Request for Quotation / Application for Quality System Registration and if applicable Conformity Assessment Activities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Registration(s) being requested:** | | | | | |
|  | EN ISO 13485:2016 |  | ISO 13485:2016 |  | ISO 9001:2015 |

If this Quality System Registration will be used to satisfy regulatory requirements as the Legal Manufacturer of a finished medical device or as the manufacturer of a finished device which is sold in an MDSAP jurisdiction, please check the applicable regulations below:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Applicable Regulations** | | | | | | | |
|  | MDSAP- Medical Device Single Audit Program | | | | | | |
| US | | Australia | | Brazil | Canada | Japan |
| 21 CFR Part 820 | | Sched 3 Part 1 | |
| 21 CFR Part 821 | | Sched 3 Part 4 | |
|  | MDR 2017/745 – Medical Device Regulation | | | | | | |
| Annex IX | | | Annex XI Part A | | | |
|  | IVDD 98/79/EC | | | | | | |
|  | 722/2012 - Tissues of Animal Origin | | | | | | |
|  | Other / Additional |  | | | | | |
|  | IVDR 2017/746 – In-Vitro Diagnostic Regulation \*Designation pending  Expression of interest in certification services | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Company Information** | | | | |
| Company Name: |  | | | |
| Manufacturer Name if different from above:  (as per meaning within the regulation) |  | | | |
| Address: |  | | | |
| Applicant is a subsidiary of: |  | | | |
| Number of Employees: |  | Number of Shifts: | |  |
| Main Phone Number: |  | | | |
| Management Representative |  | Title: |  | |
| Email Address: |  | Direct Phone Number: |  | |
| If applicable: Person Responsible for Regulatory Compliance: |  | Title: |  | |
| Email Address: |  | Direct Phone Number: |  | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Billing address (if different from above): | |  | | |
| Billing Contact: |  | | Email: |  |

**Information about facilities**

|  |  |  |  |
| --- | --- | --- | --- |
| Is this application being submitted to add an additional location to an existing NSAI certified ISO 13485:2016 quality management system? | | Yes | No |
| Are multiple facilities or locations to be included in this assessment? | | Yes | No |
| Please indicate the language used in your facility(s): |  | | |
| Note: NSAI will only review Quality System documentation and EU Regulatory technical documentation and associated reports in English. | | | |

Please complete the following information table **for each facility** **/ location** included in this assessment.

\*copy and paste the table to provide information ‘A’ through ‘G’ for each facility.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A | Facility Address: | |  | | | | | | | | |
| B | Number of employees: | | |  | | Number of employees and number of shifts (If applicable) | | | | |  |
| C | Brief description of the facility and principal activities occurring at this site including work shifts and indicating the approximate number of employees in each activity | | | | | | | | | | |
| Description: | | | | | | | | | | |
| D | Please list all products which are manufactured at this location: | | | | | | | | | | |
| List: | | | | | | | | | | |
| E | Normal working hours at this facility: | | | | | |  | | | | |
| F | Working hours of the shifts (if applicable): | | | | | |  | | | | |
| G | Please tick all appropriate Technologies at this location | | | | | | | | | | |
|  | Metal | | |  | | | Pharmaceuticals |  | Packaging, including labelling | |
|  | Plastics / Rubber | | |  | | | Cleanroom |  | Aseptic Processing | |
|  | Non-metal mineral processing  (e.g. glass, ceramics) | | |  | | | Processing materials of human, animal or microbial origin |  | Lyophilisation | |
|  | Non-metal non-mineral processing (e.g. textiles, , leather, paper) | | |  | | | Electronic components including communication devices |  | Reprocessing of medical devices approved under national law | |
|  | Biotechnology | | |  | | | Sterilization  **Please state method of sterilization:** | Method: | | |
|  | Chemical Processing | | |
|  | Servicing/Refurbishment | | |  | | | Other technology, please state: | Technology: | | |
|  | Precision Mechanics & Optics | | |  | | |  |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Outsourced Processing** | | | |
| Do you outsource any processes?  \*if yes please specify and indicate critical processes – Associated Site Certification | | | Yes  No |
| Outsourced Process | Name / Address | Certified by: | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
|  |  |  | |

|  |  |  |
| --- | --- | --- |
| **Critical Suppliers of Products and Services as defined by your purchasing process**  ***Note*: A critical supplier is a supplier delivering materials, components, or services that may influence**  **the safety and performance of the device \*NBOG BPG 2010-1.** | | |
| **Product/Service** | **Supplier Name / Address** | **Supplier Certified by** |
| e.g. Sterilisation | e.g. SterCo, Inc. California, USA | e.g. NSAI |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **Please Note:** Only to be completed by companies which are applying for CE Marking conformity assessment under **MDR 2017/745 / IVDR 2017/746.**  List all potential commercial competitor(s) for the medical device which you intend to submit to NSAI for CE marking. Note: this is to enable NSAI to conduct a thorough conflict of interest check when assigning an audit team as per requirement MDR 2017/745 Annex VII 1.2.3 (d) | |
| **Client Product to be CE Marked with NSAI** | **Potential Commercial Competitor Name(s)** |
| e.g. Transcatheter aortic valve replacement | ValveTech, Inc., ABC Valves, ACME Valves, |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

\*Add additional lines as required.

**MDSAP Specific Facility Information:**

Please complete the Technologies and Tasks spreadsheet for each facility covered by this application and submit with application – where tasks are indicated as Not Applicable, please provide clear justification.



­­­­­­**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Certification Details:**  Proposed Scope of Certification for this Application: (e.g. design, manufacture, and distribution of ....) | | | | | |
| Please provide the proposed scope of certification | | | | | |
|  | | | | | |
| If necessary, provide alternatives to the above proposed scope for different certification schemes: | | | | | |
|  | | | | | |
| **Product(s) Details:** | | | | | |
| Brief description of products and relevant product classification(s)  \*Further details may be attached on a separate sheet | | | | | |
|  | | | | | |
| **Product Name/Generic Device Group Name** | **Device Description** | **EU Device Classification and applicable Annex VIII Classification Rule** | **MDA/MDN Code \*Ref MDCG 2019-14** | **MDS Code**  **\*Ref MDCG 2019-14** | **Site address where product is manufactured** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| \*Add additional lines as required. | | | | | |

|  |  |
| --- | --- |
| Other relevant information for companies which are applying for CE Marking conformity assessment under MDR 2017/745 | |
| Have you conducted an MDR compliant clinical investigation to support your devices conformity assessment under MDR 2017/745: | Yes  No |
| If the above answer is no, are you planning to conduct an MDR compliant clinical investigation to support your devices conformity assessment under MDR 2017/745: | Yes  No  N/A |
| If you are planning an MDR compliant clinical investigation, please indicate when you intend to initiate this study i.e., Q2 2023 |  |
| Does your device(s) contain substances which are carcinogenic, mutagenic or toxic to reproduction(‘CMR’), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council **or** substances having endocrine-disrupting properties: | Yes  No |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Existing Certification** | | NA | |  | | |
| Please list any Certifications currently held by your company: | | | | | | |
| **Certified to** | **Name of Certification Body** | | **Certificate #** | | | **Expiry Date** |
|  |  | |  | | |  |
|  |  | |  | | |  |
|  |  | |  | | |  |
| Please confirm that copies of your current certificates will be submitted when emailing this form. | | | Yes  No | |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Transfer of QMS Registration(s)** | | NA |  |
| If you are requesting a transfer of the above QMS Registration(s) to NSAI, please provide the following: | | | |
| Date of last site audit: |  | | |
| Type of last site audit:  (e.g. Registration/Surveillance/Reassessment) |  | | |

|  |
| --- |
| Any Other relevant Details: |
| Details: |

|  |  |
| --- | --- |
| **Scheduling** | |
| Please indicate your preferred NSAI audit dates. The NSAI Customer Service Representative assigned to you will make every effort to accommodate your request. | |
| Preferred QMS audit dates |  |
| Preferred Technical Documentation submission dates |  |

|  |  |  |
| --- | --- | --- |
| **Use of Consultants** | | |
| Do you utilize an external Consultant(s)? | Yes  No |  |
| If yes, please provide all relevant details |  | |

**Request for Quotation / Application for Quality System Registration and if applicable Conformity Assessment Signatures**

Note, where NSAI utilises a subcontract auditor/product reviewer for conformity assessment activities, that individual meets all relevant MDR 2017/745 competency and impartiality requirements. Subcontract auditor/product reviewers are precluded from further subcontracting work to organisations or individuals.

*Important information regarding this Request for Quote (RFQ) / Application for Registration and or Conformity Assessment Activities:*

The information submitted in this document will be utilized by NSAI to generate and provide a quotation for services to your company. Upon formal, written acceptance of said quotation and signing of the provided contract by your company, the information in this document shall be recognized as an integral part, by NSAI, of the application for quality system registration, and if applicable conformity assessment activities.

|  |  |
| --- | --- |
| Applicant Signature: |  |
| Name (please print): |  |
| Position / Title: |  |
| Date: |  |

Completed Request for Quotation / Application for Quality Systems Registration and or Conformity Assessment Activities questionnaire should be sent to:

|  |  |
| --- | --- |
| **Customers within U.S.** | **Customers located outside U.S.** |
| NSAI, Inc  Medical Devices  20 Trafalgar Square  Suite 603  Nashua, NH 03063  [Sales.medical@nsai.ie](mailto:Sales.medical@nsai.ie) | NSAI  Medical Devices  1 Swift Square  Northwood  Santry, Dublin 9  [Sales.medical@nsai.ie](mailto:Sales.medical@nsai.ie) |

If an MDSAP application is being made please complete the form on the following page.

**COMPLIANCE TO REGULATORY REQUIREMENTS**

**FOR APPLICATIONS under the MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)**

By signing this application and upon qualification:

* The manufacturer agrees to the release of any document(s) that NSAI and/or the recognizing Regulatory Authorities considers necessary to demonstrate the medical device manufacturer’s conformance to applicable standards and regulatory requirements. These documents would include any audit documentation, records of observations or reports resulting from a quality management system audit.
* The manufacturer agrees to allow NSAI and recognizing Regulatory Authorities access to the Legal Manufacturer’s premises, and /or any of the above listed sites, as well as critical suppliers, at any time for the purposes of performing unannounced audits. The manufacturer agrees to have the appropriate contractual arrangements with their critical suppliers to allow for unannounced audits.
* The manufacturer agrees to provide all necessary support in acquiring the necessary travel papers, including VISA, to facilitate NSAI access to the above listed locations and critical suppliers.
* The manufacturer understands that NSAI may end this contract with the Legal Manufacturer if permanent unannounced access to the above listed sites and critical suppliers are no longer assured.
* The manufacturer understands that NSAI may cancel any unannounced audit at any time if the safety and security of NSAI or recognizing Regulatory Authority personnel cannot be assured.
* The manufacturer agrees to pay all applicable fees related to unannounced audits which will be billed at the contracted quoted day and travel rates.
* The manufacturer agrees that if a visa is required to visit the country where the manufacturer or contracted critical supplier is located, an invitation to visit, leaving the date of visit open, shall be provided with the signed copy of the quotation.

|  |  |
| --- | --- |
| Applicant Signature: |  |
| Name (please print): |  |
| Position / Title: |  |
| Date: |  |