Application Form A

TÜV NORD Certification

Conformity Assessment Procedure - Quality System/Product

Application for the performance of a conformity assessment procedure according to the European directives for medical device

In case of questions, please contact medical@tuev-nord.de

Applicant: Please insert the complete company name	

Application Type

- ☐ Initial certification
- ☐ Transfer from another Notified Body
- ☐ Extension / re-certification
  Registration no. of effected certificate/s:
- ☐ Change (e.g. products, addresses, suppliers/subcontractors/OEM)
  Registration no. of effected certificate/s:

  Reason of change/s: please provide a detailed explanation of the change

Quality System

93/42/EEC MDD

- ☐ Annex II without (4)
  Full QS-System
- ☐ Annex V
  QS-System Production
- ☐ Annex V (I s)
  QS-System Production, Products of class I, sterile
- ☐ Annex V (I m)
  QS-System Production, Products of class I with measuring function
- ☐ Annex VI
  QS-System Product

Product / Design

93/42/EEC MDD

- ☐ Annex II (4)
  EC Design-Examination

TÜV NORD Certification

Conformity Assessment Procedure - Quality System/Product

Applicant:	

Applicant Assurance

	Conformity Assessment Procedure according Directive 93/42/EEC Annex			
	II w/o 4	II.4	V	VI
The applicant assures that no application, for this/these product(s), has been lodged with any other notified body for the same product-related quality system.	Yes	-	-	-
The applicant assures that no application has been lodged with any other notified body for the same device.	-	-	Yes	Yes
The applicant assures that no application has been lodged with any other notified body for the same type.	Yes	Yes	Yes	Yes
The applicant assures to fulfill the obligations imposed by the approved quality system.	Yes	-	Yes	Yes
The applicant assures to keep/maintain the approved quality system adequate and efficacious.	Yes	-	Yes	Yes
The applicant assures to notify the notified body of TÜV NORD CERT GmbH about all substantial changes to the quality system or the product range(s) covered.	Yes	-	Yes	Yes
The applicant assures to notify the notified body of TÜV NORD CERT GmbH about any plans for substantial changes implemented in the approved device.	-	Yes	-	-
The applicant assures to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action.	Yes	Yes	Yes	Yes
The applicant assures to notify the competent authorities of the following incidents immediately on learning of them: (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.	Yes	Yes	Yes	Yes
The applicant assures to notify the notified body of TÜV NORD CERT GmbH without any delay about any reportable incidents, recalls and issued advisory notices.	Yes	-	Yes	Yes

Date _____ Name _____ Signature Applicant _____

Data Applicant / Representative

Application:	
VAT No.	
Street, No.:	
Zip Code / City:	/
Country:	
Manufacturer ID:	Please enter the registration number with which you are registered at your competent authority for medical devices, as manufacturer.
Contact data:	Contact person:
	Telephone:
	Fax:
	E-Mail:

EC-Representative

Information about an EC-Representative is necessary for a manufacturer who places a device on the market under his own name and doesn't have a registered place of business in a member state of the EU. Since 2021, a UK-based EC representative is no longer accepted.

EC-Representative:	☐ **EC-representative not required**
Street, No.:	
Zip Code / City:	/
Country:	
Representative ID:	Please enter the registration number with which your representative is registered at his competent authority for medical devices, as representative.
Contact data:	Contact person:
	Telephone:
	Fax:
	E-Mail:

Application Form C:

TÜV NORD Certification

Information about the Product

Application for the products to be taken into the scope of the certificate.

Before processing the forms, please read the notes in the appendix under "Explanation to the processing of the application forms".

If there are more products to be considered, please download the additional form "C" from our website https://www.tuev-nord.de/de/unternehmen/zertifizierung/medizinprodukthersteller/download/.

Applicant:	
Product Designation please also specify all variants, Article numbers and all components in case of Systems or Sets. You may refer to a product list attached to this application. Note: Application and attachment will only be valid together	Product name/Brand name:
	Type/Types
	P/N / REF:
Application	☐ Extension / re-certification (follow-up application) ☐ Transfer from another Notified Body ☐ New product (initial application) ☐ Change of Name ☐ Enhancement / Change / new variant ☐ Changed intended use ☐ Description of change ☐ Product deregistration
Intended use	According information of use or clinical evaluation.
Product description	Please insert here a short description of the product.
Product Category	Please enter all applicable product categories (MD, MDS) Non active and active medical devices (MD) Medical devices with special constituents, raw materials or regulations, special procedures (MDS)
Product Group	☐ UMDNS or ☐ GMDN Code: Description:
Classification	Classification according directive 93/42/EEC Annex IX Rule No.: Class:
Performance Data	
Specification	

TÜV NORD Certification

Information about the Product

Applicant:	Product:

Production In case of outsourced processes please submit information with application form D	☐ Development, production and testing of the product take place only in the own facility. ☐ Development, production and testing of the product take place partly or completely in a proprietary subsidiary. ☐ Development, production and testing of the product take place partly or completely at an external subcontractor. ☐ Development, production and testing of the product take place completely at an external OEM.
Reusability	☐ The product is intended for single use only ☐ The product is intended reusable
Sterilization (MDS 7006), Refurbishing	☐ The product is sold sterile ☐ The product needs to be sterilized prior use by the user. ☐ The product can be sterilized several times Sterilization procedure /-method: Applied standard for validation:
Shelf life	
Biological evaluation	Applied standard: Please refer also applied part of the standards (e.g. EN ISO 10993-1, -5, -7).
Clinical evaluation	Basis for clinical evaluation: ☐ Literature route ☐ Own clinical data / studies ☐ Combination of literature route and own clinical data / studies.
Special constituents	☐ The product contains a substance which, if used separately, can be considered to be a medicinal product (MDS 7001). Description of the constituents: ☐ The product contains constituents which have been manufactured utilizing tissues of animal origin which do **not fall** under regulation (EC) 722/2012 (TSE, BSE) (MDS 7002). ☐ The product contains constituents which have been manufactured utilizing tissues of animal origin which fall under regulation (EC) 722/2012 (TSE, BSE) (MDS 7002). ☐ The product contains derivatives of human blood (MDS 7003). ☐ The product contains parts/components of micromechanics (MDS 7007). ☐ The product contains nanomaterials (MDS 7008). ☐ The product contains coatings and/or materials which are biological active and/or being wholly or mainly absorbed (MDS 7009). ☐ The product contains software / utilized software / is controlled by software (MDS 7010). ☐ The product is networkable, has smart features. ☐ The product contains Phthalates. ☐ The product contains Latex.

Information about the Product

Applicant:	Product:

Application of further directives	☐ Safety objectives of other that the European directives for medical devices have been considered e.g. Machinery directive 2006/42/EC (MDS 7004) Applied directive/s:
Evaluation of technical documentation	☐ The technical documentation was already evaluated by a Notified Body Name of the Notified Body: Date of evaluation report:
Furth important information about the product	
Attachments to this application	

Date	Name	Signature Applicant

TÜV NORD CERT GmbH confirms that the above mentioned product is covered under the scope of the certificate.

Date	Reg. No. Certificate	Signature TÜV NORD CERT GmbH

Remarks of the Notified Body:

Application Form D:

TÜV NORD Certification

Subsidiaries, subcontractors, supplier, OEM

Applicant:	**Product:**

Application for subsidiaries, critical subcontractors, suppliers of crucial components or of the entire device to be taken into the scope of the certificate.

Before processing the forms, please read the notes in the appendix under "Explanation to the processing of the application forms".

If there are more products to be considered, please download the additionally form "D" from our website.

Subsidiary / Subcontractor/ Supplier / OEM		**Outsourced process**				**Description/Details about outsourced processes**
		Development	**Manufacturing/Production**	**Product testing**	**Sterilization**	
Function	☐ **Own subsidiary** ☐ **Supplier** ☐ **Subcontractor** ☐ **OEM**	☐	☐	☐	☐	
Name						
Street, No.:						
Zip Code/ City:	/					
Country:						

TÜV NORD Certification

Subsidiaries, subcontractors, supplier, OEM

Applicant:	Product:

Subsidiary / Subcontractor/ Supplier / OEM		Outsourced process: Development	Manufacturing/Production	Product testing	Sterilization	Description/Details about outsourced processes
Function	☐ Own subsidiary ☐ Supplier ☐ Subcontractor ☐ OEM	☐	☐	☐	☐	
Name						
Street, No.:						
Zip Code/ City:	/					
Country:						
Function	☐ Own subsidiary ☐ Supplier ☐ Subcontractor ☐ OEM	☐	☐	☐	☐	
Name						
Street, No.:						
Zip Code/ City:	/					

TÜV NORD Certification

Subsidiaries, subcontractors, supplier, OEM

Applicant:	Product:

Subsidiary / Subcontractor/ Supplier / OEM		Outsourced process: Development	Manufacturing/Production	Product testing	Sterilization	Description/Details about outsourced processes
Country:						
Function	☐ Own subsidiary ☐ Supplier ☐ Subcontractor ☐ OEM	☐	☐	☐	☐	
Name						
Street, No.:						
Zip Code/ City:	/					
Country:						
Function	☐ Own subsidiary ☐ Supplier ☐ Subcontractor ☐ OEM	☐	☐	☐	☐	
Name						
Street, No.:						

Application Form D:

TÜV NORD Certification

Subsidiaries, subcontractors, supplier, OEM

Applicant:	**Product:**

Subsidiary / Subcontractor/ Supplier / OEM		**Outsourced process**				**Description/Details about outsourced processes**
		Development	**Manufacturing/Production**	**Product testing**	**Sterilization**	
Zip Code/ City:	/					
Country:						

TÜV NORD CERT GmbH confirms that the above mentioned subsidiary / subcontractor/ supplier / OEM are covered under the scope of the certificate.

Date	Reg. No. Certificate	Signature TÜV NORD CERT GmbH

PRINT

SAVE SEND BY E-MAIL

Remarks of the Notified Body::

Explanation to the processing of the application forms

Use of the application forms

Application form A

Form A contains the actual application for the performance of a conformity assessment procedure. It must invariably be completed before the conformity assessment procedure is implemented and it must be signed by a competent person of the manufacturer or his EC-Representative.

It is important that no application has been lodged concurrent to another Notified Body for the same product.

Application form B

On form B please enter all the "master data" for your company. If you have an EC-Representative according article 14 of the MDD please enter this in the lower part of the form.

This data are essential for issuing certificates and for information of the competent authorities for medical devices via the DIMDI. We as a Notified Body are obligated to submit this data. More information about the DIMDI can be obtained under www.dimdi.de.

In case of changes of these data please submit this change/s with form B.

Application form C

In form C all product specific data needs to be entered. This form needs to be submitted in case of initial certification, extension/re-certification and essential changes of products or new variants. For each product, maximum for one product category a single form needs to be submitted. By this data it will be specified which products are covered by the conformity assessment procedure. This is also important because it's possible that in the annex of the issued certificate only product categories are listed and not each single product/variant.

Furthermore we are obligated to report all products to the competent authorities via the DIMDI. These data are then submitted to the European database EUDAMED.

As soon as the product was added to the scope of the certificate the Notified Body of TÜV NORD CERT GmbH confirms this by signature. CE mark can be affixed to product after receipt of this confirmation.

Form C must be signed by a competent person of the manufacturer or his EC-Representative.

Application form D

With form D all information about subsidiaries, critical subcontractors, crucial suppliers or OEM needs to be submitted which are involved by out sourced process in the manufacturing of the product. For each product which is manufactured by out sourced processes a single form D needs to submitted.

Form D needs to be submitted for each product which is manufactured by out sourced processes and for which also a form C was submitted.

Subsidiaries, critical subcontractors, crucial suppliers or OEM which have not been announced to the Notified Body are excluded from the scope of the certificate.

Explanation to the processing of the application forms

Explanation to single data fields:

Application form A

Applicant	Please enter the full name of your company. This name will be printed on the certificates.
Application type	Please tick if appropriate and insert necessary information.
Quality-System	Please tick the chosen conformity assessment procedure.
Product / Design	Please tick the chosen conformity assessment procedure.

Application form B

A certificate can only be issued if the following data are complete and correct.

Applicant	In this field the name entered in form A will be shown.
VAT No.	Please enter the VAT no. of your company.
Street, No., Zip code, City, Country	Please enter the full address of your company. This address will be printed on the certificate
Manufacturer ID	This information is necessary for companies who place a device on the market under his own name and have a registered place of business in a member state of the EC. Please enter the registration number with which you are registered at your competent authority for medical devices, as manufacturer. For example, Germany according to the scheme: DE/0000099999
Contact data	Please enter the data for our contact person in your company.

EC-Representative

The following information are necessary for companies who place a device on the market under his own name and **doesn't have** a registered place of business in a member state of the EC.

A certificate can only be issued if the following data are complete and correct.

EC-Representative	Please enter the name of your representative. These data needs to be submitted to DIMDI together with data of the certificate.

Explanation to the processing of the application forms

Application form B

Street, No., Zip code, City, Country	Pleases enter the complete address of your representative. These data needs to be submitted to DIMDI together with data of the certificate.
Representative ID	Please enter the registration number with which representative is registered at his competent authority for medical devices, as representative. For example, Germany according to the scheme: DE/0000099999. These data needs to be submitted to DIMDI together with data of the certificate.
Contact data	Please enter the data of the contact person of your representative.

Application form C

Applicant	In this field the name entered in form A will be shown.
Product Designation	
Product name/Brand name	Please enter the name of the product according to the product label.
Type/Types	If applicable please enter the different types of the product Please enter the name of the product according to the product label. If there is not enough space in the field please submit a list with the types of the product as attachment.
P/N / REF	Please enter part no. / REF of the product according to the product label.
Application	Please tick appropriate application.
Intended use	Please enter the exact intended use of the product. If applicable enter also all restrictions of use for the product. This information should be identically with the information of use and/or the clinical evaluation.
Product description	Please enter a short description of the product. From this description the mode of operation and the use of the product should be clear.
Product Category	In the following table you will find the possible product categories. Please enter all applicable product categories according to the intended use (MD) and if applicable special constituents, raw materials or properties of the product (MDS) If no of the available categories apply to you product please enter the appropriate category “other” (MPNS, MPAS).

Application form C

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 0107	Non-active contraceptive medical devices
MD 0108	Non-active devices for disinfecting, cleaning and rinsing
MD 0109	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MD 0110	Non-active medical devices for ingestion
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
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
Non-active dental medical devices and accessories	
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants
General active medical devices	

Application form C

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 1110	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MD 1111	Software
MD 1112	Medical gas supply systems and parts thereof
Devices for imaging	
MD 1201	Active devices utilizing ionizing radiation
MD 1202	Active devices utilizing non-ionizing radiation
Monitoring devices	
MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters
Devices for radiation therapy and thermo therapy	
MD 1401	Active devices utilizing ionizing radiation
MD 1402	Active devices utilizing non-ionizing radiation
MD 1403	Active devices for hyper- and hypothermia
MD 1404	Active devices for (extracorporal) shock-wave therapy (lithotripsy)

Application form C

Medical devices with special constituents, raw materials or regulations, special procedures	
MDS 7001	Medical devices incorporating medicinal substances drugs (Directive 2001/83/EC)
MDS 7002	Medical devices manufactured utilizing tissues of animal origin (including Regulation 722/2012)
MDS 7003	Medical devices with derivatives of human blood (Directives 2000/70/EG and 2001/104/EG)
MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
MDS 7005	Currently not used
MDS 7006	Medical devices in sterile conditions
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

Product Group	Please enter the correct code and description according UMDS or GMDN.
Classification	Please enter the medical device class which you have identified for your product by application of the classification rules in directive 93/43/EEC annex IX (Is, Im, IIa, IIb, III) and the applied rule.
Performance Data	Please describe essential parameter of you product. E.g.: laser output max. 5mW, pulse frequency max. 5Hz or processing time of composite approx. 8 min.
Specification	Please enter essential specifications of the product. E.g. dimensions, concentration of essential ingredients
Production **Critical subcontractors** **Supplier of crucial components or of the entire devices** **OEM**	Please submit information if relevant parts of development, manufacturing and/or testing are sourced out. If so, please submit further information with form D.

Explanation to the processing of the application forms

Application form C

Reusability	Please tick appropriate if your product is intended for single use or if it is reusable.
Sterilization, Refurbishing	Please enter necessary information for products which are delivered sterile or which need to be sterilized prior use by the user.
Sterilization procedure /-method	Please enter the sterilization procedure / method (e.g. steam, ethylene oxide Sterilization, sterilization irradiation).
Applied standard for validation	Please enter applied standard for validation of sterilization.
Shelf life	Please enter the defined self life for the product in years.
Biological evaluation	
Applied standard	Please enter all standards which have been applied for demonstration of biocompatibility of the product. Please enter also all applied parts of the standards. E.g. EN ISO 10993-1, -5, -7.
Clinical evaluation	Please tick the used data basis for the clinical evaluation of the product.
Special constituents	Please tick appropriate.
Description of the constituents	Please enter the exact name of the constituents or a brief description.
Application of further directives	
Applied directive/s	Please enter further European directive which have been considered for the product.
Evaluation of technical documentation	
Name of the Notified Body	If the technical documentation of the product was already evaluated by a Notified Body (including TÜV NORD CERT GmbH) please enter the name of the Notified Body.
Date of evaluation report	Please enter the date of the last evaluation report
Furth important information about the product	Please enter here further information about the product which you consider to be important for the conformity assessment procedure.
Attachments to this application	Please enter here all attachments which you submit with this application. E.g. list of products, further information about the product, etc.

Explanation to the processing of the application forms

Application form D

Subsidiaries, critical subcontractors, supplier of crucial components or of the entire devices

Name	Please enter the exact name of all subsidiaries, critical subcontractors, crucial suppliers or OEM which are involved by out sourced process in the development, manufacturing or testing of the product. If information for more than 5 companies needs to be submitted please use further form D
Street, No., Zip code, City, Country	Please enter the exact address of all subsidiaries, critical subcontractors, crucial suppliers or OEM which are involved by out sourced process in the development, manufacturing or testing of the product.
Out sourced process	Please tick appropriate.
Description/Details about out sourced processes	Please submit details about the out sourced processes. E.g. manufacturing out sourced for 100%, Laboratory services for sterility testing