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Product Service

**Request for Quotation Questionnaire EN46003, ISO13485, AIMDD, MDD, IVDD, AO-TSE**

**General**

**Company Information:**

Company Name: \_\_\_\_\_ Contact Pers.: \_\_\_\_\_  
 \_\_\_\_\_  
 Address: \_\_\_\_\_ Telephone: \_\_\_\_\_  
 \_\_\_\_\_ FAX: \_\_\_\_\_  
 City, State ZIP \_\_\_\_\_ Email: \_\_\_\_\_  
 \_\_\_\_\_ Website: \_\_\_\_\_

Subsidiary of / owned by: \_\_\_\_\_

Branch / Facilities: \_\_\_\_\_

Please complete the following table with the number of employees for each facility and department. In case you have several shifts, please indicate the number of shifts and the number of the employees on each shift. (In case there are more than 2 facilities, please make a copy of this table and list all the applicable facilities.)

	Number of Employees		
	Facility:		
	Number of Shifts:		
Number of the employees per shift:			
Design			
Materials / Purchasing			
Manufacturing			
Packaging			
Sterilization			
Customer Service/Sales			
Shipping			
Service			
Quality Assurance			
Regulatory Affairs			
Administration			
<b>Total</b>			

*For more than one facility:*

Address			
City, State ZIP			
Contact Person			
Telephone			

*Please attach organizational charts and a description of responsibilities.*

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**Subcontracting:**

Are important parts of the design/manufacturing subcontracted to external companies and in which way are subcontractors included in the QS (e.g. by auditing of subcontractors, are included into the QS-System to be certified, by incoming inspection, are certified to ISO 900x or EN 4600x or AIMDD / MDD / IVDD)?

	Name of subcontracted companies	How included
Design		
SW - Design		
Sub-assemblies		
Packaging		
Sterilization		
Servicing		
Accessories		
Other		

Are there any products manufactured by other companies which are placed on the market under your own name (OEM)?  No  Yes

If yes, which? \_\_\_\_\_  
\_\_\_\_\_

Do certificates for these products exist?  No  Yes (please attach copies)

Please complete the applicable attachment(s), at least one must be completed:

- Attachment 1: QM-System ISO 13485 / ISO 9000 (1 page)
- Attachment 2: AIMDD (90/385/EEC) (1 page)
- Attachment 3: MDD (93/42/EEC) (2 pages)
- Attachment 4: IVDD (98/79/EEC) (1 page)
- Attachment 5: Derivatives of Human Blood or Human Plasma (2000/70/EEC) (1 page)  
Animal Origin (2003/32/EEC)  
Drug-Device Combination

Submitted by: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

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**Attachment 1: Quality Management System**

Should the whole company be audited?  Yes  No

If no, which departments should be audited? \_\_\_\_\_

**Current Quality System Status:**

Not certified

Documented only to US QSR's  Presently certified by \_\_\_\_\_ to \_\_\_\_\_  
\_\_\_\_\_ to \_\_\_\_\_

**Quality System Documentation/Structure:**

One quality manual/set of procedures covers all facilities

One quality manual/separate procedures for each facility

Separate quality manual/procedures for each facility

Other - describe or attach diagrams \_\_\_\_\_

**Quality System Audits Requested (use additional forms as needed):**

Facility: \_\_\_\_\_ Quality standards:  ISO 13485:2003  w/o\* Design  
 ISO 13485 / CMDCAS recognized registrar  
 ISO 9001:2000  w/o Design  
 EN 46003 based on ISO 9001:1994

Pre-Audit: Target Date \_\_\_\_/\_\_\_\_/\_\_\_\_  Certification Audit: Target Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Facility: \_\_\_\_\_ Quality standards:  ISO 13485:2003  w/o\* Design  
 ISO 13485 / CMDCAS recognized registrar  
 ISO 9001:2000  w/o Design  
 EN 46003 based on ISO 9001:1994

Pre-Audit: Target Date \_\_\_\_/\_\_\_\_/\_\_\_\_  Certification Audit: Target Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Facility: \_\_\_\_\_ Quality standards:  ISO 13485:2003  w/o\* Design  
 ISO 13485 / CMDCAS recognized registrar  
 ISO 9001:2000  w/o Design  
 EN 46003 based on ISO 9001:1994

Which activities regarding the products should be covered by the scope of the certificate?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\*w/o: without

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**Attachment 2: AIMDD**

Please complete this page for each product category (devices with same description/intended use/indications). Please provide product literature, instructions for use, brochures etc., if available.

(Use only one form per

a) Product Category: \_\_\_\_\_  
Product category)

b) Intended use: \_\_\_\_\_

c) UMDNS (GMDN optional)\* Product Category name: \_\_\_\_\_

d) UMDNS (GMDN optional)\* Product Category number: \_\_\_\_\_

\*Please underline Nomenclature System. UMDNS: Universal Medical Device Nomenclature System / GMDN: Global Medical Device Nomenclature (see <http://www.gmdn.org>).

**Product Examination Requested:**  Not applicable

Requirements depend on assessment route selected. Discuss with your TÜV Product Service representative.

Product description: \_\_\_\_\_

- AIMDD Annex 3 (Type Examination)
- AIMDD Annex 2.4 (Design Dossier Examination)

For each product that requires a type- or design examination please submit a complete Design Dossier or Device Documentation (for the content see TÜV Product Service information sheet "Technical Files / Design Dossiers").

**Conformity Assessment Route Requested:**

- AIMDD Annex 2.4 combined with Annex 2.3 (Complete Quality Assurance System)
- AIMDD Annex 3 combined with Annex 5 (Assurance of Production Quality)
- AIMDD Annex 3 combined with Annex 4 (EC Verification)

In case of Conformity Assessments according to AIMDD Annex 3+5 or 3+4, does the Annex 3 certificate already exist?  No  Yes (If yes, please attach Annex 3 certificates)

Facilities involved in Product:

Design: \_\_\_\_\_

Manufacturing: \_\_\_\_\_

Sterilization: \_\_\_\_\_

Service of external components  
(if applicable): \_\_\_\_\_

**Authorized EC Representative (only if necessary for EC-Directives):**

Company Name: \_\_\_\_\_

Contact Pers.: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

FAX: \_\_\_\_\_

City, State ZIP \_\_\_\_\_

Email: \_\_\_\_\_

Website: \_\_\_\_\_

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### Request for Quotation Questionnaire EN46003, ISO13485, AIMDD, MDD, IVDD, AO-TSE

#### Attachment 3: MDD

Please complete this page for each product category (devices with same description/intended use/indications). Please provide product literature, instructions for use, brochures etc., if available.

Use only one form per

Product category)

a) Product Category: \_\_\_\_\_

b) Intended use: \_\_\_\_\_

c) UMDNS (GMDN optional)\* Product Category name: \_\_\_\_\_

d) UMDNS (GMDN optional)\* Product Category number: \_\_\_\_\_

\*Please underline Nomenclature System. UMDNS: Universal Medical Device Nomenclature System / GMDN: Global Medical Device Nomenclature (see <http://www.gmdn.org>).

Classification:

- MDD I\* sterile     MDD I\*\* measuring function  
 MDD IIa         MDD IIb  
 MDD III

Classification Rule per MDD Annex IX: \_\_\_\_\_

**Product Assessment Requested:**

Not applicable

Requirements depend on assessment route selected. Discuss with your TÜV Product Service representative.

Product description: \_\_\_\_\_

- MDD<sup>1</sup> Annex III (Type Examination)  
 MDD<sup>2</sup> Annex II.4 (Design Dossier Examination)

<sup>1</sup> For Class IIb or Class III Products

<sup>2</sup> For Class III Products

For each product that requires a type- or design examination please submit a complete Design Dossier or Device Documentation (for the content see TÜV Product Service information sheet "Technical Files / Design Dossiers").

**Conformity Assessment Route Requested:**

Not applicable

- MDD<sup>3</sup> Annex II (Full Quality Assurance System)  
 MDD<sup>3</sup> Annex IV (EC Verification)  
 MDD<sup>3</sup> Annex V (Production Quality Assurance)  
 MDD<sup>3</sup> Annex VI (Product Quality Assurance)

<sup>3</sup> For Class I\* sterile devices only Annex V is applicable.

For Class I\*\* measuring devices Annex IV, V or VI is applicable.

Facilities involved in Product:

Design: \_\_\_\_\_

Manufacturing: \_\_\_\_\_

Sterilization: \_\_\_\_\_

Service: \_\_\_\_\_

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**Request for Quotation Questionnaire EN46003, ISO13485, AIMDD, MDD, IVDD, AO-TSE**

**For Class IIb or Class III MDD Products:**

In case of Conformity Assessments according to MDD Annex III+V or III+IV or III+VI, does the Annex III certificate already exist?  No  Yes (If yes, please attach Annex III certificates)

**Authorized EC Representative (only if necessary for EC-Directives):**

Company Name:	_____	Contact Pers.:	_____
	_____		_____
Address:	_____	Telephone:	_____
	_____	FAX:	_____
City, State ZIP	_____	Email:	_____
	_____	Website:	_____

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**Request for Quotation Questionnaire EN46003, ISO13485, AIMDD, MDD, IVDD, AO-TSE**

**Attachment 4: IVDD**

Please complete this page for each product category (devices with same description/intended use/indications). Please provide product literature, instructions for use, brochures, etc., if available.

(Use only one form per

a) Product Category: \_\_\_\_\_ Product category)

b) Intended use: \_\_\_\_\_

c) EMDS\* Product Category name: \_\_\_\_\_

d) EMDS\* Product Category number: \_\_\_\_\_

\*EMDNS: European Diagnostics Market Statistics Nomenclature (see <http://www.edma-ivd.be>)

Classification:  IVDD, List A  IVDD, List B  IVDD, Self-testing

**Product Assessment Requested:**  Not applicable

Requirements depend on assessment route selected. Discuss with your TÜV Product Service representative.

Product description: \_\_\_\_\_

- IVDD<sup>1</sup> Annex V (Type Examination)
- IVDD<sup>2</sup> Annex IV.4 (Design Examination)
- IVDD<sup>3</sup> Annex III.6 (Design Examination)

<sup>1</sup> For Annex II List A or List B Products to be combined with IVDD Annex VII

<sup>2</sup> For Annex II List A Products to be combined with IVDD Annex IV

<sup>3</sup> For Self-testing devices except blood glucose measurement systems

For each product that requires a type- or design examination please submit a complete Design Dossier or Device Documentation (for the content see TÜV Product Service information sheet "Technical Files / Design Dossiers").

**Conformity Assessment Route Requested:**  Not applicable

- IVDD Annex IV (Production Quality Assurance)
- IVDD Annex VII (Full Quality Assurance System)

Facilities involved in Product:

Design: \_\_\_\_\_ Manufacturing: \_\_\_\_\_

Sterilization: \_\_\_\_\_ Service: \_\_\_\_\_

**Authorized EC Representative (only if necessary for EC-Directives):**

Company Name: \_\_\_\_\_ Contact Pers.: \_\_\_\_\_

Address: \_\_\_\_\_ Telephone: \_\_\_\_\_

FAX: \_\_\_\_\_

City, State ZIP \_\_\_\_\_ Email: \_\_\_\_\_

Website: \_\_\_\_\_

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**Request for Quotation Questionnaire EN46003, ISO13485, AIMDD, MDD, IVDD, AO-TSE**

**Attachment 5: 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 to be 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 registration for the European market?

No  Yes

Was the product or a predecessor consulted at the European Agency for the Evaluation of Medicinal Products (EMA) before?

No  Yes

*Animal Origin:*

Is your product manufactured utilizing animal tissue or derivatives rendered non-viable?

No  Yes

If yes, which species / tissue(s) / derivative(s) and who is responsible for processing (derivation) of the animal tissue?

\_\_\_\_\_  
\_\_\_\_\_

*Drug-Device Combination:*

Is a substance which can be considered to be a medicinal product an integral part of the device?

No  Yes

If yes, is the medicinal substance covered by an official registration for the European market?

No  Yes (If yes, please attach registration)

Was the product or a predecessor consulted according MDD Annex II section 4.3 before at one of the European Competent Authorities?

No  Yes

Is the substance genetically engineered?

No  Yes