|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 Plan  If 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)** |  |

|  |  |  |
| --- | --- | --- |
| **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](mailto:medicaldevices@nsaiinc.com) or [medicaldevices@nsai.ie](mailto:medicaldevices@nsai.ie)  and include your Client Service Representative when emailing this form | |
| **Postal Address** | NSAI, Inc  20 Trafalgar Square  Suite 603  Nashua, NH  03063 USA  T: 1 603 882 4412 | NSAI  1 Swift Square  Northwood  Santry  Dublin 9  D09 A0E4, Ireland  T: 353 1 807 3800 |

|  |  |  |  |
| --- | --- | --- | --- |
| **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** |  | | |