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 products and quality systems for medical devices

Appendix E Information for conformity assessment procedure according to regulation of 93/42/EEC

TÜV NORD CERT GmbH
Certification body for medical devices

Langemarkstraße 20
45141 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.

Applicant (precise legal form of company name)	

Product information and the environmental conditions

Device Name (Model / Brand (Trade name) / Article / Type):

Category according to EN ISO 15225 (please select as applicable):

☐	Active implantable products (01)	☐	Reusable instruments (09)
☐	Anaesthesia and respiratory devices (02)	☐	Single use devices (10)
☐	Dental products (03)	☐	Technical aids for disabled persons (11)
☐	Electrical and mechanical medical devices (04)	☐	Diagnostic and therapeutic radiation devices (12)
☐	Hospital hardware (05)	☐	Complementary therapy products (13)
☐	Products of In-vitro-Diagnostic (06)	☐	Products of biological origin (14)
☐	Non active implantable products (07)	☐	Products for health care institutions and adjustments (15)
☐	Ophthalmologic and optical products (08)		

Product Categories:

NANDO[1] Code UMDNS[2] Code or GMDN[3] Code:

Classification: Rule:

Intended use of a medical device / normal use

Please provide detailed description. If applicable, please add attachments. E.g. location, destination, target group, duration of use, ingredients, applied technologies, etc.

[1] NANDO New Approach Notified and Designated Organisations
[2] UMDNS Universal Medical Devices Nomenclature System (further information can be found on: www.DIMDI.de)
[3] GMDN Global Medical Device Nomenclature (further information can be found on: www.gmdnagency.com)

Performance:	**Specifications:**

Shelf life / product life time

Period:

Sterilization validation:

☐ delivered sterile ☐ Sterilisation by the applicant ☐ Sterilisation by a subcontractor

☐ Resterilisation acceptable

Method of sterilisation: validation / revalidation at: Standards used:

Biological assessment:
according to EN ISO 10993-ff

First assessment date:

Basis of clinical assessment

☐ Literature route ☐ Clinical study

Date of the first assessment:

What safety objectives of other directives were considered

E.g. Directive 2006/42/EC on machinery or Directive 89/686/EEC for Personal Protection

Does the product contain pharmaceutical substances?

☐ Yes ☐ No

If yes, please state the substance name.

Does the product contain material of animal origin?

☐ Yes ☐ No

If yes, please state the name of the material, source and original country.

Questionnaire for certification of products and quality systems for medical devices

<u>Appendix E</u> Information for conformity assessment procedure according to regulation of 93/42/EEC

TÜV NORD Certification

OEM[4] Product			
Are there products manufactured by an OEM? ☐ Yes ☒ No If yes, under which conditions: ☐ The OEM acts itself as the manufacturer for the product in compliance with the Medical Device Directive and has the corresponding certificate issued by a notified body. Please attach the relevant certificates of the OEM. ☐ The OEM **doesn't** act itself as the manufacturer for the product in compliance with the Medical Device Directive, but it has the certificate issued by a Notified Body, which covers the product class/product category. Please attach the relevant certificates of the OEM. ☐ The OEM **doesn't** act itself as the manufacturer for the product in compliance with the Medical Device Directive, neither has a certificate issued by a Notified Body, which covers the product class/product category			
Are the products, semi-finished products, components or software manufactured by a subcontractor or are there relevant production stages performed by subcontractors?			
☐ Yes, please complete Appendix C ☐ No		Name of subcontractor(s):	
Under which defined conditions is the product manufactured?			
☐	Temperature	☐	ESD controll area
☐	Humidity	☐	Radiation Protection Areas
☐	Air particle concentration	☐	Cleanroom condition according to EN ISO14644 Cleanroom classification:
☐	Microbiological status	☐	Others:
Has the technical documentation already been evaluated by a Notified Body?			
☐ Yes Name of Notified Body: _____ Assessment Date according to testing report: _____		☐ No, not yet	
In which language is the technical documentation available?[5]			
German ☐ English ☐			

Name _____ Date _____ Customer signature _____

DELETE PRINT SAVE SEND BY E-MAIL

[4] OEM = Original Equipment Manufacturer

[5] We only accept the technical documentation in English or German. If the technical documentation (individual components) is available in other languages, it must be certified and translated into English or German.