



# NSAI

## 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**

### ICU Medical, Inc.

**951 Calle Amanecer  
San Clemente,  
CA 92673  
USA**

*to the Product Family*

### IV Connector and Sets & Intravascular Administration Sets

GMDN Code: 12159, 12170, 18067, 32172, 34099, 35071, 35072, 35375, 38569, 41222, 41646, 42631, 42727,  
42743, 42750, 43324, 58977, 60538

*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>252.602</b>
<b>Original Approval:</b>	<b>16 October 2003</b>
<b>Last Amended on:</b>	<b>13 October 2015</b>
<b>Remains valid until:</b>	<b>16 October 2018</b>

**Signed:**

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

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**  
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**