TNV Certification Pvt. Ltd.

APPLICATION QUESTIONNAIRE FOR MEDICAL DEVICES CERTIFICATION

Part 1. Basic Information

Sl.	Subject	Particular
1	Name of Organization	
2	Postal Address	
3	Phone	
4	Mail	
5	Legal Status of Company: Pvt. Ltd./Public Ltd./ Proprietorship/ Partnership	
6	***Statutory & Regulatory Requirements: (Related to the Medical Device manufacturing)**	
7	***Scope of the Activities**	
	***Key Process undertaken for the Scope**	
9	Number of Sites (Multi Site Issue)	
10	Number of Sites to be audited	
11	Does your organization is already certified for QMS / MD-QMS, Third Party Audit or any other MSS.	
12	Outsourced Process: if any; which affects the conformity of the product/service?	
13	In case of outsourced process, what type and extent of controls have been applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of your MS?	
14	In case of outsourced process, how have you evaluated and determined organization's ability to meet your requirement and legal compliances?	

Part 2. List of the Products

Sl.	Product Information	Risk Class	Intended Use
1			
2			
3			
4			
5			

Part 3. Critical Information

Sl.	Subject	Particular
1	Does key managers at your organization are conversant with English language?	YES ☐ NO ☐
2	Have your organization have ever been penalized for Regulatory violation?	YES ☐ NO ☐
3	Are you using supplier for Critical Process / Part	YES ☐ NO ☐
	If yes, please provide particular of Suppliers	NA
	How you verify the evidence of conformity with the requirement of ISO 13485	NA
	Does supplier (Critical process / part) is already certified	NA
4	Does Risk Classification of the MD is High (GHTF C and D) like *Lung ventilator /orthopedic Implants or Heart valves/ implantable defibrillator*	YES ☐ NO ☐
5	Does your company provide installation at customer site	YES ☐ NO ☐
6	**Applicability of Typical regulatory schemes to applied scope**	YES ☐ NO ☐
	i. Medical Device Regulation (MDR)	YES ☐ NO ☐
	ii. In-Vitro Diagnostic Devices Directive (IVD)	YES ☐ NO ☐
	iii. Active Implantable Medical Devices Directive (AIMD)	YES ☐ NO ☐
	iv. Does your jurisdictions include Critical Regulatory Zone	YES ☐ NO ☐
	i) Canada – Health Canada, Canadian Medical Devices Conformity Assessment System (CMDCAS)	NA
	ii) Australia – Therapeutic Goods Administration, Therapeutic Goods Regulations Additionally other countries are adopting or considering adopting ISO 13485 into their Medical Device Regulations.	NA

Part 4. Technical Areas

Main Technical Areas	Technical Areas	Mark which applicable
Non-active Medical Devices	General non-active, non- implantable medical devices	☐
	Non-active implants	☐
	Devices for wound care	☐
	Non-active dental devices and accessories	☐
	Non-active medical devices other than specified above	☐
Active Medical Devices (Non- Implantable)	General active medical devices	☐
	Devices for imaging	☐
	Monitoring devices	☐
	Devices for radiation therapy and thermo therapy	☐
	Active (non-implantable) medical devices other than specified above	☐
Active Implantable Medical Devices	General active implantable medical devices	☐
	Implantable medical devices other than specified above	☐
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators, and control materials for: • Clinical Chemistry • Immunochemistry (Immunology) • Haematology / Haemostasis / Immunohematology • Microbiology • Infectious Immunology • Histology/Cytology • Genetic Testing	☐
	IVD Instruments and software	☐
	IVD medical devices other than specified above	☐
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	☐
	Moist heat	☐
	Aseptic processing	☐
	Radiation sterilization (e.g., gamma, x-ray, electron beam)	☐
	Low temperature steam and formaldehyde sterilization	☐
	Thermic sterilization with dry heat	☐
	Sterilization with hydrogen peroxide	☐
	Sterilization method other than specified above	☐
Devices incorporating/Utilizing Specific Substances/ Technologies	Medical devices incorporating medicinal substances	☐
	Medical devices utilizing tissues of animal origin	☐
	Medical devices incorporating derivates of human blood	☐
	Medical devices utilizing micromechanics	☐
	Medical devices utilizing nanomaterials	☐
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	☐
	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above.	☐
Parts and Services	Raw materials	☐
	Components	☐
	Subassemblies	☐
	Calibration services	☐
	Distribution services	☐
	Maintenance services	☐
	Transportation services	☐
	Other services	☐

Part 5. Additional Information

Sl.	Subject			Particular
1	Type of Application			
	Initial certification	☐	Recertification	☐

Sl.	Subject			Particular
	Combination audit	☐	Transfer Cum Surveillance	☐
2	**Details of Employee (for multi-site, indicate only sites to be covered unsder certification)**			
	Subject		Part Time	Effective
	Main Location			
	Additional Location – 1			
	Additional Location – 2			
	Total			
	Do you have any Specific Programme/Timescale For Achieving Registration?			
	Have you called on the services of a consultant? (Documentation, Design etc as per 5.2 of IAF MD 09)			

Part 6. Submission and Acknowledgment

Subject	Particular
Contact Person Name	
Designation	
Date:	
Signature:	
Declaration: The information provided above is/are true & correct to the best of our knowledge and Belief and I request TNV to provide offer for the MSS Certification by mail. I gave gone through the procedure and requirements of the standards as published by the TNV on its website www.isoindia.org	
Signature (only when form is being submitted in physical form)	

For TNV Certification Pvt. Ltd. Use Only:-			
Does accreditation request is available with the TNV (Refer accreditation letter)		☐ **Yes**	☐ **No**
Does territory of the application is in active list (Refer accreditation letter)		☐ **Yes**	☐ **No**
Does Scope demand is available with the TNV (Refer accreditation letter)		☐ **Yes**	☐ **No**
Does MSS request is available with TNV (Refer accreditation letter)		☐ **Yes**	☐ **No**
Reviewed By:		Date:	
Can the application be further processed?		☐ **Yes**	☐ **No**
Does Technical Expert Required to process this application?		☐ **Yes**	☐ **No**
Name of Expert, If required:			
Comment: (if Any)			