide a list of devices to be covered by the conformity assessment, as indicated below.
If necessary, please provide supporting information to understand the nature of the devices, e.g. draft instructions for use, brochures, etc.

For IVD codes please see NBOG_F_2012-3, for GIVD code: Global IVD Classification by MedTech Europe (see http://www.medtecheurope.org/node/810).

- Device class (List A, List B, or Self Testing Devices)
- IVD code
- Model name
- Article code
- GIVD Device category name

- GIVD Device category number
- Device specifics (micromechanics, nanomaterials, sterile, software, radioactive/measurement of radioactivity)

Please sort the list in following order: Class, IVD code, model name

REQUESTED TYPE OF CONFORMITY ASSESSMENT PROCEDURE:

Class	Annex
List A	☐ Annex IV including (4) (full quality assurance system + EC design examination) **or** ☐ Annex V (EC type examination)* **and** ☐ Annex VII (production quality assurance)
List B	☐ Annex IV without (4) (full quality assurance system) **or** ☐ Annex V (EC type examination)* **and** ☐ Annex VI (EC verification) **or** ☐ Annex VII (production quality assurance)
Devices for self-testing (except blood glucose measurement systems)	☐ Annex III.6 (design examination) **or** ☐ Annex IV without (4) (full quality assurance system) **or** ☐ Annex V (EC type examination)* **and** ☐ Annex VI (EC verification) **or** ☐ Annex VII (production quality assurance)

* := in case a valid type examination certificate for the respective product is already available, please provide a copy together with the filled questionnaire

V DERIVATIVES OF HUMAN BLOOD OR HUMAN PLASMA, ANIMAL ORIGIN, DRUG-DEVICE COMBINATION

Product:

DERIVATIVES OF HUMAN BLOOD OR HUMAN PLASMA:

- Is a substance which can be considered a derivative of human blood or human plasma an integral part of the device?
  ☐ No ☐ Yes

  If *yes*, is the derivative of human blood or human plasma covered by an official marketing authorization for the European market?
  ☐ No ☐ Yes

- Was the product or a predecessor of the product consulted at the European Medicines Agency (EMA) before?
  ☐ No ☐ Yes

ANIMAL ORIGIN:

- Is your product manufactured utilizing animal tissue or derivatives rendered non-viable?
  ☐ No ☐ Yes

  If *yes*, please list all animal species of which material or derivatives were utilized in the production of your product:

- Has the product or a predecessor of the product already been consulted according to MDD at one of the European Competent Authorities?
  ☐ No ☐ Yes
  If yes, please specify:

DRUG-DEVICE COMBINATION:

- Is a substance which can be considered a medicinal product an ancillary part of the device?
  ☐ No ☐ Yes
  If *yes*, is the medicinal substance covered by an official registration for the European market?
  ☐ No ☐ Yes (Please attach registration)

- Has the product or a predecessor of the product already been consulted according to MDD at one of the European Competent Authorities?
  ☐ No ☐ Yes
  If yes, please specify:

- Is the substance genetically engineered?
  ☐ No ☐ Yes