**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 [ ]  NoIf Yes, Please provide details:Is any conviction or Suspension happened: [ ]  Yes [ ]  NoIf yes, please provide date of Conviction/Suspension: |
| **Consultancy By :****Name of consultant, company name and** **Contact number****(if used the services of a consultant)**  |  |

|  |
| --- |
| 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:

-----------------------------------------------------------------------------------------------------------------

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: