

**IVDR Request for Quotation**

**for**

**NSAI Medical Device Services**

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

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| **Certifications(s) being requested:** | | | | | |
|  | EN ISO 13485:2016 |  | ISO 13485:2016 |  | ISO 9001:2015 |
|  | This QMS application is for:  Initial certification  Re-certification  Transfer of certification to NSAI | | | | |

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| **Applicable Regulations/Registrations** | | | | | | | | |
|  | 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 | |
|  | IVDR 2017/746 – In-Vitro Diagnostic Regulation | | |  | | Annex IX | | |
|  | Other / Additional | N/A | | | | | | |

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| **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 Name: |  | Title: |  | |
| Email Address: |  | Direct Phone Number: |  | |
| Person Responsible for Regulatory Compliance: |  | Title: |  | |
| Email Address: |  | Direct Phone Number: |  | |

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

**Information about facilities**

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| Are multiple facilities or locations to be included in this assessment? | | Yes | No |
| Is this application being submitted to add an additional location to an existing NSAI certified ISO 13485:2016 quality management system? | | 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 ‘H’ for each facility.

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| A | Facility Address: | |  | | | | | | |
| B | Number of employees: | | |  | | | Number of employees /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 *(MDCG 2021-14)* | | | | | | | | |
|  | IVT 2001: Metal processing | | |  | | IVT 2008: Cleanroom and associated controlled environments | | |
|  | IVT 2002: Plastic processing | | |  | | IVT 2009: Processing materials of human, animal or microbial origin | | |
| *IVT 2003: Non-metal mineral processing (e.g., glass, ceramics) – Not Designated* | | | | *IVT 2010: Electronic components including communication devices -– Not Designated* | | | | |
|  | IVT 2204: Non-metal non-mineral processing (e.g., textiles, rubber, leather, paper) | | |  | | IVT 2011: Packaging, including labelling | | |
|  | IVT 2005: Biotechnology | | |  | | IVS 1005: Sterilization  **Please state method of sterilization:** | Method: | |
|  | IVT 2006: Chemical Processing | | |  | | Other technology, please state: | Technology: | |
|  | IVT 2007: Pharmaceuticals | | |
| H | Please tick all appropriate Activities applicable at this location: | | | | | | | | |
|  | Management | | |  | | Wearhouse and/or Logistics | | |
|  | Distribution | | |  | | Design and Development | | |
|  | Final inspection or Product Release | | |  | | Calibration | | |
|  | Manufacturing/Production | | |  | | Installation | | |
|  | Service/Repair | | |  | | Quality/Regulatory Assurance | | |
|  | Sales | | |  | | Other: Please Specify | | |

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| **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 to\*: | Certified by: | |
| e.g. Final packaging |  |  |  | |
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\*Indicate what standard this Company’s QMS is certified to.

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| **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 to** |
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| List all potential commercial competitor(s) for the IVD 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 IVDR 2017/746 Annex VII 1.2.3 (d) | |
| **Client Product to be CE Marked with NSAI** | **Potential Commercial Competitor Name(s)** |
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\*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.



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| **Certification Details:**  Proposed Scope of Certification for this Application: (e.g. design, manufacture, and distribution of ....) | | | |
| Please provide the proposed scope of certification (for new clients only) | | | |
| IVDR1  ISO 134852  MDSAP3 | | | |
| If necessary, provide alternatives to the above proposed scope for different certification schemes: | | | |
|  | | | |
| Is Design and Development included in the QMS scope:  Yes  No | | | |
| For MDSAP only. Brief description of products and relevant product classification(s): | | | |
|  | | | |
| Please state the Device Class/Classes: | | | |
| Class A | Class B | Class C | Class D |
| In addition, please complete the accompanying form MTF-4002 ‘Device Portfolio Information Form’ attached adjacent. Please follow the instructions indicated in the document.  Please return Device Portfolio Information Form in **both xls and pdf format**. | | |  |
| Has the MTF-4002 IVDR Device Portfolio been filled in completely?  NSAI will not approve any RFQ that’s missing a completed MTF-4002. | | | Yes  No |

Shall only include the category of devices and/or generic device groups that are covered by the QMS.

2 Shall indicate what processes are managed within the QMS and for what type of products.

3 Shall indicate activities and devices covered by the QMS.

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| Other relevant information for companies which are applying for CE Marking conformity assessment under IVDR 2017/746 | |
| Have you conducted **clinical performance studies**, **interventional clinical performance studies or certain other performance studies** to support your devices conformity assessment under IVDR 2017/746? | Yes  No |
| If the above answer is no, are you planning to conduct **clinical performance studies**, **interventional clinical performance studies or certain other performance studies** to support your devices conformity assessment under IVDR 2017/746. | Yes  No  N/A |
| If you are planning a **clinical performance studies**, **interventional clinical performance studies or certain other performance studies**, 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 |

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

\*Add additional lines as required.

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| **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) |  | | |

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| Any Other relevant Details: |
| Details: |

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| **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 |  |

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

**IVDR 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 IVDR 2017/746 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.

**Signing this RFQ does not constitute a formal application for IVDR Conformity Assessment. This RFQ will be the basis for a Quote/Contract. Signing that Quote/Contract will be the formal application for IVDR Conformity Assessment.**

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| Applicant Signature:  Electronic signatures or use of pen and scan are only accepted) |  |
| Name (please print): |  |
| Position / Title: |  |
| Date: | *DD-Mmm-YYYY* |
| Acknowledge\*: | By signing this form, you agree to pay the application fee\*\* as outlined in the NSAI Medical Device Pricelist (available at [www.nsai.ie/medicaldevices](http://www.nsai.ie/medicaldevices)). NSAI will begin processing this RFQ upon receipt, however scheduling activities will not proceed until the application fee has been paid in full.  Yes  No |
| PO number for Application fee (if applicable): |  |

\*Failure to pay the application fee will prevent the NSAI from issuing any quote or contract proposal for the requested service(s).

**\*\*The application fee covers the first-year annual certification fee. This application fee enables the NSAI to prepare a comprehensive quote that discloses all costs associated with the initial certification, ensuring transparency and predictability**.

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

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