



**NSAI**

**Substantial Change Notification  
Management Systems / Certificate Information**

Company Name	
File number	

Facility Address	
Street	
City	
Zip Code	
Country	

Company Contact	
Telephone	
Email	

Signature	
Date of Submission	
Effective Date of Change:	

**Management System Change:**

- New Ownership
- New Company Name
- Change to scope of Existing Registration
- Change in Management Representative or key personnel
- Change in Management System
- Changes to Quality Manual
- Change of EU Representative
- Change in Critical Supplier
- Relocation of Design or Production activities
- Addition or reduction in Facilities
  - Move to a New Location
  - Expansion of existing Facility
  - Elimination of existing Facility
- Addition or reduction of headcount/shifts
- Addition or reduction of Outsourced Processes

**Brief Description of Change:**

**Reason for Change:**

**Please complete for changes to / additional facilities:**

Facility Address:

Related number of Employees:

Number of Employees per shift (if applicable):

Normal working hours at this facility:

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:

**Does this change or impact the following:**

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:**

Quality Manual / Procedures

Quality Plan

Validation Plan / Report

Risk Analysis

Risk Management Plan

Copy of existing QMS certificate(s)

Additional Comments (if necessary):

**Please forward the completed form to: [reports@nsaiinc.com](mailto:reports@nsaiinc.com)**

Or, mail completed forms to the following address:

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In North America:

**NSAI, Inc.**

20 Trafalgar Square

Suite 603

Nashua, NH

03063 USA

T 1 603 882 4412

F 1 603 882 1985

Others

**NSAI**

1 Swift Square

Northwood

Santry

Dublin 9, Ireland

T 353 1 807 3800

F 353 1 807 3838

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**This Page Reserved for NSAI use:**

<i>Reviewed by:</i>	<i>Date:</i>
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*Review Queries:*

- 1.
- 2.
- 3.
- 4.

*NSAI Follow-up Actions Required:*

- Not Considered Substantial*
- No Action Required*
- Amendment of Registration Details Required:*
  - Database Update*
  - Issue New Certificate*
- Additional Information from Client is required*
- Special On-site Visit and Verification Required*

*Audit Duration -*  
*Rationale -*

- Change in Ownership – Next Impartiality Issue Goldmine Update*
- Review and Verify during Next On-site Audit:*