**Contact and business details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Company Name :** |  | | |
| **Address:** |  | **Country/**  **city zip** |  |
| **Contact Person:** |  | **Position:** |  |
| **Phone/fax:** |  | **E-Mail:** |  |
| **VAT/GST identification number** |  | **Homepage:** |  |
| **Regulatory Correspon-dent** *– if applicable –*  *Please fill in complete address* |  | **Certification Standard** | ICEMD 9000  ICEMD 13485  ISO 9001  ISO 13485 |
| **Scope for Certification (Also fill Annexure 1 for List of Medical Devices)** |  | | |
| **Accreditation Desired** | NABCB  Others | | |
| **Status of Application or Certification to any other Certification Body:**  *Note: Copy of certificate and audit reports of previous CB required to be provided.* | Certification Standard:  ICMED 9000 Certification Body: Certificate Validity Date:  ICMED 13485 Certification Body: Certificate Validity Date:  ISO 9001 Certification Body: Certificate Validity Date:  ISO 13485 Certification Body: Certificate Validity Date:  If any of above Certificate are under suspension or cancelled :  Yes  No  ***Status of application with other CB, if not yet Certified:*** | | |
| **Status of Product Related Legal Compliance:** | Any Judicial Proceedings by regulatory authority for Product or relating to operations of company is going on or pending:  Yes  No  If Yes, Please provide details:  Is any conviction or Suspension happened:  Yes  No  If yes, please provide date of Conviction/Suspension: | | |
| **Consultancy By :**  **Name of consultant, company name and**  **Contact number**  **(if used the services of a consultant)** |  | | |

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| --- | --- | --- | --- |
| Please state the company locations and branch offices, which should be included in the certification (*if more than 3 locations are applicable, please use separate document as enclosure*). | | | |
|  | Headquarter | 1st Additional Location | 2nd Additional Location |
| **Address:** |  |  |  |
| **City, State ZIP:** |  |  |  |
| **Contact Person:** |  |  |  |
| **Position:** |  |  |  |
| **Phone/fax:** |  |  |  |
| **E-Mail:** |  |  |  |
| **Number of Employees:** | Full Time:  Part Time: | Full Time:  Part Time: | Full Time:  Part Time: |
| **Number of shifts** |  |  |  |
| **employee number for each shift** | *Shift 1 :*  *Shift 2:*  *Shift 3:* | *Shift 1 :*  *Shift 2:*  *Shift 3:* | *Shift 1 :*  *Shift 2:*  *Shift 3:* |
| Activities Performed |  |  |  |
| Subcontracted Process(es)/services *please use Annex 2* |  |  |  |
| **Number of employees in:** | Headquarter | 1st Additional Location | 2nd Additional Location |
| Design |  |  |  |
| Sterilisation |  |  |  |
| Sale |  |  |  |
| Labelling and Packaging |  |  |  |
| Maintenance |  |  |  |
| quality assurance |  |  |  |
| Product premarket review |  |  |  |
| Administration |  |  |  |
| Miscellaneous |  |  |  |
| Performed activities on each location |  |  |  |

**Please include the organizational chart and the current trade register excerpt**

Are there any temporary sites associated with the scope of certification (e.g. installation, commissioning, offsite servicing, etc)

Yes:  No:

|  |  |  |
| --- | --- | --- |
| **Do all locations operate under a common quality system?** | Yes: | No: |
| **If no, please give us further explanations and describe the structure of the QMS** | | |
|  | | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| |  |  | | --- | --- | | please attach the following documents: | | | * Corporate Brochure * Product information/Brochure/Manuals (for relevant products) * Organizational chart of headquarter and branch offices * Copy of other relevant existing certificates of your company * Copy of existing Certificates of the OEM manufacturer –if applicable- * Copy of trade register excerpt * Copies of already existing Medical Devices Licenses (In India or other countries) * Contractual arrangement and type of activities assigned to a Regulatory Correspondent *–if applicable-* * Annex I (List of Products which fall under the application) * Annex II (subcontracted processes/services) |  | | | |

I here by confirm that above information is true.

Authorized Signatory Name: Designation:

Signature: Date:

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For use of TUV India :

Is all the information available:  Yes  No

Information provided are clear and unambiguous:  Yes  No

Proposal for Certification can be made:  Yes  No

If not, following more information/clarification is required from Client:

Reviewed By Name: Designation:

Signature: Date: