**APPLICATION FORM**

All fields should be filled correctly

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Organization/Company details** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Company Name (Legal entity requiring certification): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Site-1 Address (to be certified): | | | | | | | | | | | | | | | | | | | Please detail the processes and Activities at site-1 | | | | | | | | | | | | | | | | | | | | | |
| Postcode: | | | | | | | State: | | | | | | | | | | | | | | | | | Country: | | | | | | | | | | | | | | | | |
| **If more than one site is to be certified, specify the other site address**  **YES NO** | | | | | | Site-2 address | | | | | | | | | | | | | | Site-3 address | | | | | | | | | | | | | | Site-4 address | | | | | | |
|  | | | | | | | | | | | | | |  | | | | | | | | | | | | | |  | | | | | | |
| Postcode- | | | | | | | | | | | | | | Postcode- | | | | | | | | | | | | | | Postcode- | | | | | | |
| State- | | | | | | | | | | | | | | State- | | | | | | | | | | | | | | State- | | | | | | |
| Please detail the processes and Activities | | | | | |  | | | | | | | | | | | | | |  | | | | | | | | | | | | | |  | | | | | | |
| E-mail: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | | | | | | | | | | | | | | | | | | Fax: NA | | | | | | | | | | | | | | | | | | | | | | |
| Website: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Chief Executive/MD: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Mobile: | | | | | | | | | |
| Contact Person Name: | | | | | | | | | | | | | | | Position:  Email: | | | | | | | | | | | | | | | | | | Mobile: | | | | | | | |
| Company Status (Please Tick)  Proof Document to be attached in Annex-1 (Company Registration or Certificate of Incorporation) | | | | | | | | | | | | | | | Public Limited | | | | | | | | | | | | | | | | | | | | | | | | | |
| Private Limited | | | | | | | | | | | | | | | | | | | | | | | | | |
| Partnership | | | | | | | | | | | | | | | | | | | | | | | | | |
| Government | | | | | | | | | | | | | | | | | | | | | | | | | |
| Proprietary | | | | | | | | | | | | | | | | | | | | | | | | | |
| Limited Liability Partnership | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other (Please Specify): | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Please indicate the management system standard(s) required** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ISO 9001:2015 | | | | | | | | | | | | | | | ISO 13485:2016 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Type of Audit required** | | | | Combined | | | | | | | | | | | | Joint | | | | | | | | Integrated | | | | | | | | | | | | | Single | | | |
| 1. **A. Requirement of Certification** | | | | | | | | | | | | | | | | | | | | | | | | New Certification  Transfer of Certification | | | | | | | | | | | | | | | | |
| **B. If Transfer Certification from other Certification Body** | | | | | | | | | | | | | | | | | | | | | | | | Please specify below | | | | | | | | | | | | | | | | |
| Management system standard | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Certification body | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Certificate expiry date | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Note:*** *Provide the copy of existing Certificate* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Integrated management systems** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is your management system integrated with other standards? | | | | | | | | | | | | | | | | | | | | | | | NO  YES - please provide details in Annex-2 | | | | | | | | | | | | | | | | | |
| 1. **Did you use consultancy related to the management system?** | | | | | | | | | | | | | | | | | | | | | | | | NO  YES- please specify below | | | | | | | | | | | | | | | | |
| Consultancy Company Name | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of the Consultant | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Extend and work performed | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Does the organization have staff speaking in other than English and Hindi?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | NO  YES- please specify below | | | | | | | | | | | |
| Other Languages | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Are there any specific (relevant) legal obligations/regulatory approval/licenses related to the product, process and operations applicable for the organization?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | NO  YES- please specify below and provide the related proof documents/certificates in Annex-3 | | | | | | | | | | | | |
| License Number | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Validity | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Please describe the products, activities and/or services of your company** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Requested scope of certification**   Note: The scope should explain concisely the purpose and output covered by the management system; it should describe what the organization does, not how it does it. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Date of Last Internal Audit & Management Review Meeting if conducted** | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 1. **Are you outsourcing any of the activities within the scope of certification?** | | | | | | | | | | | | | | | | | | | | | | | | NO  YES- please specify below | | | | | | | | | | | | | | | | |
| Overview of outsourced activities | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **A. Please provide details of the site-specific information for certification** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Total number of Employees working | | | | | | | | | | | | Permanent:  Part-time: | | | | | | | | | | | | | | Total number of shifts | | | | | | | | | | | | |  | |
| **Shift Details** | | | | | | | | | | | | Shift-1 | | | | | | | | Shift-2 | | | | | | | | | | Shift-3 | | | | | | Shift-4 | | | | |
| Time | | | | | | | | | | | |  | | | | | | | |  | | | | | | | | | |  | | | | | |  | | | | |
| Number of Staff | | | | | | | | | | | |  | | | | | | | |  | | | | | | | | | |  | | | | | |  | | | | |
| **Repeat 13.A, if more than one site is to be certified** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **13.B. Quality Management Process** | Management/  Administration | | | | Regulatory Affairs | | | | | R&D | | | | Quality Assurance | | | | | | | Maintenance/ Production | | | | | | Sales & Marketing | | | | | Procurement | | | IT | | | Others | | |
| Number of employees per process |  | | | |  | | | | |  | | | |  | | | | | | |  | | | | | |  | | | | |  | | |  | | |  | | |
| **Repeat 13.B, if more than one site is to be certified** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **What is the intended use of your product? (for ISO 13485:2016)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Are your products sterile?** | | | | | | | | | | | | | | | | | | NO  YES- please provide details of the sterilization method below | | | | | | | | | | | | | | | | | | | | | | |
| Sterilization Method | | | | | | | | | | | | | | | | | | ETO Sterilization  γ- Sterilization  Other methods of Sterilization- Please Specify below | | | | | | | | | | | | | | | | | | | | | | |
| When/how was the sterilization conducted? | | | | | | | | | | | | | | | | | | During production  Outsource  Intend for end-user sterilization | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Is the software used in the product?** | | | | | | | | | | | | | | | | | | NO  YES- please provide details for software below | | | | | | | | | | | | | | | | | | | | | | |
| As an independent medical device used as software? | | | | | | | | | | | | | | | | | | NO  YES | | | | | | | | | | | | | | | | | | | | | | |
| As a component/part of the finished medical device? | | | | | | | | | | | | | | | | | | NO  YES | | | | | | | | | | | | | | | | | | | | | | |
| As an embedded part of the finished medical device? | | | | | | | | | | | | | | | | | | NO  YES | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Have you had any incidents leading to or pending prosecution/insurance claims/enforcement notices in the last year?** | | | | | | | | | | | | | | | | | | | | NO  YES-please specify details below | | | | | | | | | | | | | | | | | | | | |
| **Note:** Section 14 to 17 are applicable for ISO 13485 Audit | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Please list the requirements of ISO 13485/ISO 9001 that you do not deem applicable to the proposed scope of the management system:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clause | | | | | | | | | Justification for exclusion | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Organizational and process complexity** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Does the organization have a large product range and/or complexity of medical device? | | | | | | | | | | | | | | | | | | | | | | | NO  NA  YES- please specify details below | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Does the organization use suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished product? | | | | | | | | | | | | | | | | | | | | | | | NO  NA  YES- please specify details below | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Does the organization install products on the customer’s premises? | | | | | | | | | | | | | | | | | | | | | | | NO  NA  YES- please specify details below | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

**Annex-1**

**Proof for Company Registration or Certificate of Incorporation document**

**Annex-2**

**Fill the below table for integrated audit requirements for more than one management system standard**

|  |  |  |
| --- | --- | --- |
| **In case of an integrated audit needs to be performed (audit on two or more management system standards) please indicate the level/extend of integration of the management system:** | | |
| Management Reviews consider the overall business strategy and plans | NO | YES |
| Integrated approach to internal audits | NO | YES |
| Integrated approach to policy and objectives | NO | YES |
| Integrated approach to systems processes | NO | YES |
| Integrated documentation set including work instructions, to a good level of development as appropriate | NO | YES |
| Integrated approach to improvement mechanisms (corrective and preventive action; measurement and continual improvement) | NO | YES |
| Integrated approach to planning, with good use of business wide risk management approaches | NO | YES |
| Unified management support and responsibilities | NO | YES |

**Annex-3**

**Proof for legal obligations/regulatory approval/licenses**

**Declaration Form**

We hereby declare that the above-mentioned details are correct as per our knowledge. Also, we agree to pay the application processing fee and other fees charged for the services provided by KCS in time without any delay.

Authorized Signatory:

Name:

Position: Company Seal

Place:

Date: