MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.129 / Critical Care Catheters

This is a declaration made in accordance with the requirements of the European Council Directive 93/42/EEC of 14th June 1993, concerning medical devices (MDD)

Manufacturer	ICU Medical, Inc.
Business Address:	951 Calle Amanecer, San Clemente, California 92673 USA
EU Authorized Representative:	Medical Device Safety Service, GmbH (MDSS) Schiffgraben 41 D-30175 Hannover, Germany
Medical Devices: Identification of object of the declaration:	List numbers and descriptions are included in Attachment A of this document
MDD Classification:	Class III Rule 7 Annex II, Section 3.2 and Annex II, Section 4

Statement of Conformity:
We, ICU Medical, Inc. solely declare that the above products, described herein, comply with the Essential Requirements and applicable provisions of the Council Directive 93/42/EEC of 14th June 1993, concerning medical devices and the transitional provisions of (EU) 2017/745 Article 120(3).

This declaration is based on:
Devices are certified according to Annex II, Section 3.2 and Annex II, Section 4 of the council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

EC Certificate Number: 252.129

Product Scope: Critical Care Catheters

Notified Body: National Standards Authority of Ireland (NSAI)
1 Swift Square, Northwood, Santry,
Dublin 9, Ireland

Notified Body Number: 0050

Authorised Signatory:

Issuers Name: Sheila Antonio — 6/12/2024
Dept: Director, Regulatory Affairs — Signature — Date

Place of Issue: San Clemente, California	Date of Issue: 6/12/2024

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Attachment A – Product List

PN	Description	Classification, Rule	GMDN Code
011-41217-01	TD Catheter, 8F, 5 Lumen, 110 cm, RA/RA	Rule 7	34925
011-41223-01	TD Catheter, 7F, 4 Lumen, 110 cm	Rule 7	34925
011-41227-01	TD Catheter, 7F, 4 Lumen, 110 cm, S-Tip	Rule 7	34925
011-41229-01	TD Catheter, 7F, 4 Lumen, 110cm, Heparin Coated	Rule 7 and 13	34925
011-41231-05	TD Torque-Line Catheter, 7F, 4 Lumen, 110 cm	Rule 7	34925
011-41232-01	TD Catheter, 8F, 5 Lumen, 110cm, RA/RV, Heparin Coated	Rule 7 and 13	34925
011-41233-01	TD Catheter, 8F, 5 Lumen, 110cm, RA/RA, Heparin Coated	Rule 7 and 13	34925
011-41239-05	TD Torque-Line Catheter, 7F, 4 Lumen, 110cm, Heparin Coated	Rule 7 and 13	34925
011-41251-05	TD Torque-Line Catheter, 7F, 4 Lumen, 110 cm, S-Tip	Rule 7	34925
011-41400-13	Central Venous Catheter, Heparin Coated, 3 Lumen,16/18/18G, 20cm, PMAP Basic Kit	Rule 7 and 13	10729
011-41430-01	Central Venous Catheter, 2 Lumen, 16/16 G, 20 cm, MAP, Basic Kit	Rule 7	10729
011-41431-01	Central Venous Catheter, 3 Lumen, 16/18/18 G, 20 cm, MAP, Basic Kit	Rule 7	10729
011-41433-01	Central Venous Catheter, Heparin Coated, 2 Lumen, 14/18 G, 20cm, MAP, Basic Kit	Rule 7 and 13	10729
011-41434-01	Central Venous Catheter, Heparin Coated, 2 Lumen, 16/16 G, 20cm, MAP, Basic Kit	Rule 7 and 13	10729
011-41435-01	Central Venous Catheter, Heparin Coated, 3 Lumen, 16/18/18 G, 20cm, MAP, Basic Kit	Rule 7 and 13	10729
011-41436-01	Central Venous Catheter, Heparin Coated, 3 Lumen, 16/18/18 G, 30cm, MAP, Basic Kit	Rule 7 and 13	10729
011-41437-01	Central Venous Catheter, Heparin Coated, 2 Lumen, 16/16 G, 30cm, MAP, Basic Kit	Rule 7 and 13	10729
011-50404-01	TriOx SO2 Umbilical Artery Catheter U440, 4F, 40cm	Rule 7	31659
011-50458-01	TriOx ScvO2 Central Venous Oximetry Catheter, Heparin Coated, Basic Kit	Rule 7 and 13	31659
011-50473-01	TriOx ScvO2 Central Venous Oximetry Catheter	Rule 7	31659
011-50324-07	TriOx SvO2 PA Catheter P7110-EH, 7.5F, 110cm, Heparin Coated	Rule 7 and 13	34925
011-50325-07	TriOx SvO2 PA Catheter P7110-E, 7.5F, 110cm	Rule 7	34925
011-50327-07	TriOx SvO2 PA Catheter P7110-EP-H, 7.5F, 110cm, Extra Port, Heparin Coated	Rule 7 and 13	34925
011-50328-07	TriOx SvO2 PA Catheter P7110-EP8-H, 8F, 110cm, Extra Port, Heparin Coated	Rule 7 and 13	34925
011-50355-05	TriOx SvO2 PA Catheter P575-15CM-EH, 5.5F, 75cm, Heparin Coated	Rule 7 and 13	34925
011-50407-02	TriOx SO2 Intravascular Catheter P540-H, 5.5F, 40cm, Heparin Coated	Rule 7 and 13	31659
011-52509-14	TriOx SvO2/CCO PA Catheter, 8F, 110cm, Q-Tip, Heparin Coated	Rule 7 and 13	34925
011-52511-14	TriOx SvO2/CCO PA Catheter, 8F, 110cm, Q-Tip	Rule 7	34925
011-52515-14	TDQ, CCO Catheter, 8F, 110 cm, Heparin Coated	Rule 7 and 13	34925

END OF ATTACHMENT A - PRODUCT LIST

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Standards Applied

Standard Reference	Standard Title
EN ISO 13485:2016+A11:2021	Medical Devices - Quality Management Systems
EN ISO 14971:2019+ A1:2021	Medical devices. Application of risk management to medical devices
EN ISO 11135-1:2014+A1:2019	Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices
EN 556-1:2001/ AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN 15986:2011	Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates
EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008+A1:2022	Biological Evaluation of Medical Devices - Ethylene Oxide sterilization residuals
ISO 10993-10:2021	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
EN ISO 11137-1:2015+A2:2019	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015+A1:2023	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 11067-1:2019/ Amd1:2023	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)
EN ISO 7886-1:2018	Sterile hypodermic syringe for single use Part 1: Syringe for manual use - CORR: June 30, 2018; CORR: October 31, 2019
EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
EN 60601-1:2006/ A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/ A1:2021	Medical electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility
ANSI/AAMI ST72	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing

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Standard Reference	Standard Title
ISTA 2/3	Transportation simulation performance testing
EN ISO 10555-1:2013/ A1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
EN ISO 10555-3:2013	Intravascular catheters – Sterile and single-use catheters – Part 3: Central Venous Catheters
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
EN ISO 11070:2014+ A1:2018	Sterile single-use intravascular introducers, dilators and guidewires
EN ISO 11737- 1:2018	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2019	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process