



NSAI

**Quality Management Systems (QMS) Related
Substantial Change Notification**

Company Name	
--------------	--

Facility Address	
Street	
City	
Zip Code	
Country	

Company Contact					
Telephone:		Fax:		Email:	

Date of submittal	
-------------------	--

Quality Management System (QMS) Change:

- New Ownership
- New Company Name
- Change in Management Representative
- 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

<u>Brief Description of Change:</u>
--

<u>Reason for Change:</u>

Does this change or impact the following?:

- | Yes | No | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Product Use |
| <input type="checkbox"/> | <input type="checkbox"/> | Product indications or contra-indications |
| <input type="checkbox"/> | <input type="checkbox"/> | Product labels or Instructions for Use (IFU) |
| <input type="checkbox"/> | <input type="checkbox"/> | Validations |
| <input type="checkbox"/> | <input type="checkbox"/> | Risk Management Plan |

Supporting Documentation Attached:

- Quality Manual / Procedures
- Quality Plan
- Validation Plan / Report
- Risk Analysis
- Risk Management Plan

Additional Comments (if necessary):

Please forward the completed form to: medicaldevices@nsaiinc.com
or medicaldevices@nsai.ie

Or, mail completed forms to the following address:

In North America:
NSAI, Inc.
402 Amherst St.
Nashua, NH
03063

Others:
NSAI
1 Swift Square,
Northwood,
Santry
Dublin 9, Ireland

This Page Reserved for NSAI use:

<i>Reviewed by:</i>	<i>Date:</i>
---------------------	--------------

Review Queries:

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

NSAI Follow-up Actions Required:

- No action required / Place on file*
- Amendment of registration details required:*
 - Database update*
 - Issue new certificate*
- Additional information from client is required*
- Special On-site visit and verification required*
- Review and verify during next on-site audit:*