



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The design, manufacture, sterilization and distribution of intravenous catheters, IV administration sets, custom IV kits, IV connectors, molded sub-assemblies and accessories, enteral feeding valves, vial access devices, infusion sets, monitoring devices and sterile leur access valve disinfectant cap. The manufacture, repair and servicing of optical modules for oxygen measurement. Irradiation sterilization of medical devices in accordance with ISO 11137-1:2006.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4496)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4496
Certification Granted: Sep 04, 2003
Effective Date: Jun 05, 2017
Expiry Date: Jun 04, 2020



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



Annex to Certificate Number: MD19.4496

Scope of Registration :

The design, manufacture, sterilization and distribution of intravenous catheters, IV administration sets, custom IV kits, IV connectors, molded sub-assemblies and accessories, enteral feeding valves, vial access devices, infusion sets, monitoring devices and sterile leuc access valve disinfectant cap. The manufacture, repair and servicing of optical modules for oxygen measurement. Irradiation sterilization of medical devices in accordance with ISO 11137-1:2006.

Activity

Location

Headquarters, Design,
Distribution

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673
USA
File No.: MD19.4496

Design, Manufacturing,
Distribution, Service

ICU Medical, Inc.
4455 Atherton Drive
Salt Lake City, UT 84123
USA
File No.: MD19.4496/B

Manufacturing, Sterilization,
Distribution

ICU Medical de Mexico,
S. de R.L. de C.V.
Avenida Cuarzo No. 250
Colonia Rancho Santa Clara
Maneadero Ensenada
Baja California 22790
Mexico
File No. : MD19.4496/C

Supplier Quality

ICU Medical, Inc.
961-B Calle Amanecer
San Clemente, CA 92673
USA
File No.: MD19.4496/F

**Verified by:
Operations Manager**