Request for Quotation for Quality Management System Certification and if applicable Conformity Assessment Activities for Medical Device Regulation.

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| **1 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 | | | | | | |
|  | Addition of site/location to existing certificate\* | | Current NSAI certificate ID: | | | |  |

\*For adding site or location to existing NSAI certificate the information in section 3 and 4 needs to be filled in. Other fields are filled in as needed only.

If this Quality Management System Certification 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:

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| **2 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 IX, including chapter II (class IIb implants and class III) | | | Annex XI Part A (only for class IIa and lower) | | | |
|  | This MDR request is for:  Initial certification  Re-certification  Transfer of certification to NSAI | | | | | | |
|  | 722/2012 - Tissues of Animal Origin | | | | | | |
|  | Other / Additional |  | | | | | |
| For IVDR 2017/746 – In-Vitro Diagnostic Regulation, please complete MTF-4001 (available on request from NSAI) | | | | | | | |

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| **3 Company Information** | | | | | | | | |
| Company Name: | |  | | | | | | |
| Manufacturer Registered Name if different from above:  (as per definition of “Manufacturer” within the MDR) | |  | | | | | | |
| EUDAMED SRN (Single Registration Number, for MDR requests): | |  | | | | | | |
| Address, including Country: | |  | | | | | | |
| Applicant is a subsidiary of: | |  | | | | | | |
| Number of Employees: | |  | | | Number of Shifts: | | |  |
| Enterprise Category[[1]](#footnote-2): | | Choose an item. | | | | | | |
| 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: | |  | | |

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| **4 Information about facilities** | | | |
| 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 Management 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 below table to provide information ‘A’ through ‘H’ for each facility.

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| A | Facility Address: | |  | | | | | | | | |
| B | Number of employees: | | |  | | | 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 | 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 applicable 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(s) of sterilization:** | | | Method: | | |
|  | Chemical Processing | | |
|  | Servicing/Refurbishment | | |  | Other technology, please state: | | | Technology: | | |
|  | Precision Mechanics & Optics | | |  |  | | |  | | |
| H | Please tick all appropriate Activities applicable at this location: | | | | | | | | | | |
|  | Management | | |  | Warehouse and/or Logistics | | |  | Distribution | |
|  | Design and Development | | |  | Final inspection or Product Release | | |  | Calibration | |
|  | Manufacturing/Production | | |  | Installation | | |  | Service/Repair | |
|  | Quality/Regulatory Assurance | | |  | Other | | | Specify: | | |
|  | Sales | | |

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| **5 Outsourced Processing** | | |
| Do you outsource any processes?  \*if yes please specify and indicate critical processes – Associated Site Certification | | Yes  No |
| Outsourced Process | Name / Address of outsource to company | Certified to\*: |
| e.g. Final packaging |  |  |
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\*Indicate what standard this company’s QMS is certified to.

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| **6 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 (see NBOG BPG 2010-1.)** | | |
| **Product/Service** | **Supplier Name / Address** | **Supplier Certified to** |
| e.g. Printed Circuit Board (PCB) manufacturing | e.g. PCB, Inc. 123 California, USA | ISO 13485 |
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| **7 Commercial competitor** | |
| **Please Note:** Only to be completed by companies which are looking for CE Marking conformity assessment under **MDR 2017/745** List all potential commercial competitor(s) for the medical device(s) 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 (or group) to be CE Marked with NSAI** | **Potential Commercial Competitor Name(s)** |
| e.g. Transcatheter aortic valve replacement | ValveTech, Inc., ABC Valves, ACME Valves, |
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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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| **8 Certification Details**  Proposed Scope of Certification for this Request: (e.g. design, manufacture, and distribution of ....) |
| Please provide the proposed scope of certification (for new clients only): |
| MDR[[2]](#footnote-3):  ISO 13485[[3]](#footnote-4):  MDSAP[[4]](#footnote-5): |
| 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) |
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| **9 MDR Product informtion** | | |
| For MDR only: Complete the MTF-3015 “Device Portfolio Information Form” included in the application package (xls-file). Please follow the instructions indicted in the document. Only record the devices that are available for conformity assessment now (i.e., do not add products that you are planning to submit at a later stage)  Please return Device Portfolio Information Form in **both xls and pdf format**. |  | |
| Are any of the product, listed in MTF-3015, used as systems or procedure packs: | Yes  No | |
| Will you sterilise a system or procedure pack under Article 22 (3):  If yes, what sterilization method(s): | Yes  No | |
| Has the MTF-3015 MDR Device Portfolio been filled in completely?  NSAI will not approve any RFQ that’s missing a completed MTF-3015. | Yes  No | |
| Are **all** devices included in the MTF-3015 medical devices, according to MDR Article 2.1 definition? | Yes  No | |
| Is any of the devices included in MTF-3015 listed in MDR Annex XVI? | Yes  No | |
| If, yes, which: | | |
| **10 MDR Other information** | | | |
| 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 | |

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| **11 Existing Certification** | | | | | N/A |
| Please list any Certifications currently held by your company (mandatory for clients seeking transfer to NSAI): | | | | | |
| **Certified to** | **Name of Certification Body** | **Certificate #** | | **Expiry Date** | |
|  |  |  | | *DD-Mmm-YYYY* | |
|  |  |  | |  | |
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| Please confirm that copies of your current certificates will be submitted when emailing this form. | | Yes  No |  | | |

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| **12 Transfer of QMS Certificate(s)** | | N/A |
| If you are requesting a transfer of the above QMS Certificate(s) to NSAI, please provide the following: | | |
| Date of last site audit: | *DD-Mmm-YYYY* | |
| Type of last site audit:  (e.g. Initial/Surveillance 1 or 2/Re-certification) |  | |

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| **13 Any Other relevant Details:** |
| Details: |

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| **14 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: | *Mmm-YYYY* |
| Preferred Technical Documentation submission dates: | *Mmm-YYYY* |

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| **15 Use of Consultants** | | |
| Do you utilize an external Consultant(s)? | Yes | No |
| If yes, please provide all relevant details |  | |

**Request for Quotation (RFQ) for Quality System Certification and if applicable MDR Conformity Assessment Signatures**

**Note:** Where NSAI utilises a subcontract auditor/product reviewer for conformity assessment activities, that individual meets all relevant MDR 2017/745, SCC and MDSAP 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) for Certification and or MDR 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 MDR Conformity Assessment. This RFQ will be the basis for a Quote/Contract. Signing that Quote/Contract will be the formal application for MDR Conformity Assessment.**

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| Applicant Signature: Electronic signatures or use of pen and scan are accepted only) |  |
| Name (please print): |  |
| Position / Title: |  |
| Date: | *DD-Mmm-YYYY* |

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

|  |  |
| --- | --- |
| **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) | NSAI  Medical Devices  1 Swift Square  Northwood  Santry, Dublin 9  [medicaldevices@nsai.ie](mailto:medicaldevices@nsai.ie) |

1. 1. The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer

   than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet

   total not exceeding EUR 43 million.

   2. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and

   whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million.

   3. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and

   whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million. [↑](#footnote-ref-2)
2. Shall only include the category of devices and/or generic device groups that are covered by the QMS. [↑](#footnote-ref-3)
3. Shall indicate what processes are managed within the QMS and for what type of products. [↑](#footnote-ref-4)
4. Shall indicate activities and devices covered by the QMS. [↑](#footnote-ref-5)