TÜVNORD

Questionnaire EN ISO 13485 certification

As an accredited certification body for DIN EN ISO 13485, we require up-to-date information on your company for the preparation of quotations and for the planning and preparation of certification, extension and re-certification audits. This is required by the German Accreditation Body (DAkkS) at the beginning of each certification period and in case of significant changes in the scope of your certification. We kindly ask you to complete the questionnaire and to attach the required evidence.

1. General information	
Company with legal form	
Street	
Postal code	
City	
Country	Test
Contact person	☐ Mr ☐ Ms ☐ Diverse
First- and Surname	
Function / Role	
Phone	
Mobile	
E-Mail	
Commercial register no.	
Industry	
Tax no. non-EU countries	
VAT ID	
Homepage	

2. Information about the main location / head oĀ ce / parent company			
Number of employees		Number of shifts	
FTE Full-time equivalent		Employees per shift	
Activities carried out			
Development	☐	Distribution	☐
Production	☐	Maintenance	☐
Packaging	☐	Administration	☐
Sterilisation	☐	Quality assurance	☐
Storage	☐	Installation / Service	☐
Other			
For multi-site procedures - Please provide further information on locations in Annex 1			
Number of employees in the scope of certification across all sites		FTE Full-time equivalent in the scope of certification across all sites	

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3. Rolle(n) des Unternehmens (Mehrfachnennungen möglich)	
☐ Manufacturer ☐ Authorised representative ☐ Importer	☐ System & Procedure Pack Producer ☐ Trader / Sales partner ☐ Other (please describe):

4. Welche ZertiÃzierungen streben Sie an?		
Activity	**Standard / service**	
☐ Initial certification	☐ DIN EN ISO 9001	☐ DIN EN ISO 13485
☐ RecertiÃcation	☐ MDSAP (via TUV USA)	☐ MDR (separate application)
☐ Transfer	☐ Ukraine registration	
☐ Extension	☐ DIN EN ISO 13485 / KRINKO (Germany only; please use P11F007)	
☐ Change (please use additional P11F002)	☐ Other:	

5. Scope of certiÃcation	
e.g.: „Development, production and distribution of...“.	**Please provide further details on products, manufacturing technologies and services in Annex 2**
Desired scope DIN EN ISO 9001	Exclusions, sections not applicable
Desired scope DIN EN ISO 13485	Exclusions, sections not applicable

6. Factors that could have an inÃuence on the audit eff rt (multiple selection possible)	
No Design / development	☐
Products with low risk or low process risk (e.g. simple processes, no validations necessary)	☐
Sophisticated management system	☐
High number of employees with the same, simple job	☐
Exclusively transport/trade within the scope of certification	☐
Products with high risk or high process risk (e.g. processes requiring validation)	☐
Large location with low employee density	☐

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Installation activities at the customer		☐
High level of automation		☐
Identical activities in all shifts		☐
High proportion of outsourced activities		☐
High proportion of employees in the fiel		☐
Combined audit with several standards / guidelines / regulations		☐
Complicated logistics with multiple buildings, locations		☐
Interpreter needed		☐
In-house sterilisation	Method(s):	☐

Have you been supported by a consultant when setting up your management system?		☐ Yes ☐ No
Consultancy		☐
Contact		☐
Have you received in-house training from a TÜV NORD company?		☐ Yes ☐ No
Training providers		☐
Training content		☐
When are you planning the audit?		☐
Do you have outsourced processes?	**Please provide further details on subcontractors in Annex 3.**	☐ Yes ☐ No

7. What type of certiĀcation is being sought? (Multiple selection possible)	
Single-site certification (all locations are independently certified)	☐
Multi-site certification (sites are certified in one g oup)	☐
Combined / Integrated certification (several management systems are audited simultaneously)	☐
Do you want a simultaneous audit of all management systems?	☐ Yes ☐ No
Would you like a remote audit (maximum 50% of the audit time)?	☐ Yes ☐ No
Do you have the necessary infrastructure for the remote audit?	☐ Yes ☐ No

8. Degree of integration when auditing several standards at the same time	
In case of a simultaneous certification procedure with several standards, please fill in the ollowing items:	
Integrated management system documentation including procedural and work instructions	☐ Yes ☐ No

Management reviews that take into account the overall business strategy and corporate plan	☐ Yes ☐ No
An integrated approach to internal audits	☐ Yes ☐ No
An integrated approach to the organisation‘s policies and goals	☐ Yes ☐ No
An integrated approach to system processes (process descriptions)	☐ Yes ☐ No
An integrated approach to improvement mechanisms (corrective and preventive actions; measurement and continuous improvement)	☐ Yes ☐ No
Integrated management support and responsibilities (joint management representatives)	☐ Yes ☐ No

9. Information on the transfer of a certification from other certiĀcation bodies	
Are the audit reports from the last certification period available?	☐ Yes ☐ No
Were there any non-conformities during the last audit?	☐ Yes ☐ No
Have all non-conformities from the last audit been closed?	☐ Yes ☐ No
Please attach the current certificates to be transferred in electronic form here:	
Why do you want to change the certifier	

Note: In the case of an order to take over a certification, please enclose all certificates issued by the last certification body and relevant for transfer, all audit reports and reports on non-conformities of the last certification period.

10. Existing certifications

Please enter your existing certifications here.

Certificate number	Standard	Certification Body	Date of certification audit	Valid until

11. Do you want to tell us something?

12. Note for preparing an oÃer and planning a (re-)certification or extension audit: Documents provided to TÜV NORD CERT in advance

- ☐ Extract from a professional or commercial register (or comparable evidence), if applicable
- ☐ Organisational chart / evidence of the organisational structure
- ☐ Current certificates (if available)

13. Note for planning a (re-)certification or extension audit: Documents to be made available to the auditor or the audit team in advance

- ☐ Extract from a professional or commercial register (or comparable evidence, if applicable)
- ☐ Management system documentation (e.g.: Table of contents or presentation of the structure of the management system documentation)
- ☐ Organisational chart/evidence of the organisational structure
- ☐ Corporate policy
- ☐ Management review (e.g.: cover sheet or table of contents with date and signature)
- ☐ Current annual planning of internal audits and evidence of audit report(s) (e.g.: cover sheet with date and signature)
- ☐ As applicable: List of critical suppliers, certifi ates, quality agreements and evidence for supplier evaluation.
- ☐ Standard-specific documents, if appli able
- ☐ Procedural instructions in German or English language

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Appendix 1: Information on company locations and branches

Company locations and branches to be included in the scope			
	1st location	2nd location	3rd location
Location name			
Address			
City			
Postal code			
Country			
Contact person			
Position			
Phone			
E-Mail			
Homepage			
Number of employees			
FTE Full-time equivalent			
Number of shifts			
Employees per shift			
Activities carried out at the respective site			
Development	☐	☐	☐
Production	☐	☐	☐
Packaging	☐	☐	☐
Sterilisation	☐	☐	☐
Storage	☐	☐	☐
Distribution	☐	☐	☐
Maintenance	☐	☐	☐
Administration	☐	☐	☐
Quality assurance	☐	☐	☐
Installation / Service	☐	☐	☐
Other	☐	☐	☐
Joint quality management system with the head offi	☐ Yes ☐ No, reason:	☐ Yes ☐ No, reason:	☐ Yes ☐ No, reason:
Desired scope			

For additional locations, please use a new questionnaire.

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Appendix 2: Information on products, manufacturing technologies and services

Products Manufacturing Technologies and Services		
Classification of Main technical Areas (IAF MD 9) for EN ISO 13485 will be made by applying (EU) 2017/745 (MDR) codes. Please note, that this is not an MDR application and select as applicable: ☐ Companies with Class I or higher products please select all applicable MDA / MDN and MDS product codes. ☐ Companies manufacturing components or providing services, please select the most applicable MDT / MDS / S codes for the most appropriate product technology or service(s).		
MDA, MDN, MDS, MDT		
	MDA	**Active Implantable Products**
☐	MDA 0101	Active implantable products for stimulation/inhibition/monitoring*
☐	MDA 0102	Active implantable devices delivering drugs or other substances
☐	MDA 0103	Active implantable devices substituting or replacing organ functions
☐	MDA 0104	Active implantable devices utilising radiation and other active implantable devices
	MDA	**Active non-implantable devices for imaging, monitoring and/or diagnostic purposes**
☐	MDA 0201	Active non-implantable imaging devices utilising ionizing radiation
☐	MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation
☐	MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters
☐	MDA 0204	Other active non-implantable devices for monitoring and/or diagnosis
	MDA	**Active non-implantable therapeutic products and general active non-implantable products**
☐	MDA 0301	Active non-implantable devices utilising ionizing radiation
☐	MDA 0302	Active non-implantable devices utilising non-ionizing radiation
☐	MDA 0303	Active non-implantable devices utilising hyperthermia / hypothermia
☐	MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)
☐	MDA 0305	Active non-implantable devices for stimulation or inhibition
☐	MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemopheresis
☐	MDA 0307	Active non-implantable respiratory devices
☐	MDA 0308	Active non-implantable devices for wound and skin care
☐	MDA 0309	Active non-implantable ophthalmologic devices
☐	MDA 0310	Active non-implantable devices for ear, nose and throat
☐	MDA 0311	Active non-implantable dental devices
☐	MDA 0312	Other active non-implantable surgical devices
☐	MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
☐	MDA 0314	Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
☐	MDA 0315	Standalone software including software design for medical devices

☐	MDA 0316	Medical gas supply systems and parts thereof
☐	MDA 0317	Active non-implantable devices for cleaning, disinfection and sterilisation
☐	MDA 0318	Other active non-implantable devices
	MDN	**Non-active implants and surgically invasive products for long-term use**
☐	MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
☐	MDN 1102	Non-active osteo- and orthopaedic implants
☐	MDN 1103	Non-active dental implants and dental materials
☐	MDN 1104	Non-active soft tissue and other implants
	MDN	**Non-active non-implantable devices**
☐	MDN 1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care
☐	MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
☐	MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filte s and related tools
☐	MDN 1204	Non-active non-implantable medical devices for wound and skin care
☐	MDN 1205	Non-active non-implantable orthopaedic and rehabilitation devices
☐	MDN 1206	Non-active non-implantable ophthalmologic devices
☐	MDN 1207	Non-active non-implantable diagnostic devices
☐	MDN 1208	Non-active non-implantable instruments
☐	MDN 1209	Non-active non-implantable dental materials
☐	MDN 1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases
☐	MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing
☐	MDN 1212	Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
☐	MDN 1213	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal oute
☐	MDN 1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices
	MDS	**Products with special properties**
☐	MDS 1001	Devices incorporating medicinal substances
☐	MDS 1002	Devices manufactured utilising tissues or cells of animal origin, or their derivatives
☐	MDS 1003	Devices manufactured utilising tissues or cells of human origin, or their derivatives
☐	MDS 1004	Devices which are also machinery as defined in point a) of the second paragraph of Article 2 of Directive 2006/42/EC

☐	MDS 1005	Devices in sterile condition: ☐ EO ☐ Radiation (gamma, electron, X-rays) ☐ Moist heat ☐ Hydrogen peroxide ☐ Aseptic filling ☐ Formaldehyde incl. low-temperature steam-formaldehyde sterilization ☐ Thermical sterilization processes, dry heat ☐ Plasma
☐	MDS 1006	Reusable surgical instruments
☐	MDS 1007	Devices incorporating or consisting of nanomaterial
☐	MDS 1008	Devices utilising biological active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body.
☐	MDS 1009	Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the per ormance of active or active implantable devices
☐	MDS 1010	Devices with a measuring function
☐	MDS 1011	Devices in systems or procedure packs
☐	MDS 1012	Products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745
☐	MDS 1013	Class III custom-made implantable devices
☐	MDS 1014	Devices incorporating as an integral part an in vitro diagnostic medical device
	MDT	**Products for which special technologies or processes are used**
☐	MDT 2001	Metal processing
☐	MDT 2002	Plastic processing
☐	MDT 2003	Non-metal mineral processing including glass, ceramics
☐	MDT 2004	Non-metal non-mineral processing including textiles, rubber, leather, paper
☐	MDT 2005	Biotechnology
☐	MDT 2006	Chemical processing
☐	MDT 2007	Production of pharmaceuticals
☐	MDT 2008	Clean room production
☐	MDT 2009	Processing of materials of human or animal origin (no accreditation for human material)
☐	MDT 2010	Manufacture or processing of electronic components including communication devices
☐	MDT 2011	Packaging, including labelling
☐	MDT 2012	Installation, refurbishment
☐	MDT 2013	Reprocessing of medical devices
	IVD	**In vitro diagnostics** Reagents and reagent products, calibrators, and control materials for
☐	IVD 4601	Clinical Chemistry
☐	IVD 4602	Haematology, haemostaseology, immunohaematology
☐	IVD 4603	Immunology

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☐	IVD 4604	Pregnancy and ovulation
☐	IVD 4605	Sample containers
☐	IVD 4606	In vitro diagnostics instruments and software
	S	**S-Codes**
☐	S 0121	Maintenance, repair and installation of medical devices (installation services)
☐	S 0139	Trade of medical devices
☐	S 0140	Custom made; for ☐ Dental technology ☐ Orthopedic and orthopedic shoe technology ☐ Rehabilitation technique
☐	S 0141	Transportation services
☐	S 0145	Semi-finished products and components
☐	S 0146	Raw materials
	TNC	**TNC-Scopes (KRINKO/BfArM)**
☐	TNC 9103	Reprocessing of reusable medical devices up to “critical C”
☐	TNC 9105	Reprocessing of reusable medical devices up to “critical B”

*For scopes highlighted in grey, TÜV NORD CERT is currently not designated/accredited

Questions mandatory to be answered by companies providing parts and/or services	
Is the product a nearly finished and a sembled medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling)	☐ Yes ☐ No
Is the product intended to be a component/part of a medical device?	☐ Yes ☐ No
Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabeling, remanufacturing of other medical devices)?	☐ Yes ☐ No
Is the product supplied sterile?	☐ Yes ☐ No
Does the product contain software developed by the client organization or a supplier?	☐ Yes ☐ No
Is “Design and Development” in the scope of the EN ISO 13485 certification?	☐ Yes ☐ No
Is the product (raw materials, parts, components, subassemblies, maintenance services, or other services) intended to support associated medical devices?	☐ Yes ☐ No

More information, products, technologies

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Appendix 3: Information on outsourced processes and subcontractors

Services and processes outsourced to external companies / critical suppliers			
	1st subcontractor	2nd subcontractor	3rd subcontractor
Name subcontractor			
Adress			
Homepage			
Quality assurance* agreement available	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Supplier evaluation available*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Certification of an accredited / notified body*	☐ None ☐ EN ISO 9001 ☐ EN ISO 13485 ☐ 93/42/EWG ☐ (EU) 2017/745 ☐ Other	☐ None ☐ EN ISO 9001 ☐ EN ISO 13485 ☐ 93/42/EWG ☐ (EU) 2017/745 ☐ Other	☐ None ☐ EN ISO 9001 ☐ EN ISO 13485 ☐ 93/42/EWG ☐ (EU) 2017/745 ☐ Other
Outsourced process	☐ Development ☐ Production ☐ Assembly ☐ Coating ☐ Cleaning ☐ Sterilisation ☐ Packaging ☐ Storage ☐ Transport ☐ Verification / Validation ☐ Marketing / Sales ☐ Installation / Service ☐ Other	☐ Development ☐ Production ☐ Assembly ☐ Coating ☐ Cleaning ☐ Sterilisation ☐ Packaging ☐ Storage ☐ Transport ☐ Verification / Validation ☐ Marketing / Sales ☐ Installation / Service ☐ Other	☐ Development ☐ Production ☐ Assembly ☐ Coating ☐ Cleaning ☐ Sterilisation ☐ Packaging ☐ Storage ☐ Transport ☐ Verification / Validation ☐ Marketing / Sales ☐ Installation / Service ☐ Other

*Evidence may be required prior to (re)certification audit
For additional subcontractors, please use a new questionnaire.

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We confirm all information and agree that our information will be stored as part of the offer preparation and process / order processing.

Place and date	Name	Signature

Print Save Send via E-mail

Please email the completed form to:
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