Questions for Quoting	TÜVRheinland® Precisely Right.

Please submit the completed questionnaire to:

TÜV Rheinland (India) Pvt. Ltd. 27/B, 2nd Cross Road, Electronic City, Phase 1, Bangalore – 560 100, India.	**Contact Details:** Phone: +91- 8046498030 E-Mail: shruti.k@ind.tuv.com

1. Details about the company and contact persons

Legal company name			
Contact person		**Job Title**	
Street		**ZIP-Code, Place**	
Phone no.		**E-mail (contact person)**	
Fax no.		**Website**	

2. Certification Standard

☐ ISO 13485 ☐ ICMED 9000 ☐ ICMED 13485

3. Details about your quality management system

Please specify the scope of your QMS, as stated in your quality manual:	< Example for scope: Design and development, manufacture and distribution of medical devices >
Please mark activities **excluded** from the scope of the QMS (if applicable):	☐ Production ☐ Design & Development ☐ Others* (Please specify)
Do any quality management system (QMS) certificates for your company already exist If Yes * (Please specify details)	☐ Yes ☐ No
Did you receive consultancy regarding the implementation of your QMS?	☐ Yes, by: ☐ No

Consulting company	Telephone	Address
- -	-	-

- Please enclose copies of already existing QA system certificates.

4. List of products with classification

Device Name (Including Intended use)	Medical device catageory			Tissues of Animal Origin used?	Does product contain nanoparticles < 100nm?	Sterile? * ☐ Yes ☐ No				Invasive Device? ☐ Yes ☐ No			Classification (Notified Device Risk Category as per MDR 2017)
	MD	IVD	AIMD			Steam	ETO	Irradiation	Other	Implant	Short Term	Long Term	
1	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
2	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
3	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

* 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 (according to ISO 14644)?	☐ Yes	☐ No

*** MD – Medical Device, IVD – In-Vitro Diagnostic, AIMD – Active Implant Medical Device**

5. Total number of sites & employees

Please specify the (approximate) number of employees in the particular departments **Name and Address of the Organization as well as of the possible subsidiaries/branches**		**Departments**								**Sum**	No. of shifts:
		Design/Development	Quality (QA/RA/QC)	Purchasing	Production	Warehouse	Sales	Service	Other		
1											
2											
3											
Comments:											

- Please enclose an organization chart.

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)	☐

6. Details about outsourced processes

Processes	Name and location of subcontractors which perform outsourced processes
Design and Development	
Production	
Packaging	
Sterilisation	
Warehouse	
Service	
Any Other	
Comment :	

Do you wish the Pre-audit (voluntary):	☐ Yes ☐ No Date :	
In which language can the audit be carried out?	☐ English	If other, Please specify
In which language is your QM system described?	☐ English	if other, Please specify

7. Controlled environmental conditions / specification about sterile products

Do you manufacture under defined environmental conditions? If yes, which parameters or certain areas are controlled and monitored?	☐ Yes ☐ No
☐ temperature ☐ humidity ☐ total particle counts ☐ microbial counts	☐ ESD controlled areas ☐ radiation protected areas ☐ others:
Do you maintain work environment for medical devices as per Annexure 'A' of MDR 2017?	☐ Yes ☐ No

Do you produce sterile products?	☐ Yes ☐ No
If yes, to which sterilization procedure?	
☐ by ethylene oxide according to ISO 11135 ☐ by irradiation according to ISO 11137	☐ By moist heat according to ISO 17665 ☐ Others:
• is the sterilization performed in house or External? • If external - attach the QMS ISO 13485 certificate of sterilization organization	☐ In house ☐ External
Is the sterilization process validated with the specified products?	☐ Yes ☐ No

8. Time scale/scheduling:

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

- Please use date format YYYY-MM

9. <u>Please send the following documents along with Questionnaire for quote</u>

- Quality Manual – Addressing all the requirements as per criteria document.
- Site map of manufacturing facility
- List of Products including Intended use (Products brochuer)
- The Licence copy's issued by the State / Central Government authority: Such as FDA Licence, Pollution control board approval / Consent letter and any other.

Date: Client Signature

Review by TUV Rheinland India Pvt. Ltd.

Date: Signature