The form functions may not be fully supported in all browsers, we therefore recommend downloading the PDF and opening it with Adobe Acrobat Reader.

Questionnaire for certification of quality management systems according to EN ISO 13485

TÜV NORD CERT GmbH
Certification body for medical devices

Am TÜV 1
45307 Essen
Germany

Phone.: +49(0)201-825 2236
E-mail: medical@tuev-nord.de

Please complete the form and send it to medical@tuev-nord.de.

1. Contact and business details

Company Name:			
Address: *Please fill in complete address*		**Country/ zip code:**	
Contact person: *(Family and given name)*		**Position:**	
Phone/fax:		**E-mail:**	
VAT identification number:		**Homepage:**	
National Registration No. (e.g. DIMDI in Germany):			

Please include the organizational chart and the current trade register excerpt

We do not have a site in Europe ☐

In this case please state contact details of your European Representatives/Agent:

Company Name:	
Contact Person:	
Street:	
State ZIP:	City:
Telephone:	Fax:
E-mail:	
Homepage:	
National Registration No.	

We offer the following Services

Certification According to **Quality Management Systems in their most current versions** Please tick off the desired services and fill out the stated appendixes.

DIN EN ISO 9001	☐	**MDSAP (via TUV USA)**	☐
DIN EN ISO 13485	☐	**Ukraine Registration**	☐
DIN EN ISO 13485 / KRINKO (Germany only)	☐		

Ready?	
Checklist please attach the following documents:	
☐	• Corporate Brochure
☐	• Product information / Brochure / Manual (for relevant products)
☐	• Overview of your product based on the risk category and product coding
☐	• Copy of other relevant existing certificates of your company (etc. EC Directives)
☐	• Copy of existing Certificates of the OEM manufacturer - if applicable -
☐	• Copy of trade register excerpt
☐	• Organizational chart of headquarter and branch offices
☐	• If necessary, contact details of your European Representative

2. Information on the scope of the certificates

Please name the desired scope of the DIN EN ISO 9001 certificate	
	Have you introduced an appropriate quality system completely? Yes: ☐ No: ☐
	Are you already certified to this standard? Yes: ☐ No: ☐
Exclusion of the Standard:	

Please name the desired scope of the DIN EN ISO 13485 certificate	
	Have you introduced an appropriate quality system completely? Yes: ☐ No: ☐
	Are you already certified to this standard? Yes: ☐ No: ☐
Exclusion of the Standard:	

3. Information about the company locations and branch offices

Please state the company locations and branch offices, which should be included in the certification			
	Headquarter	1st. Branch office	2nd. Branch office
Address:			
City, State ZIP:			
Contact Person: *Given- and family name*			
Position:			
Phone/fax:			
E-mail:			
Number of Employees: *Calculated as fulltime employees*			
Number of shifts:			
employee number of each shift:			
Number of employees in:			
• Design & Development			
• Material, Purchasing			
• Production			
• Sterilisation			
• Sale			
• Labelling and Packaging			
• Maintenance			
• Quality Assurance			
• Administration			
• Miscellaneous			

Performed activities on each location			

Please include the organizational chart and the current trade register excerpt

Do all locations operate under a common quality system? Yes: ☐ No: ☐

If no, further explanation please

4. Information on outsourced processes and sub-contractors

Please state which QM relevant services / processes are awarded to external companies / suppliers. For example it could be the development, marketing/Sales, manufacturing (or parts of the manufacturing).

Are relevant processes of the quality management system outsourced? ☐ Yes / ☐ No

Information about your external services (Please tick off where applicable)

	Which parts of the manufacturing process subcontracted: (If Subcontractors hold Certifications and Please Attach):	Quality agreement available?		Subcontractor certified?	
		Yes	No	Yes	No
☐	**Development** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Design** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Production / assembly** Product Component: Subcontractor:	☐	☐	☐	☐
☐	**Section Assembly** Product / Component: Subcontractor	☐	☐	☐	☐
☐	**Cleaning** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Coating** Product / Component: Subcontractor:	☐	☐	☐	☐

Questionnaire for certification of products and quality systems for medical devices

Information on outsourced processes and sub-contractors

TÜV NORD Certification

☐	**Labelling** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Sterilisation** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Packaging** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Storage** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Testing / Verification / Validation** Product / Component: Subcontractor:	☐	☐	☐	☐
☐	**Marketing and Sales** Product / Component: Subcontractor:	☐	☐	☐	☐

Comments:

Subcontractors Register			
	1.	2.	3.
Address:			
City, State ZIP:			
Contact Person: Given- and family name			
Position:			
Phone/fax:			
E-mail:			
Outsourced activity / process:			

Subcontractors Register			
	4.	5.	6.
Address:			
City, State ZIP:			
Contact Person: Given- and family name			
Position:			
Phone/fax:			
E-mail:			
Outsourced activity / process:			

If more subcontractors are used as listed above,
please send a separate list with the above requested data.

5. Information about products and technologies

Please select as applicable

- for Companies with class I devices, please select all applicable MD and MDS product code(s)
- for Companies providing components or services, please select the main product technology or services, please select the applicable S-Code(s)

NANDO Codes (MD, MDS)		
	MD 0100	**General non-active, non-implantable medical devices**
☐	MD 0101	Non-active devices for anaesthesia, emergency and intensive care
☐	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
☐	MD 0103	Non-active orthopaedic and rehabilitation devices
☐	MD 0104	Non-active medical devices with a measuring function
☐	MD 0105	Ophthalmologic devices
☐	MD 0106	Non-active instruments
☐	MD 0108	Non-active devices for disinfecting, cleaning and rinsing
☐	MD 0110	Non-active medical devices for ingestion
	MD 0200	**Non-active implants**
☐	MD 0201	Non-active cardiovascular implants
☐	MD 0202	Non-active orthopaedic implants
☐	MD 0203	Non-active functional implants, others
☐	MD 0204	Non-active soft tissue implants
	MD 0300	**Non-active medical devices for wound care**
☐	MD 0301	Bandages and wound dressings
☐	MD 0302	Suture material and clamps
☐	MD 0303	Other medical devices for wound care
	MD 0400	**Non-active dental medical devices and accessories**
☐	MD 0401	Non-active dental equipment and instruments
☐	MD 0402	Dental materials
☐	MD 0403	Dental implants
	MD 1100	**General active medical devices**
☐	MD 1101	Active devices for extracorporal circulation, infusion and haemopheresis
☐	MD 1102	Active respiratory devices, devices for oxygen therapy incl. hyperbaric chambers and inhalation anaesthesia
☐	MD 1103	Active devices for stimulation or inhibition
☐	MD 1104	Active surgical devices
☐	MD 1105	Active ophthalmologic devices
☐	MD 1106	Active dental devices
☐	MD 1107	Active devices for disinfection and sterilization
☐	MD 1108	Active rehabilitation devices and active prostheses
☐	MD 1109	Active devices for patient positioning and transport
☐	MD 1111	Software
☐	MD 1112	Medical gas supply systems and parts thereof

	MD 1200	**Devices for imaging**
☐	MD 1201	Active devices utilizing ionizing radiation
☐	MD 1202	Active devices utilizing non-ionizing radiation
	MD 1300	**Monitoring devices**
☐	MD 1301	Monitoring devices of non-vital physiological parameters
☐	MD 1302	Monitoring devices of vital physiological parameters
	MD 1400	**Devices for radiation and heat therapy**
☐	MD 1401	Active devices utilizing ionizing radiation
☐	MD 1402	Active devices utilizing non-ionizing radiation
	MDS 7000	**Medical devices with special components, raw materials or regulations, special procedures**
☐	MDS 7001	Medical devices incorporating medicinal substances drugs (Directive 2001/83/EC)
☐	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
☐	MDS 7006a	E.O.
☐	MDS 7006b	Gamma
☐	MDS 7006c	Steam
☐	MDS 7006d	Plasma
☐	MDS 7006e	Perchloracetic acid
☐	MDS 7006g	Hydrogen peroxide
☐	MDS 7007	Medical devices utilizing micromechanics
☐	MDS 7008	Medical devices utilizing nanomaterials
☐	MDS 7009	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
☐	MDS 7010	Medical devices incorporating software / utilizing software / controlled by software
	IVD 4600	**In Vitro Diagnostica**
☐	IVD 4601	Clinical chemistry
☐	IVD 4602	Hematology
☐	IVD 4603	Immunology
☐	IVD 4605	Specimen receptacles
☐	IVD 4606	Instruments and software and components for instruments
☐	IVD 4607	Distribution
		S-Codes
☐	S 0106	Microbiology, hygiene, cleaning, disinfection and sterilisation
☐	S 0107	Environmental control
☐	S 0108	Cleanroom manufacturing
☐	S 0110	processing, preservation, testing and treatment of tissues, cells and substances of animal origin
☐	S 0121	Maintenance, repair and installation of medical Devices (Installation Services)
☐	S 0122	Disposal
☐	S 0123	Patent affairs
☐	S 0124	Material and manufacturing techniques
☐	S 0125	Thin and thick film technology
☐	S 0126	Precision mechanics and optics
☐	S 0127	Welding and bonding techniques
☐	S 0128	Manufacturing techniques for ceramics
☐	S 0129	Polymer processing (extrusion, injection moulding,…)
☐	S 0130	Metal processing (prototyping, reshaping, …)
☐	S 0131	Textile/fiber processing, weaving technologies
☐	S 0132	Process techniques

☐	S 0133	Packaging technologies
☐	S 0135	Software
☐	S 0136	Micromechanics
☐	S 0137	Nanomaterials
☐	S 0138	Electronic Components
☐	S 0139	Trade of Medical Devices
☐	S 0140	Custom made devices; please specify: opticians offices, dental technology, audiology, orthopedics and orthopedic technology, rehabilitation technology:
☐	S 0142	Transportation services
☐	S 0145	Semi-finished products and components
☐	S 0146	Raw materials
☐	S 0147	Analysis of data obtained with the help of medical devices

If other, or further request, please specify

Note: The certification has no relevance for procedures according to §17b MPDG and Article 17 (EU) 2017/745.

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