



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

Parenteral / Enteral Solution Bag

GMDN Code: 35188

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorized.*

Registration Number:	252.884
Original Approval:	05 October 2012
Last Amended on:	27 November 2015
Remains valid until:	04 October 2018

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 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.**