



## Manufacturer Evidence

Status : Versioned

### Certificate change history

Date received : 15/08/2014

Certificate printed : No

New Notification

### Notification details

Evidence identifier: DV-2014-MC-13597-1

Submission identifier: DM-2014-05539-1

Version number: 1

Sponsor's own reference: Velocity

### Sponsor details

Agent name:

Sponsor name: Varian Medical Systems Australasia Pty Ltd

Contact details:

### Certification details

Manufacturer name: Velocity Medical Solutions (United States Of America)[54719]

Manufacturer address as on certification: 1350 Spring Street Suite 275 Atlanta GA 30309 United States Of America S [ : ]

Type of product:

This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under: 02

Conformity assessment procedure: Schedule 3 Part 1 (Annex II)

Source of certification: National Standards Authority of Ireland (NSAI) [0050]

Certificate number: 252.1087

Certificate issue date: (dd/mm/yyyy) 08/03/2011

Certificate expiry date: (dd/mm/yyyy) 07/12/2014

Certificate re-issue date: (dd/mm/yyyy)

Restrictions on scope:

Restriction on conformity assessment procedure:

Full Quality Assurance Certificate.

Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

### Attached documentation:

Attached documents

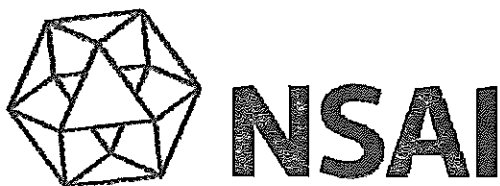
 EC Certificate - EC Certificate - Velocity - Exp 07.12.14.pdf

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:			

## History

CN=Jude Luzuriaga/OU=TGA/O=Health



# Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

*APPROVES THE QUALITY SYSTEM APPLIED BY*

## Velocity Medical Solutions, LLC

1350 Spring Street  
Suite 275  
Atlanta  
GA 30309  
USA

*to the Product Family*

### Picture Archiving and Communication System (VelocityAIS)

*on the basis of examination under the requirements of Annex II, Section 3 of Directive 93/42/EEC.  
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.1087</b>
<b>Original Approval:</b>	<b>08 March 2011</b>
<b>Last Amended on:</b>	<b>03 June 2014</b>
<b>Remains valid until:</b>	<b>07 December 2014</b>

**Signed:**

Approved by:  
Kevin D. Mullaney  
Chief Executive Officer - NSAI Inc

Approved by:  
Susan Murphy  
Risk Management Officer

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner .  
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI  
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**