Questions for quoting	TÜVRheinland®

Please send the completed questionnaire (4 pages) to:

TÜV Rheinland LGA Products GmbH Phone: +49 911 655 5225 E-mail: service@de.tuv.com		
Our locations:		
Am Grauen Stein D-51105 Köln **Your contact persons:** Gerald.Breuninger@de.tuv.com Nicole.Mechow@de.tuv.com Florian.Staudigel@de.tuv.com	Tillystraße 2 D-90431 Nürnberg **Your contact person:** Bojan.Milojevic@de.tuv.com	Alboinstraße 56 D-12103 Berlin **Your contact person:** Sandro.Holl@de.tuv.com

The information in the attachment supports you when completing this questionnaire. If you have any questions, please contact us! ***Challenge us – we take care of you!***

1. Details about the company and contact persons

Legal company name:	
Contact person:	Title:
Street:	City, State, ZIP:
Phone no.:	Fax no.:
Website:	E-mail (general):
E-Mail (contact person):	

2. List of the specified products with classification

Products (+ intended use)	EC Directive			Tissues of Animal Origin used?	Does product contain nanoparticles < 100nm?	Sterile? * ☐ yes ☐ no				Invasive Device? ☐ yes ☐ no			Classification + rules (for products acc. to MDD)
	MDD	IVDD	AIMDD			Steam	ETO	Irradiation	Other	Implant	Short term	Long Term	
1	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
2	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
3	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
4	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
5	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
6	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

* Is the sterilization process validated with the specified products?	☐ yes	☐ no
If yes, is the sterilization performed in house?	☐ yes	☐ no
Do you maintain Cleanroom conditions? If yes, which classification (acc. to EN ISO 14644)?	☐ yes	☐ no

Questions for quoting	TÜVRheinland®

Please inform us about the categorization of your medical devices in subcategories (class IIa) and/or generic device groups (class IIb) as per directive 2007/47/EC in the attachment to questions for quoting.

Do you sell products under your own company name, which are produced by other companies (OEM – PLM)?	☐ yes	☐ no
If yes, did the original equipment manufacturer (OEM) already carry out a conformity assessment procedure?	☐ yes	☐ no
If yes: is the complete technical documentation available?	☐ yes	☐ no
If it is not available: does a report by a notified body exist?	☐ yes	☐ no

Do any quality management system (QMS) certificates for your company already exist?	☐ yes	☐ no

3. Desired conformity assessment procedure (please refer to page 5 of the attachment)

MDD (93/42/EEC) EC Directive on medical devices	**IVDD** (98/79/EC) EC Directive on In vitro diagnostics	**AIMDD** (90/385/EEC) EC Directive on active implantable medical devices	**QMS** certificates
☐ Annex II (without II.4) ☐ Annex II.4 ☐ Annex III + IV ☐ Annex III + V ☐ Annex III + VI ☐ Annex IV ☐ Annex V ☐ Annex VI	☐ Annex III.6 ☐ Annex IV.3 ☐ Annex IV.3 + IV.4 + IV.6 ☐ Annex V + VI ☐ Annex V + VII ☐ Annex V + VII.3 + VII.5	☐ Annex 2	☐ No certificate ☐ EN ISO 9001 ☐ EN ISO 13485 ☐ ISO 15378 ☐ ISO 13485 under CMDCAS ☐ MDSAP
			Further international approvals: ☐ FDA Mock audit ☐ TCP Taiwan

Do you wish a Pre-audit (Recommended in case of certification for the first time)?		☐ yes	☐ no
In which language can audits be carried out?	☐ German	☐ English	☐ _____
In which language is your QM system described?	☐ German	☐ English	☐ _____
In which language is your technical documentation written?	☐ German	☐ English	☐ _____

4. Details about your quality management system

Please specify the scope of your quality management system (QMS), as stated in your quality manual:	< Example for scope: Design and development, manufacture and distribution of dental implants >
Activities excluded from the scope of the QMS: (Please mark if applicable)	☐ Production ☐ Design and development
Did you receive consultancy regarding the implementation of your QMS?	☐ yes, by: ☐ no

Questions for quoting	TÜVRheinland®

Please specify the (approximate) number of employees in the particular departments **Name and address of the headquarters, as well as of the possible subsidiaries/branches**	Departments								**Sum**	No. of shifts
	Quality Management	Design and Development	Purchasing	Production	Warehouse	Sales	Service	Other		
Comments:										

Please specify all appropriate Production Technologies applicable to your device(s)			
Joining technologies (special processes which require validation, e.g. welding, gluing, brazing and soldering)	☐	Textile/fiber processing, weaving technologies (bandages, wound dressings, implants)	☐
Polymer processing (extrusion, injection moulding for plascitcs, wound dressings, etc)	☐	Biotechnology Manufacturing techniques (pharmaceuticals, medicine, reagents)	☐
Metal (machining, grinding, cutting, finishing, etc)	☐	Manufacturing techniques for ceramics	☐
Thin and thick film manufacturing (electronic devices such as surface mount devices, sensors and printed circuit boards)	☐	Micro precision manufacturing processes (for precise devices such as catheters, bone screws, micromechanics and optics)	☐
Reprocessing (KRINKO/BfArM)	☐	Materials of animal origin	☐

Processes	**Name and location of subcontractors which perform outsourced processes**
Design and Development	
Production	
Packaging	
Sterilisation	
Warehouse	
Service	
Comments:	

5. Controlled environmental conditions / specification about your products

Do you manufacture under defined environmental conditions? ☐ yes ☐ no	
If yes, which parameters or certain areas are controlled and monitored?	
☐ temperature ☐ humidity ☐ total particle counts ☐ microbial counts	☐ ESD controlled areas ☐ radiation protected areas ☐ others:

6. Time scale/scheduling:

Please specify your desired dates for:	
the product test/product documentation review:	the Pre-audit (voluntary):
Stage 1 audit:	Stage 2 (Certification) audit:

- Please consider that the interval between stage 1 and stage 2 should be > 10 days and < 3 months.

Are you ready?	
Checklist	
Please attach the following information:	
• Company brochure	☐
• Relevant product information/brochures/instructions for use	☐
• Copies of any valid **EC Directive certificate**	☐
• Copies of any valid **QMS certificate**	☐
• Organization chart of the headquarter as well as of subsidiaries/branches (if applicable)	☐
• Copies of any valid QMS and regulatory certificates of the subcontractors	☐
• Copies of existing EC Directive certificates of OEMs (QM system as well as product-related certificates, if applicable)	☐

Place, Date	Name	Legally binding signature
_____, _____	_____	_____

Additional information about the questions for quoting	TÜVRheinland®

Which EC directive covers your product?

Is your product a medical product?

Art.1(2)a [93/42/EEC]
'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

... or is your product an accessory of a medical product?

Art.1(2)b [93/42/EEC]

'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

Is your medical product an in vitro diagnostic medical device?

Art.1(2)b [98/79/EC]

'in vitro diagnostic medical device´ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles´ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination. Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

Is your medical product an active implantable medical device?

Art.1(2)b+c [90/385/EEC]

'active medical device'
means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

'active implantable medical device'
means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

Internet link: List of relevant EC directives:
http://www.newapproach.org/Directives/DirectiveList.asp

How is your medical product classified?

1. According to MDD

Annex IX directive 93/42/EEC amended by directive 2007/47/EC

Rule 1

All **non-invasive devices** are in **Class I**, unless one of the rules set out hereinafter applies.

Rule 2

All **non-invasive devices** intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in **Class IIa**:

- if they may be connected to an active medical device in Class IIa or a higher class,
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues,

in all other cases they are in **Class I**.

Rule 3

All **non-invasive devices** intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in **Class IIb**, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in **Class IIa**.

Rule 4

All **non-invasive devices** which come into contact with injured skin:

- are in **Class I** if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,
- are in **Class IIb** if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,
- are in **Class IIa** in all other cases, including devices principally intended to manage the micro-environment of a wound.

Rule 5

All **invasive devices** with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in **Class I**:

- are in **Class I** if they are intended for transient use,
- are in **Class IIa** if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in **Class I**,
- are in **Class IIb** if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in **Class IIa**.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in **Class IIa**.

Rule 6

All **surgically invasive devices** intended for transient use are in **Class IIa** unless they are:

- intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in **Class III**,
- reusable surgical instruments, in which case they are in **Class I**,
- intended specifically for use in direct contact with the central nervous system, in which case they are in **Class III**,
- intended to supply energy in the form of ionising radiation in which case they are in **Class IIb**,
- intended to have a biological effect or to be wholly or mainly absorbed in which case they are in **Class IIb**,
- intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in **Class IIb**.

Additional information about the questions for quoting	TÜVRheinland®

Rule 7
All **surgically invasive devices** intended for **short-term** use are in **Class IIa** unless they are intended:
- either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in **Class III**,
- or specifically for use in direct contact with the central nervous system, in which case they are in **Class III**,
- or to supply energy in the form of ionizing radiation in which case they are in **Class IIb**,
- or to have a biological effect or to be wholly or mainly absorbed in which case they are in **Class III**,
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in **Class IIb**.

Rule 8
All **implantable devices** and **long-term surgically invasive devices** are in **Class IIb**[1] unless they are intended:
- to be placed in the teeth, in which case they are in **Class IIa**,
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in **Class III**,
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in **Class III**,
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in **Class III**.

Rule 9
All **active therapeutic devices** intended to administer or exchange **energy** are in **Class IIa** unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in **Class IIb**.
All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in **Class IIb**.

Rule 10
Active devices intended **for diagnosis** are in **Class IIa**:
- if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,
- if they are intended to image in vivo distribution of radiopharmaceuticals,
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in **Class IIb**.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in **Class IIb**.

Rule 11
All **active devices** intended to administer and/or remove medicines, body liquids or other substances to or from the body are in **Class IIa**, unless this is done in a manner:
- that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in **Class IIb**.

Rule 12
All **other active devices** are in **Class I**.

[1] Consider COMMISSION DIRECTIVE 2003/12/EC of 3 February 2003
on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices and

COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005
on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices

Additional information about the questions for quoting	TÜVRheinland®

Rule 13
All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.
All devices incorporating, as an integral part, a human blood derivative are in **Class III**.

Rule 14
All devices used for **contraception** or the prevention of the transmission of sexually transmitted diseases are in **Class IIb**, unless they are **implantable** or **long term invasive devices**, in which case they are in **Class III**.

Rule 15
All devices intended specifically to be used **for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses** are in **Class IIb**. All devices intended specifically to be used for **disinfecting medical devices** are in **Class IIa** unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.
This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

Rule 16
Devices specifically intended for recording **of X-ray diagnostic images** are in **Class IIa**.

Rule 17
All devices manufactured utilizing **animal tissues** or derivatives rendered **non-viable** are **Class III** except where such devices are intended to come into contact with intact skin only.

Rule 18
By derogation from other rules, **blood bags** are in **Class IIb**.

2. According to IVDD
Annex II [98/79/EC]

IVD devices according to list A:
Reagents and reagent products, including related calibrators and control materials,
for determining the following blood groups:
- ABO system,
- rhesus (C, c, D, E, e)
- anti-Kell,

for the detection, confirmation and quantification in human specimens of markers of
- HIV infection (HIV 1 and 2),
- HTLV I and II
- hepatitis B, C and D.

IVD devices according to list B:
Reagents and reagent products, including related calibrators and control materials,
for determining the following
- blood groups: anti-Duffy and anti-Kidd,
- irregular anti-erythrocytic antibodies,
- HLA tissue groups: DR, A, B,

for the detection and quantification in human samples of
- congenital infections: rubella, toxoplasmosis,

for diagnosing of
- hereditary disease: phenylketonuria,
- human infections: cytomegalovirus, chlamydia,
- tumoral marker: PSA,

designed specifically for evaluating the risk of
- trisomy 21 (also software),

Device for self-diagnosis, including its related calibrators and control materials:
- device for the measurement of blood sugar.

IVD devices for self-testing:
Art.1(2)d [98/79/EC]: ‘device for self-testing´ means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

IVD devices for performance evaluation:
Art.1(2)e [98/79/EC]: ‘device for performance evaluation´ means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises;

Other in vitro diagnostic medical devices

What are the conformity assessment procedures?

MDD	Design phase	Production phase
Class	Annex	Annex
I	**VII *)**	
I (S)	**VII**	**V (S) **)**
	II **)	
I (M)	**VII**	**V (M) **)**
		VI (M) **)
		IV (M) **)
	II **)	
IIa	**VII**	**V**
		VI
		IV
	II	
IIb	**III**	**V**
		VI
		IV
	II	
III	**III**	**V**
		IV
	II (incl. annex II.4)	

Class I (S)	Class I sterile medical product
Class I (M)	Class I medical product with measuring function
Annex II	Full QA system without annex II.4
Annex II.4	EC design-examination (“Design dossier review”)
Annex III	EC type-examination
Annex IV	EC verification
Annex IV (M)	EC verification referring to measuring function
Annex V	QA system production
Annex V (S)	QA system production referring to sterilisation
Annex V (M)	QA system production referring to measuring function
Annex VI	QA system product
Annex VI (M)	QA system product referring to measuring function
Annex VII	EC conformity declaration

IVDD	Design phase	Production phase
Product list	Annex	Annex
Annex II, list A	**IV.4 + IV.3 + IV.6**	
	V	**VII.3 + VII.5**
Annex II, list B	**IV.3**	
	V	**VII.3**
		VI
Self-testing	**III.6**	
	V	**VII.3**
		VI
	IV.3	
Dev. for performance evaluation	**III +VIII *)**	
Other IVD	**III *)**	

Annex III	EC conformity declaration
Annex III.6	Examination of the design
Annex IV.3	Full QA system
Annex IV.4	EC design-examination (“Design dossier review”)
Annex IV.6	Verification of manufactured products
Annex V	EC type-examination
Annex VII.3	QA system production
Annex VII.5	Verification of manufactured products
Annex VI	EC verification
Annex VIII	Statement and procedures concerning devices for performance evaluation

AIMDD	Design phase	Production-phase
active implantable medical device	Annex	Annex
	2	
	3	**5**
		4

Annex 2	Full QA system and EC design-examination (“Design dossier review”)
Annex 3	EC type-examination
Annex 4	EC verification
Annex 5	QA system production

*) for assessing the Technical Documentation of products of Class I (MDD), devices for performance evaluation (IVDD) and „other IVD“ (IVDD), the involvement of a Notified Body is not required. On your request we can offer you a voluntary review of your Technical Documentation.
**) for aspects of sterilisation or metrological requirements (see Annex VII (5))

Device subcategory for class IIa devices

Non-active Medical devices		Please tick off	Amount of devices in subcategory?
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 measuring function	☐	
MD 0105	Non-active ophthalmologic devices	☐	
MD 0106	Non-active instruments	☐	
MD 0107	Contraceptive medical devices	☐	
MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing	☐	
MD 0109	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	☐	
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	☐	
MD 0204	Non-active soft tissue implants	☐	
MD 0300	**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 devices and accessories**		
MD 0401	Non-active dental equipment and instruments	☐	
MD 0402	Dental materials	☐	
MD 0403	Dental implants	☐	
	Other groups		
TRLP 9900	Non-active devices (other subcategories than mentioned above)	☐	

Attachment to questions for quoting	TÜVRheinland®

Active Medical devices		Please tick off	Amount of devices in subcategory?
MD 1100	**General active medical devices**		
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis	☐	
MD 1102	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	☐	
MD 1103	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 sterilisation	☐	
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	☐	
MD 1200	**Devices for imaging**		
MD 1201	Imaging devices utilising ionizing radiation	☐	
MD 1202	Imaging devices utilising 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 therapy and thermo therapy**		
MD 1401	Devices utilising ionizing radiation	☐	
MD 1402	Devices utilising non-ionizing radiation	☐	
MD 1403	Devices for hyperthermia / hypothermia	☐	
MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)	☐	
	Other groups		
TRLP 9500	Active therapy devices (other subcategories than mentioned above)	☐	

Class IIb Medical Devices

Please provide us with the overall estimate number of the different generic device groups (in accordance with the related GMDN codes) applicable to your company: ☐

Internet link: Homepage of GMDN agency: http://www.gmdnagency.org