

## Questionnaire for the Preparation of a Quotation

### Details of the Company

Company (Name and Legal Entity)		Country
Street	Postal Code, Place	
Homepage	E-Mail Address (Company)	
Phone (Switchboard)	Fax (Company)	
Contact Person	Position	
Direct Phone	Direct Fax	
Mobile Phone	Personal E-Mail-Address	

### Data about the Organization

Subsidiaries, branch offices, production sites and further sites which are covered by the quality system						
Location	Address and legal entity	Number of Employees				Shift Work
		Full time employees	Part time employees	Other	Trainees	
1						<input type="checkbox"/>
2						<input type="checkbox"/>
3						<input type="checkbox"/>
4						<input type="checkbox"/>
5						<input type="checkbox"/>
	Total					

Please copy this page in case there are more than 5 sites

Structure of personnel					
Areas	Number of Employees / Location				
	1	2	3	4	5
Design and development					
Production and warehouse					
Quality management and quality control					
Marketing, sales and field service					
Administration and others					
Total					

Please add an organization chart of your company

If you need assistance in filling in this form or if you would like us to fill this in together please contact us by phone +49-(0)711-253597-0.

## Short Description of the Company's Activities of the Company


Please add detailed information about your company

## Aimed Scope of Certification

Certification according to the following quality standards		
	Standard	Accreditation
<input type="checkbox"/>	EN ISO 13485	ZLG <sup>1</sup>
<input type="checkbox"/>	EN ISO 13485 with additional acceptance in Taiwan	under the TCP <sup>2</sup>
<input type="checkbox"/>	EN ISO 13485 with additional acceptance in Canada	in co-operation with DQS <sup>3</sup>
<input type="checkbox"/>	EN ISO 9001	TGA <sup>4</sup>
With respect to		
<input type="checkbox"/>	the whole company	
<input type="checkbox"/>	the following particular parts:	
Certification of medical devices according to the European Medical Device Directive 93/42/EEC targeting the CE mark (please fill page 3, too)		
<input type="checkbox"/>	Annex II Full quality assurance system	
<input type="checkbox"/>	Annex V Production quality assurance	
<input type="checkbox"/>	Annex VI Product quality assurance	
Certification of in vitro diagnostic devices according to the European IVD Directive 98/79/EC targeting the CE mark (please fill page 4, too)		
<input type="checkbox"/>	Annex III.6	
<input type="checkbox"/>	Annex IV Full quality assurance system	
<input type="checkbox"/>	Annex VII Production quality assurance	

Please add copies of your certificates in case your quality system is already certified

Are you interested in a **pre-audit**?

yes

no

**Possible date** for the audit

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In which languages can the audit be conducted?

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\_\_\_\_\_

Place, Date

\_\_\_\_\_

Signature or name (in case of electronic transfer)

<sup>1</sup> Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

<sup>2</sup> Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports

<sup>3</sup> DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

<sup>4</sup> TGA - Trägergemeinschaft für Akkreditierung - German Association for Accreditation GmbH

### Details of the Medical Devices,

for which a certification according to EC-Directive 93/42/EEC is intended

Devices or device categories				
	Name / intended use / short description of the product	Class	Rule	OEM <sup>5</sup>
1				<input type="checkbox"/>
2				<input type="checkbox"/>
3				<input type="checkbox"/>
4				<input type="checkbox"/>
5				<input type="checkbox"/>

#### Please add detailed product information (e. g. instructions for use)

Please copy this page if more than 5 products within the certification scope

Are these devices					
Characteristics	Device				
	1	2	3	4	5
sterile medical devices (sterilization by moist heat)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
sterile medical devices (sterilization by ethylene oxide)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
sterile medical devices (sterilization by irradiation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
sterile medical devices (other sterilization methods)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
active medical devices (driven by energy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
medical devices with a measuring function	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
medical devices incorporating a drug	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
medical devices incorporating materials of animal origin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please list activities of subcontractors/suppliers including name and address		
	Name and address of subcontractors/suppliers	Activity
1		
2		
3		
4		
5		

Please add copies of the suppliers'/subcontractors' certificates

Please copy this page if more than 5 subcontractors are involved

<sup>5</sup> Products, which are placed under your own name on the market but are produced by other companies

**Details of the In Vitro Diagnostic Devices,**  
for which a certification according to EC-Directive 98/79/EC is intended

Devices or device categories			
	Name / intended use / short description of the product	Classification	OEM <sup>6</sup>
1			<input type="checkbox"/>
2			<input type="checkbox"/>
3			<input type="checkbox"/>
4			<input type="checkbox"/>
5			<input type="checkbox"/>

**Please add detailed product information (e. g. instructions for use)**

Please copy this page if more than 5 products within the certification scope

Are the abovementioned products					
Classification	Device				
	1	2	3	4	5
Devices for self-testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reagents and reagent products, including related calibrators and control materials,					
for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for determining the following blood groups: anti-Duffy and anti-Kidd	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for determining irregular anti-erythrocytic antibodies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for diagnosing the following hereditary disease: phenylketonuria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for determining the following human infections: cytomegalovirus, chlamydia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for determining the following HLA tissue groups: DR, A, B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
for determining the following tumoral marker: PSA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
and software, designed specifically for evaluating the risk of trisomy 21	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please list activities of subcontractors/suppliers including name and address		
	Name and address of subcontractors/suppliers	Activity
1		
2		
3		
4		

Please add copies of the suppliers'/subcontractors' certificates

Please copy this page if more than 4 subcontractors are involved

<sup>6</sup> Products, which are placed under your own name on the market but are produced by other companies