Questionnaire for the performance of a Quality System Certification Medical Devices Manufacturers

Company's name:

Application for the performance of a quality system certification procedure according to following standard(s) (Please mark "X" where applicable)

	ISO 13485:2016 (This certificate is not for product registration with Health Canada)		**Medical Device Single Audit Program** **ISO 13485:2016 (MDSAP);** Jan 01, 2019 – HC will be accepting ONLY MDSAP certificate for product licence; Please complete MF120-A2
	EN ISO 13485:2016 *		MDD 93/42/EEC Annex _____(Pls Specify) * (For CE Mark, please complete (i) MF120-A1 – list of products (ii) P11F010e (Application for CE)
	Others (Please specify below, ex: ISO 9001, pre-audit etc.)		Notes:

* *certification provided under TUV NORD CERT accreditation/ notification*

The applicant and the registrar/auditing organization recognize the currently valid version of:
1. General Terms and Conditions of the Certification Body
2. Agreement on the Issue of a Conformity Certificate under CAN/CSA 13485 (under CMDCAS, if applicable)
3. Agreement on the Issue of ISO 13485 Certificate (under MDSAP, if applicable)

The applicant assures that:
- an undertaking by the company to fulfil the obligations imposed by the quality system approved,
- an undertaking by the company to keep the approved quality system adequate and efficacious,

For all procedures according to CAN/CSA ISO 13485 / CMDCAS / MDSAP:
This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in 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 leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.

Date	Name	Signature (Applicant)

QUESTIONNAIRE

Company's name: (complete name)			
Street, No. :			
Postal code / City:			
Country:			
State:			
Contact person & Designation:			
Contact:	**Phone:**	**Fax:**	**E-mail:**
Number of Employees:	**total staff:**	**QA-staff:**	
	1st Shift:	**2nd Shift:**	**3rd Shift:**
Size of facility / Total number of sites:			
Product Families List the Class II, III, IV medical licences and all the other medical devices that you intend to sell in countries specidied below in Annex	Please complete either (i) MF120-A1 List of Products (ISO and MDD Certificates) (ii) MF120-A2 Product Registrations and Establishment licence (MDSAP)		
List the countries where the medical device is sold in (fill in all the relevant details in MF-120 A1 or A2) Information related to the **Representatives** (Contact persons) (Name, Address, Contact and Type of activities assigned) (For MDSAP, Pls. fill in the details in MF-120 A2)	Australia, Brazil, Canada, Japan, USA (MDSAP recognized countries) ; Others (specify, ex : Europe, China etc)		

QUESTIONNAIRE

Manufacturing: **(If Subcontractors have Certifications, Please Attach to the Questionnaire)** **Please specify clearly: Manufacturing Processes IN-HOUSE (eg molding, machining, welding, assembly etc)** **1)**_____ **2)**_____ **3)**_____ **4)**_____	**Which parts of the manufacturing process are subcontracted / outsourced:** ☐ **None** ☐ **100 % subcontracted** ☐ **Manufacturing except labelling / packaging** ☐ **Manufacturing except finishing** ☐ **Component manufacturing subcontracted** Component: _____ Subcontractor: _____ ☐ **Sterilization, Type of Sterilization:**_____ Subcontractor: _____ ☐ **Coating / Painting / Anodizing** Subcontractor: _____ ☐ **Sub-assembly subcontracted** Subcontractor: _____ ☐ **Labelling / Packaging subcontracted** Subcontractor: _____ ☐ **Software Development subcontracted** Subcontractor: _____ ☐ **Manufacturing except:** Subcontractor:_____
Additional Information:	

QUESTIONNAIRE

Quality System Information: **Exclusions: 7.3 (Design and Development) (yes / no)** **Non-Applicabilities: (please specify or mention the clauses of ISO 13485)** **1)**_____ **2)**_____ **3)**_____ **4)**_____ **5)**_____	☐ **Quality System is fully implemented** **If no, what percent: %.** **Standard:** _____ ☐ **Consultants used for Quality System implementation** **If yes, who:** _____ ☐ **Research, Design and Development are subcontracted** **If yes, who:** _____ ☐ **Sales / Marketing are subcontracted** **If yes, who:** _____ ☐ **Other departments subcontracted.** **If yes, which:** **Requested Scope** (please specify the scope, subject to approval from the Certification body):
Site ____	☐ **Name:** ☐ **Address:** ☐ **Contact person & Designation:** ☐ **Function / Processes: (To include subcontracted processes too)** ☐ ☐ ☐
Number of Employees:	**total staff:** | **QA-staff:** **1st Shift:** | **2nd Shift:** | **3rd Shift:**

QUESTIONNAIRE

Site ____	☐ **Name:** ☐ **Address:** ☐ **Contact person & Designation:** ☐ **Function / Processes: (To include subcontracted processes too)** ☐ ☐ ☐		
Number of Employees:	**total staff:**	**QA-staff:**	
	1st Shift:	**2nd Shift:**	**3rd Shift:**
	1st Shift:	**2nd Shift:**	**3rd Shift:**
Note: Please use additional sheet if there are more than 02 sites			
Additional Information / Comments:			

QUESTIONNAIRE

TUV-USA Review and Acceptance:

Review (Official Use)	☐ **Type of Audit: CA / RC / SA1 / SA2 / XA / TRF: _____** ☐ **EAC Scope accepted** ☐ **Medical Device code accepted** ☐ **Exclusion and Non-applicabilties of QMS mentioned** ☐ **List of Products attached** ☐ **Product scope accepted** ☐ **Audit team scope available (Refer to ATEA for the final audit team)** **Lead Auditor:** **Auditor/s:** ☐ **Appointed person available** **Appointed Person for file review:** ☐ **Confirmed total number of sites (including HQ) to be covered under the scope of certification is _____** ☐ **Contract with Client available (after when the offer is accepted)** ○ **ISO 13485:_____ (MF110) [AND/OR]** ○ **MDSAP contract (MF170)** ○ **EN ISO and MDD Contract for TNC Germany**
Additional Comments	
Acceptance (Official Use)	_____ _____ **Date** **Name**