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| **General Information** |
| **PO Number:** |  |
| **Company Name** |  | **File/Certificate Number** |  |
| **Facility Address:** |  |
| **Company Liaison and Contact Details:** | Name: |  |
| Email: |  |
| Telephone: |  |
| **Date of Submission**  |  |

| **QMS Change Description**  |
| --- |
| **Type of Change** | Please Tick as Applicable:[ ]  New Ownership [ ]  New Company Name[ ]  Change to scope of Existing Registration[ ]  Addition of a new product range or process[ ]  Removal of a product range or process [ ]  Change in Management Representative / NSAI Contact[ ]  Changes to Quality Manual [ ]  Change in Critical Supplier(s)[ ]  Change in employee number[ ]  Addition or reduction in Facilities[ ]  Relocation of Design or Production activities[ ]  Add a New Location/Site (Please contact your Client Service Representative on submission of this form)[ ]  Expansion of existing Facility[ ]  Elimination of existing Facility[ ]  Other: *please describe below*  |
| **Brief Description of Change** |  |
| **Reason for Change** |  |
| **Impact of the Change on:**  | Please Tick as Applicable:Yes No [ ]  [ ]  Product Use[ ]  [ ]  Product indications or contra-indications[ ]  [ ]  Product labels or Instructions for Use (IFU)[ ]  [ ]  Validations[ ]  [ ]  Risk Management PlanIf yes, please indicate the NSAI product families affected:  |
| **Supporting Documentation Attached**  | Please Tick as Applicable:[ ]  Quality Manual / Procedures [ ]  Quality Plan[ ]  Validation Plan / Report[ ]  Risk Analysis[ ]  Risk Management Plan[ ]  Copy of existing QMS certificate(s) |
| **Effective Date of Change** |  |
| **Additional Comments (If necessary)** |  |

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| **Signature** |
| We declare the information in this form is correct and has been submitted as instructed. Information not provided, or provided in the wrong format, may result in prolonged review time, delays, or termination of review.We acknowledge and accept that for changes in ownership, name, new facilities, etc.,MCN-1001 Client Contract Schedule 1, MCN-1002 Client Contract Schedule 2 and Client Registration Agreements are maintained and continue to apply. |
| Signed on Behalf of the Applicant |
| **Please****Sign****Here** | ▶ |  |
| **Print Name** |  |
| **Position / Title:** |  |

| **Form Submission**  |
| --- |
| **Please forward the completed form to**: |
| **Email**  | medicaldevices@nsaiinc.com or medicaldevices@nsai.ieand include your Client Service Representative when emailing this form |
| **Postal Address** | NSAI, Inc20 Trafalgar SquareSuite 603Nashua, NH03063 USAT: 1 603 882 4412 | NSAI1 Swift SquareNorthwoodSantryDublin 9D09 A0E4, Ireland T: 353 1 807 3800 |

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| **For NSAI Use Only** |
| **Reviewed By** |  | **Date:** |  |
| **NSAI Follow-Up Actions Required** | Please Tick as Applicable:[ ]  *Not Considered Substantial*[ ]  *No Action Required* [ ]  *Amendment of Registration Details Required:* [ ]  *Database Update* [ ]  *Issue New Certificate*[ ]  *Additional Information from Client is required*[ ]   *Special Assessment and Verification Required**Audit Duration -**Rationale -*[ ]   *Change in Ownership – Next Impartiality Issue Goldmine Update*[ ]   *Review and Verify during Next Audit:*[ ]   *Other* |
| **NSAI Review Queries and Disposition**  |  |