Please send the completed questionaire via email to zert@berlincert.de or to:

Berlin Cert - Prüf- und Zertifizierstelle für Medizinprodukte GmbH

Dovestrasse 6

10587 Berlin

Fax: 030/314-23719

1. Company and contact name

Company and legal form:	
Street:	Country:
Phone (headquarters):	Postal Code, Place:
Email (headquarters):	Fax (headquarters):
	Homepage:
Contact name:	
Last name:	First name:
Phone (extension):	Position:
Email (personally):	Fax (extension):

2. Short description of the industry and the company's activities

3. Aimed Scope of Certification

Quality management system (QMS)	EU directive 93/42/EWG for medical devices (MDD)
☐ DIN EN ISO 13485	☐ Annex II, Full quality assurance system
☐ DIN EN ISO 9001[1, 2]	☐ Annex V, Quality assurance production
☐ DIN EN ISO 14001[2]	☐ Annex VI, Quality assurance product
☐ DIN EN ISO 50001[2]	
☐ BS OHSAS 18001[2]	(Please fill out annex „product“)

Requested scope:

- ☐ Design and Development (QMS Part 7.3; Necessary for MDD Annex II)
- ☐ Production (QMS Part 7.5.1 und 7.5.2; Necessary for MDD Annex II and V)
- ☐ Installation (QMS Part 7.5.1.2.2)
- ☐ Maintenance (QMS Part 7.5.1.2.3)
- ☐ Sales

of (please state products/services):

Scope of Certification:

- ☐ Entire company
- ☐ Following individual area:

Is your quality system already certified? ○ yes ◉ no

If yes, please add copies of your currently valid certificates!

Possible date for the audit:

_____ _____

Place, Date Signature or name (in case of electronic transfer)

1 accredited certifications for DIN EN ISO 9001 are carried out in cooperation with for you Cert GmbH. When choosing, you accept that a copy of all data might be sent to this organisation.

2 accredited certifications for DIN EN ISO 9001, DIN EN ISO 140011, DIN EN ISO 50001, BS OHSAS 18001 are carried out in cooperation with GUT Certifizierungsgesellschaft für Managementsysteme mbH. When choosing, you accept that a copy of all data might be sent to this organisation.

Annex Organizational Structure

No.	Location	Adresses and if required a deviating corporate name of the subsidiaries/ locations/branches, which have been involved in the QM System	Number of shifts	Number of employees				
				Full Time	Part Time	Minor employes	Trainees	Shift workers
1.								
2.								
3.								
4.								
5.								

Allocation of employees for the following fields:	Number of employees at the 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					

Please submit in this questionnaire an organizational chart of the company.

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

Relevant standards:

(Alternatively submit list of standards)

Processes / technologies / procedures used in company *Please refer the used technologies / procedures / processes to the locations*	Locations				
	1	2	3	4	5
Vigilance processing	☐	☐	☐	☐	☐
Cleaning and desinfection of products	☐	☐	☐	☐	☐
Environmental control / cleanroom monitoring	☐	☐	☐	☐	☐
Estimation of bioburden	☐	☐	☐	☐	☐
Sterilization with: ☐ Ethylene oxide ☐ Radiation ☐ moist heat	☐	☐	☐	☐	☐
Cleanroom technique	☐	☐	☐	☐	☐
Cleanroom manufacturing	☐	☐	☐	☐	☐
Aseptic processing	☐	☐	☐	☐	☐
Measurement techniques	☐	☐	☐	☐	☐
Telemetry	☐	☐	☐	☐	☐
Protection against radiation	☐	☐	☐	☐	☐
Testing on eletromagnetic compatibility (EMC)	☐	☐	☐	☐	☐
Software validation	☐	☐	☐	☐	☐
Process techniques	☐	☐	☐	☐	☐
Packaging technologies	☐	☐	☐	☐	☐
Validation of packaging of sterile medical devices	☐	☐	☐	☐	☐
Product and packaging stability, stability tests	☐	☐	☐	☐	☐
Maintenance	☐	☐	☐	☐	☐
Disposal	☐	☐	☐	☐	☐
Material and manufacturing techniques	☐	☐	☐	☐	☐
Thin and thick film technology	☐	☐	☐	☐	☐
Precision mechanics/optics	☐	☐	☐	☐	☐
Welding and bonding techniques	☐	☐	☐	☐	☐
Manufacturing techniques of ceramics	☐	☐	☐	☐	☐
Polymer processing (extrusion, injection moulding,...)	☐	☐	☐	☐	☐
Metal processing (prototyping, reshaping,...)	☐	☐	☐	☐	☐
Textile-/fiber processing, Weaving technologies	☐	☐	☐	☐	☐
Micromechanics	☐	☐	☐	☐	☐
Nanomaterials	☐	☐	☐	☐	☐
Validation and monitoring within the reprocessing of medical products	☐	☐	☐	☐	☐
Assessment of the technical-functional safety of reprocessed medical devices	☐	☐	☐	☐	☐
Electronic engineering	☐	☐	☐	☐	☐
Design and development of software	☐	☐	☐	☐	☐

Annex product

Information to the medical devices aiming a certification to the EU Directive 93/42/EWG:

	Products or product lines				
	Designation, Purpose, Short Description	UMDNS	Class	Rule	OEM[3]
1.					☐
2.					☐
3.					☐
4.					☐
5.					☐

Are the medical devices mentioned above products with the following characteristics:	**Product**				
	1.	2.	3.	4.	5.
Medical devices incorporating medicinal substances according to Directive 2001/83/EC (MDS7001)	☐	☐	☐	☐	☐
Medical devices utilising tissues of animal origin (MDS 7002)	☐	☐	☐	☐	☐
Machines according to the directive 2006/42/EC (MDS7004)	☐	☐	☐	☐	☐
Sterile medical devices (MDS7006): ☐ Moist heat ☐ Ethylene oxide ☐ Rays ☐ Others	☐	☐	☐	☐	☐
Medical devices incorporating software / utilising software / controlled by software (MDS7010)	☐	☐	☐	☐	☐
Products with a measuring function	☐	☐	☐	☐	☐
Products with telemetry function	☐	☐	☐	☐	☐

If applicable, please give us an information which steps of the procedure shall take place at which subcontractors.

	Company name and address	**Working steps**
1.		
2.		
3.		
4.		

Please add copies of the subcontractors certificates.

Please copy this page if there are more than 5 subcontractors are involved.

Please submit detailed product documents (e.g. brochures, directions)

3 These are products, which are placed on the market under the name of your company, but which are bought as ready for sale from a “Original Equipment Manufacturer“

Annex additonal details

Additonal details BS OHSAS 18001:
BG Hazard Class (if known):

Additional details ISO 50001:	
Employees involved in energy management: (effective personal, a.e. Top-Management, EnMS-Team, employees with influence in energy consumption or -efficiany, etc.)	
Energy consumption of the last year:	
Sources of energy in use and consumption (if possible):	
Electricity (kWh/a):	Gas (kWh/a):
Oil (kWh/a):	District heat (kWh/a):
Number of main consumers (over 2 % in total energy consumption):	
Decentralized power generating facilities:	Thermic processes:
Chemical processes:	Engines/motors:

Will you submit an application to the main customs office regarding „tax capping“?	◯ yes	◯ no
Do you submit an application to the BAFA regarding „particular compensation regulations acc. to EEG“?	◯ yes	◯ no
Is your company a non-KMU and thus affected by §8 EDL-G?	◯ yes	◯ no

General details (voluntary):
When should the certification take place?
Did you make use of consulting services? If yes, by whom?
How did you come to know us?