

Please send the completed questionnaire 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/EEG for medical devices (MDD) <i>Only relevant for own medical devices which are not class I</i>
<input type="checkbox"/> DIN EN ISO 13485 <input type="checkbox"/> DIN EN ISO 9001 ¹ <input type="checkbox"/> DIN EN ISO 14001 ¹ <input type="checkbox"/> DIN EN ISO 50001 ¹ <input type="checkbox"/> BS OHSAS 18001 ¹	<input type="checkbox"/> Annex II, Full quality assurance system <input type="checkbox"/> Annex V, Quality assurance production <input type="checkbox"/> Annex VI, Quality assurance product <div style="text-align: right;">(Please fill out annex „product“)</div>

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, DIN EN ISO 14001, DIN EN ISO 50001, BS OHSAS 18001 are carried out in cooperation with GUT Zertifizierungsgesellschaft 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 employees	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:

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

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	BE	OEM
1.					<input type="checkbox"/>	<input type="checkbox"/>
2.					<input type="checkbox"/>	<input type="checkbox"/>
3.					<input type="checkbox"/>	<input type="checkbox"/>
4.					<input type="checkbox"/>	<input type="checkbox"/>
5.					<input type="checkbox"/>	<input type="checkbox"/>

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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical devices utilising tissues of animal origin (MDS 7002)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Machines according to the directive 2006/42/EC (MDS7004)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterile medical devices (MDS7006): <input type="checkbox"/> Moist heat <input type="checkbox"/> Ethylene oxide <input type="checkbox"/> Rays <input type="checkbox"/> Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical devices incorporating software / utilising software / controlled by software (MDS7010)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Products with a measuring function	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Products with telemetry function	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)

Annex additional details

Additional 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 -efficiency, 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):

Did you make use of consulting services? If yes, by whom?

How did you come to know us?