



# 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*

### Critical Care Catheters

**GMDN Code: 10729, 10759, 35889, 34925, 36218, 31659**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex  
II, excluding (4)*

*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>252.129</b>
<b>Original Approval:</b>	<b>15 September 1995</b>
<b>Last Amended on:</b>	<b>26 July 2016</b>
<b>Remains valid until:</b>	<b>16 May 2019</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.**



# NSAI

## EC Design Examination 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)*

**HAS EXAMINED THE DESIGN DOSSIER**

**Submitted by**

### ICU Medical, Inc

**951 Calle Amanecer**

**San Clemente**

**CA 92673**

**USA**

*For Product Family*

### Critical Care Catheters

**GMDN Code: 10729, 10759, 35889, 34925, 36218, 31659**

**CONCLUSION of EXAMINATION:**

*NSAI have performed an examination of the design dossier relating to the above named product family and  
conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II,  
Section (4)*

**Registration Number: 252.129**

**Original Approval: 15 September 1995**

**Last Amended on: 26 July 2016**

**Remains valid until: 16 May 2019**

**Signed:**

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

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

**CONDITIONS OF VALIDITY:**

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**

**Approved model numbers are included in the associated attachment**

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the  
product must receive further approval from NSAI.

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



# NSAI

## Attachment to Certificate 252.129 dated 15 September 1995

**This Certificate covers 45 model(s)**

Model Reference	Detail
011-41216-01	TD Catheter, 8F, 5 Lumen, 110 cm RA/RV
011-41217-01	TD Catheter, 8F, 5 Lumen, 110 cm, RA/RA
011-41223-01	TD Catheter, 7F, 4 Lumen, 110 cm
011-41227-01	TD Catheter, 7F, 4 Lumen, 110 cm, S-Tip
011-41229-01	TD Catheter, 7F, 4 Lumen, 110cm, Heparin Coated
011-41231-05	TD Torque-Line Catheter, 7F, 4 Lumen, 110 cm
011-41232-01	TD Catheter, 8F, 5 Lumen, 110cm, RA/RV, Heparin Coated
011-41233-01	TD Catheter, 8F, 5 Lumen, 110cm, RA/RA, Heparin Coated
011-41237-05	TD Torque-Line Catheter, 8F, 5 Lumen, 110cm, RA/RA, Heparin Coated
011-41239-05	TD Torque-Line Catheter, 7F, 4 Lumen, 110cm, Heparin Coated
011-41240-05	TD Torque-Line Catheter, 8F, 5 Lumen, 110 cm, RA/RA
011-41248-05	Monitoring Torque-Line Catheter, 7F, 2 Lumen, 110 cm
011-41250-05	Monitoring Torque-Line Catheter, 7F, 3 Lumen, 110 cm, RA



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011-41251-05	TD Torque-Line Catheter, 7F, 4 Lumen, 110 cm, S-Tip
011-41252-05	TD Torque-Line Pacing Catheter, 8F, 5 Lumen, 110cm, RV Pacing, Heparin Coated
011-41300-01	TD Pacing Catheter, 8F, 5 Lumen, 110cm, RV Pacing, Heparin Coated
011-41400-13	Central Venous Catheter, Heparin Coated, 3 Lumen, 16/18/18G, 20cm, PMAP Basic Kit
011-41430-01	Central Venous Catheter, 2 Lumen, 16/16 G, 20 cm, MAP, Basic Kit
011-41431-01	Central Venous Catheter, 3 Lumen, 16/18/18 G, 20 cm, MAP, Basic Kit
011-41432-01	Central Venous Catheter, 3 Lumen, 16/18/18 G, 30 cm, MAP, Basic Kit
011-41433-01	Central Venous Catheter, Heparin Coated, 2 Lumen, 14/18 G, 20cm, MAP, Basic Kit
011-41434-01	Central Venous Catheter, Heparin Coated, 2 Lumen, 16/16 G, 20cm, MAP, Basic Kit
011-41435-01	Central Venous Catheter, Heparin Coated, 3 Lumen, 16/18/18 G, 20cm, MAP, Basic Kit
011-41436-01	Central Venous Catheter, Heparin Coated, 3 Lumen, 16/18/18 G, 30cm, MAP, Basic Kit
011-41437-01	Central Venous Catheter, Heparin Coated, 2 Lumen, 16/16 G, 30cm, MAP, Basic Kit
011-50404-01	TriOx SO2 Umbilical Artery Catheter U440, 4F, 40cm
011-50405-01	TriOx SO2 Umbilical Artery Catheter U425, 4F, 25cm
011-50458-01	TriOx ScvO2 Central Venous Oximetry Catheter, Heparin Coated, Basic Kit
011-50465-01	TriOx ScvO2 Central Venous Oximetry Catheter, Basic Kit



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011-50472-01	TriOx ScvO2 Central Venous Oximetry Catheter, Heparin Coated
011-50473-01	TriOx ScvO2 Central Venous Oximetry Catheter
011-52515-01	TDQ, CCO Catheter, 8F, 110cm, Heparin Coated
011-50324-07	TriOx SvO2 PA Catheter P7110-EH, 7.5F, 110cm, Heparin Coated
011-50325-07	TriOx SvO2 PA Catheter P7110-E, 7.5F, 110cm
011-50327-07	TriOx SvO2 PA Catheter P7110-EP-H, 7.5F, 110cm, Extra Port, Heparin Coated
011-50328-07	TriOx SvO2 PA Catheter P7110-EP8-H, 8F, 110cm, Extra Port, Heparin Coated
011-50337-07	TriOx SvO2 PA Catheter P7110-EP8, 8F, 110cm, Extra Port
011-50344-07	TriOx SvO2 PA Pacing Catheter P7110-EZ8-H, 8F, 110cm, RV Pacing, Heparin Coated
011-50354-05	TriOx SvO2 PA Catheter P575-10CM-EH, 5.5F, 75cm, Heparin Coated
011-50355-05	TriOx SvO2 PA Catheter P575-15CM-EH, 5.5F, 75cm, Heparin Coated
011-50407-02	TriOx SO2 Intravascular Catheter P540-H, 5.5F, 40cm, Heparin Coated
011-52509-14	TriOx SvO2/CCO PA Catheter, 8F, 110cm, Q-Tip, Heparin Coated
011-52510-14	TriOx SvO2/CCO PA Catheter, 8F, 110cm, J-Tip, Heparin Coated
011-52511-14	TriOx SvO2/CCO PA Catheter, 8F, 110cm, Q-Tip
011-52515-14	TDQ, CCO Catheter, 8F, 110 cm, Heparin Coated