



Form

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



Product Service

## **GENERAL**

### 1. COMPANY INFORMATION:

#### a) Applicant

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

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



**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):			
<b>Quality Management Process:</b>	<b>Number of employees per site per process (as applicable):</b>		
Management:			
Regulatory affairs:			
Quality Management:			
Design/Development:			
Production:			
Measurement/Analysis/Improvement:			
Communication:			
Purchasing:			
Monitoring and measurement of products:			
Further activities:			
<b>Information about employees:</b>	<b>Number of employees per site (as applicable):</b>		
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 1 <sup>st</sup> shift:			
Number of employees working in 2 <sup>nd</sup> shift:			
Number of employees working in 3 <sup>rd</sup> 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

**Form**

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



**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)

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

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:

/ /

Form

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



Product Service

**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):

Form

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



Product Service

**DESIRED AUDIT DATE(S):**

**Date  
(YYYY/MM/DD)**

**Initial certification:**

**Stage 1 Audit:**

**Stage 2 Audit:**

**Change of Certification Body:**

**Transfer Audit:**

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



Product Service

### 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)

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

#### PRODUCT GROUPS AND CATEGORIES:

<b>Product Category/NBOG Code</b> (acc. to <a href="#">NBOG_F_2012-1</a> )	
<b>Intended Use and Indication:</b>	
<b>Class:</b>	MDD III                      MDD IIb                      MDD IIa MDD I* sterile                      MDD I** with measuring function
<b>Classification Rule</b> (acc. to Annex XI):	

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



Product Service

<b>Sterilization</b>	non-sterile sterile method:	<b>Sterilization</b>
<b>MDS Code (if applicable):</b> (acc. to <a href="#">NBOG F_2012-1</a> )	<b>MDS 7001</b> Medical devices incorporating medicinal substances, according to Directive 2001/83/EC <b>MDS 7004</b> Medical devices referencing the Directive 2006/42/EC on machinery <b>MDS 7006</b> Medical devices in sterile condition <b>MDS 7007</b> Medical devices utilizing micromechanics <b>MDS 7008</b> Medical devices utilizing nanomaterials <b>MDS 7009</b> Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed <b>MDS 7010</b> Medical devices incorporating software/ utilizing software/controlled by software	

**REQUESTED TYPE OF CONFORMITY ASSESSMENT PROCEDURE:**

Class	Annex
<b>III</b>	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)
<b>IIb</b>	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)



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



Product Service

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

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



Product Service

**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

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)

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



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



### 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)

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

#### 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

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



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

