



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	
Contact person	<input type="checkbox"/> Mr <input type="checkbox"/> Ms <input type="checkbox"/> 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 office / parent company			
Number of employees		Number of shifts	
FTE Full-time equivalent		Employees per shift	
Activities carried out			
Development	<input type="checkbox"/>	Distribution	<input type="checkbox"/>
Production	<input type="checkbox"/>	Maintenance	<input type="checkbox"/>
Packaging	<input type="checkbox"/>	Administration	<input type="checkbox"/>
Sterilisation	<input type="checkbox"/>	Quality assurance	<input type="checkbox"/>
Storage	<input type="checkbox"/>	Installation / Service	<input type="checkbox"/>
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	

This document has been approved according to CERT-401-VA-007. Details are available from the QM-Department.

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3. Rolle(n) des Unternehmens (Mehrfachnennungen möglich)

<input type="checkbox"/> Manufacturer	<input type="checkbox"/> System & Procedure Pack Producer
<input type="checkbox"/> Authorised representative	<input type="checkbox"/> Trader / Sales partner
<input type="checkbox"/> Importer	<input type="checkbox"/> Other (please describe):

4. Welche Zertifizierungen streben Sie an?

Activity	Standard / service	
<input type="checkbox"/> Initial certification	<input type="checkbox"/> DIN EN ISO 9001	<input type="checkbox"/> DIN EN ISO 13485
<input type="checkbox"/> Recertification	<input type="checkbox"/> MDSAP (via TUV USA)	<input type="checkbox"/> MDR (separate application)
<input type="checkbox"/> Transfer	<input type="checkbox"/> Ukraine registration	
<input type="checkbox"/> Extension	<input type="checkbox"/> DIN EN ISO 13485 / KRINKO (Germany only; please use P11F007)	
<input type="checkbox"/> Change (please use additional P11F002)	<input type="checkbox"/> Other:	

5. Scope of certification

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 influence on the audit effort (multiple selection possible)

No Design / development	<input type="checkbox"/>
Products with low risk or low process risk (e.g. simple processes, no validations necessary)	<input type="checkbox"/>
Sophisticated management system	<input type="checkbox"/>
High number of employees with the same, simple job	<input type="checkbox"/>
Exclusively transport/trade within the scope of certification	<input type="checkbox"/>
Products with high risk or high process risk (e.g. processes requiring validation)	<input type="checkbox"/>
Large location with low employee density	<input type="checkbox"/>

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

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

7. What type of certification is being sought? (Multiple selection possible)	
Single-site certification (All locations are independently certified)	<input type="checkbox"/>
Multi-site certification (Sites are certified in one group)	<input type="checkbox"/>
Combined / Integrated Certification (Several management systems are audited simultaneously)	<input type="checkbox"/>
Do you want a simultaneous audit of all management systems?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Would you like a remote audit (maximum 50% of the audit time)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Do you have the necessary infrastructure for the remote audit?	<input type="checkbox"/> Yes <input type="checkbox"/> 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 following items:	
Integrated management system documentation including procedural and work instructions	<input type="checkbox"/> Yes <input type="checkbox"/> No

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

9. Information on the transfer of a certification from other certification bodies

Are the audit reports from the last certification period available?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Were there any non-conformities during the last audit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have all non-conformities from the last audit been closed?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?

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12. Note for preparing an offer 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, certificates, quality agreements and evidence for supplier evaluation.
- Standard-specific documents, if applicable
- 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Production	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sterilisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Storage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Distribution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Maintenance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality assurance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Installation / Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Joint quality management system with the head offi	<input type="checkbox"/> Yes <input type="checkbox"/> No, reason:	<input type="checkbox"/> Yes <input type="checkbox"/> No, reason:	<input type="checkbox"/> Yes <input type="checkbox"/> No, reason:
Desired scope			

For additional locations, please copy and paste this table below.

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Anhang 2: Informationen über Produkte, Fertigungstechnologien und Dienstleistungen

Produkte Fertigungstechnologien und Dienstleistungen		
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:		
<input type="checkbox"/> Companies with Class I or higher products please select all applicable MDA / MDN and MDS product codes.		
<input type="checkbox"/> 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
<input type="checkbox"/>	MDA 0101	Active implantable products for stimulation/inhibition/monitoring*
<input type="checkbox"/>	MDA 0102	Active implantable devices delivering drugs or other substances
<input type="checkbox"/>	MDA 0103	Active implantable devices substituting or replacing organ functions
<input type="checkbox"/>	MDA 0104	Active implantable devices utilising radiation and other active implantable devices
	MDA	Active non-implantable devices for imaging, monitoring and/or diagnostic purposes
<input type="checkbox"/>	MDA 0201	Active non-implantable imaging devices utilising ionizing radiation
<input type="checkbox"/>	MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation
<input type="checkbox"/>	MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters
<input type="checkbox"/>	MDA 0204	Other active non-implantable devices for monitoring and/or diagnosis
	MDA	Active non-implantable therapeutic products and general active non-implantable products
<input type="checkbox"/>	MDA 0301	Active non-implantable devices utilising ionizing radiation
<input type="checkbox"/>	MDA 0302	Active non-implantable devices utilising non-ionizing radiation
<input type="checkbox"/>	MDA 0303	Active non-implantable devices utilising hyperthermia / hypothermia
<input type="checkbox"/>	MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)
<input type="checkbox"/>	MDA 0305	Active non-implantable devices for stimulation or inhibition
<input type="checkbox"/>	MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemopheresis
<input type="checkbox"/>	MDA 0307	Active non-implantable respiratory devices
<input type="checkbox"/>	MDA 0308	Active non-implantable devices for wound and skin care
<input type="checkbox"/>	MDA 0309	Active non-implantable ophthalmologic devices
<input type="checkbox"/>	MDA 0310	Active non-implantable devices for ear, nose and throat
<input type="checkbox"/>	MDA 0311	Active non-implantable dental devices
<input type="checkbox"/>	MDA 0312	Other active non-implantable surgical devices
<input type="checkbox"/>	MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
<input type="checkbox"/>	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)
<input type="checkbox"/>	MDA 0315	Standalone software including software design for medical devices

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

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

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<input type="checkbox"/>	IVD 4604	Pregnancy and ovulation
<input type="checkbox"/>	IVD 4605	Sample containers
<input type="checkbox"/>	IVD 4606	In vitro diagnostics instruments and software
	S	S-Codes
<input type="checkbox"/>	S 0121	Maintenance, repair and installation of medical devices (installation services)
<input type="checkbox"/>	S 0139	Trade of medical devices
<input type="checkbox"/>	S 0140	Custom made; for <input type="checkbox"/> Dental technology <input type="checkbox"/> Orthopedic and orthopedic shoe technology <input type="checkbox"/> Rehabilitation technique
<input type="checkbox"/>	S 0141	Transportation Services
<input type="checkbox"/>	S 0145	Semi-finished products and components
<input type="checkbox"/>	S 0146	Raw materials
	TNC	TNC-Scopes (KRINKO/BfArM)
<input type="checkbox"/>	TNC 9103	Reprocessing of reusable medical devices up to "critical C"
<input type="checkbox"/>	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 assembled medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the product intended to be a component/part of a medical device?	<input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the product supplied sterile?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the product contain software developed by the client organization or a supplier?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is "Design and Development" in the scope of the EN ISO 13485 certification?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the product (raw materials, parts, components, subassemblies, maintenance services, or other services) intended to support associated medical devices?	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Supplier evaluation available*	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Certification of an accredited / notified body*	<input type="checkbox"/> None <input type="checkbox"/> EN ISO 9001 <input type="checkbox"/> EN ISO 13485 <input type="checkbox"/> 93/42/EWG <input type="checkbox"/> (EU) 2017/745 <input type="checkbox"/> Other	<input type="checkbox"/> None <input type="checkbox"/> EN ISO 9001 <input type="checkbox"/> EN ISO 13485 <input type="checkbox"/> 93/42/EWG <input type="checkbox"/> (EU) 2017/745 <input type="checkbox"/> Other	<input type="checkbox"/> None <input type="checkbox"/> EN ISO 9001 <input type="checkbox"/> EN ISO 13485 <input type="checkbox"/> 93/42/EWG <input type="checkbox"/> (EU) 2017/745 <input type="checkbox"/> Other
Outsourced process	<input type="checkbox"/> Development <input type="checkbox"/> Production <input type="checkbox"/> Assembly <input type="checkbox"/> Coating <input type="checkbox"/> Cleaning <input type="checkbox"/> Sterilisation <input type="checkbox"/> Packaging <input type="checkbox"/> Storage <input type="checkbox"/> Transport <input type="checkbox"/> Verification / Validation <input type="checkbox"/> Marketing / Sales <input type="checkbox"/> Installation / Service <input type="checkbox"/> Other	<input type="checkbox"/> Development <input type="checkbox"/> Production <input type="checkbox"/> Assembly <input type="checkbox"/> Coating <input type="checkbox"/> Cleaning <input type="checkbox"/> Sterilisation <input type="checkbox"/> Packaging <input type="checkbox"/> Storage <input type="checkbox"/> Transport <input type="checkbox"/> Verification / Validation <input type="checkbox"/> Marketing / Sales <input type="checkbox"/> Installation / Service <input type="checkbox"/> Other	<input type="checkbox"/> Development <input type="checkbox"/> Production <input type="checkbox"/> Assembly <input type="checkbox"/> Coating <input type="checkbox"/> Cleaning <input type="checkbox"/> Sterilisation <input type="checkbox"/> Packaging <input type="checkbox"/> Storage <input type="checkbox"/> Transport <input type="checkbox"/> Verification / Validation <input type="checkbox"/> Marketing / Sales <input type="checkbox"/> Installation / Service <input type="checkbox"/> Other

*Evidence may be required prior to (re)certification audit

For additional subcontractors, please copy and paste this table below.

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

Place and date

Name

Signature

Please email the completed form to:

medical@tuev-nord.de

TÜV NORD CERT GMBH

Notified Body for medical devices Am

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45307 Essen

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E-Mail: medical@tuev-nord.de