

#### APPLICATION

**for**

#### QUALITY SYSTEM REGISTRATION

**Request for Quotation /Application for Quality System Registration to:**

Registration(s) being requested:

|  |  |  |  |
| --- | --- | --- | --- |
| EN ISO 13485:2012 |  | EN / ISO 13485:2016 |  |
| **ISO 13485:2003** (Expires 01 March 2019) |  | \*ISO 13485:2016 |  |
| **ISO 9001:2008**  **(Expires 15 September 2018)** |  | ISO 9001:2015 |  |

\* Required for CMDCAS / MDSAP Registrations

If this Quality System Registration will be used to satisfy regulatory requirements as the Legal Manufacturer of a finished medical device, please check the applicable regulations below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **MDSAP –** *Medical Device Single Audit Program* | | | |
| US  21 CFR Part 820  21 CFR Part 821 | Australia  Sched 3 Part 1  Sched 3 Part 4 | Canada  Brazil | Japan |
|  | **\*CMDCAS** – *Canadian Medical Device Conformity Assessment System*  *(CMDCAS Program ends 31 December 2018)* | | | |
|  | **93/42/EEC – *Medical Device Directive***  Annex 2  Annex 5  Annex 6 | | | |
|  | **90/385/EEC – *Active Implantable Medical Device Directive***  Annex 2  Annex 5 | | | |
|  | **98/79/EC – *In-Vitro Diagnostic Medical Device Directive***  Annex 3  Annex 4  Annex 7 | | | |
|  | **2000/70/EC – Human Blood Derivatives** | | | |
|  | **722/2012 - Tissues of Animal Origin** | | | |
|  | **MDR 2017/745 – Medical Device Regulation** | | | |
|  | **IVDR 2017/746 – In-Vitro Diagnostic Regulation** | | | |
|  | **Other / Additional** | | | |

**Company Information:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Company Name:** |  | | | | | | |
| **Address:** |  | | | | | | |
| **Applicant is a subsidiary of:** |  | | | | | | |
| **Number of Employees:** |  | | **Number of Shifts:** | | |  | |
| **Main Phone Number:** |  | | | | | | |
| **Management Representative:** |  | | **Title:** |  | | | |
|  | **Email Address:** |  | | | **Direct Phone Number:** | |  |

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

|  |  |
| --- | --- |
| **Yes** | **No** |

**Facility Information:**

Are multiple facilities or locations to be included in this assessment?

**Information about facilities:**

Please complete the following information for **each** facility / location included in this assessment (replicate “a” through “e” for each facility)

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Facility Address:** |  | | |
| 1. **Number of employees:** |  | Number of employees /shift (If applicable) |  |

1. **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.**

(Further details may be attached on a separate sheet)

|  |  |  |
| --- | --- | --- |
|  | | |
| 1. **Normal working hours at this facility:** |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Please tick all appropriate Technologies at this location:** | | | | | |  | |
| Cleanroom / Aseptic process |  | Metal |  | Thick and thin film technologies |  | |
| Sterilization  Type of sterilization: |  | Welding |  | Drug device combinations |  | |
| Packaging |  | Statistical techniques / SPC |  | Manuf. Techniques for ceramics |  | |
| Plastics |  | Textile / Fibre process |  | Chemical |  | |
| Bonding |  | Precision mechanics & optics |  | Pharmaceuticals |  | |
| Electronics/Software |  | Coating technologies |  | Other |  | |

|  |  |  |
| --- | --- | --- |
| **Do you sub-contract any processes?** | **Yes** | **No** |

(if yes please specify and indicate critical processes – Associated Site Certification)

|  |  |  |
| --- | --- | --- |
| **Subcontracted Process** | **Subcontractor Name / Address** | **Subcontractor Certified by:** |
| **1.)** |  |  |
| **2.)** |  |  |
| **3.)** |  |  |

**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 Certification Scope of this Application:** *(e.g. design, manufacture, and distribution of ....)*

*Please indicate the associated scheme for each proposed Scope of Certification statement. For example:*

* *EU MDD Scope: The design, manufacture and distribution of Cardiovascular Stents and Delivery Systems and associated accessories*
* *MDSAP Scope: The design, manufacture and distribution of Cardiovascular Stents, Delivery Systems*

*Where the Accessories are not being supplied to Canadian market, and hence outside the scope of the MDSAP audit*

**Brief description of products and relevant product classification(s)**

(Further details may be attached on a separate sheet)

**Please list any Certifications currently held by your company:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Certified to:** | **Name of Certification Body** | **Certificate #** | **Expiry Date** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**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) |  |

**Other Details:**

**PLEASE INDICATE YOUR PREFERRED NSAI AUDIT DATES. The NSAI Customer Service Representative assigned to you will make every effort to accommodate your request.**

|  |  |
| --- | --- |
| **Preferred dates:** |  |

|  |  |
| --- | --- |
| **Do you utilize an external Quality System Consultant?**  *If yes, please complete* | **Name of Consultant:** |

**Request for Quotation / application for Quality System Registration Signatures:**

**Important information regarding this *Request for Quote (RFQ)/Application for Registration* questionnaire.**

The information submitted in this questionnaire will be utilized by NSAI to generate and provide a quotation for services to your company. Upon formal, written acceptance of quotation by your company, the information in this questionnaire will be recognized by NSAI as an official “Application for Quality System Registration”.

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

**Completed Request for Quotation / Application for Quality Systems Registration 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**  [**medical.devices@nsaiinc.com**](mailto:medical.devices@nsaiinc.com) | **NSAI**  **Medical Devices**  **1 Swift Square**  **Northwood**  **Santry, Dublin 9**  [**medical.devices@nsai.ie**](mailto:medical.devices@nsai.ie) |

**PLEASE READ AND SIGN ABOVE THEN COMPLETE THE FORM ON THE FOLLOWING PAGES.**

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|  |

**COMPLIANCE TO REGULATORY REQUIREMENTS**

**FOR APPLICATIONS under the MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP) OR CANADIAN MEDICAL DEVICE CONFORMITY ASSESSMENT SYSTEM (CMDCAS)**

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 will 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 above 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 :** |  |