MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number CE 674104 / Catheters and Introducers

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

Manufacturer: *Issuer of Declaration*	ICU Medical, Inc.		
Manufacturer Address:	600 North Field Drive Lake Forest, Illinois, 60045 USA		
EU Authorized Representative:	ICU Medical B.V. Hofspoor 3, 3994 VZ Houten The Netherlands		
Medical Devices: *Identification of object of the declaration:*	**List Number:**	**Product Name:**	**GMDN Code:**
	G713	ABBOCATH-T 14G 21N	40601
	G714	ABBOCATH-T 16G 21N	40601
	G715	ABBOCATH-T 18G 21N	40601
	G717	ABBOCATH-T 20G 1-1/41N	40601
	G718	ABBOCATH-T 20G 21N	40601
	G719	ABBOCATH-T 22G 1-7/8 IN	40601
	G720	ABBOCATH-T 24G 3/41N	40601
	G944	ABBOCATH-T 26G 1-5/8 IN	40601
MDD Classification:	Class: IIa	Rule VII, according to Annex IX of the MDD	

Statement of Conformity:

We ICU Medical, Inc. solely declare that the above products, described herein, complies with the Essential Requirements and applicable provisions of the Council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

This declaration is based on:
Devices are certified according to Annex II without clause 4 of the council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

EC Certificate: CE 674104

Scope: Catheters and Introducers

Issued by: BSI Group, The Netherlands B.V.,
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands
Notified body number: 2797

Authorised Signatories:

Issuers Name: Sheila Antonio — Signature — 6/12/2020
Dept: Global Regulatory Affairs — Date

Issuers Name: Dale Lovrine — Signature — 6/15/2020
Dept: Research and Development — Date

Place of Issue: Lake Forest, IL, USA — Date of issue: 12 June 2020

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Standards Applied

Standards Applied: List of applicable standards	Standard Reference	Standard Title
	EN ISO 13485:2016	Medical devices - quality management systems – Requirements for regulatory purposes
	EN ISO 14971:2012	Application of risk management to medical devices
	EN ISO 10993-1:2009/ AC:2010	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. Tests for genotoxicity, carcinogenicity and reproductive toxicity (British Standard)
	EN ISO 10993-4: 2009	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 10993-6:2009	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
	EN ISO 10993-7:2008/AC:2009	Biological Evaluation of Medical Devices Part 7: Ethylene Oxide sterilization residuals
	EN ISO 10993-11: 2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	EN ISO 11607-1: 2009	Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	EN ISO 11135-1:2007	Sterilization of Healthcare Products – Ethylene Oxide - Part 1: 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" - Part 1: Requirements for terminally sterilized medical devices
	EN ISO 10555-1:2009	Sterile, single-use intravascular catheters - Part 1: General requirements
	EN 1041:2008	Information supplied by the Manufacturer of medical devices
	EN 62366: 2008	Medical devices - Application of usability engineering to medical devices
	EN ISO 15223-1: 2016	Symbols to be used with medical device labels, labelling and information to be supplied Part 1 – General requirements
	EN 20594-1:1993/A1:1997	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and certain other Medical Equipment – Part 1: General Requirements
	EN 1707:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings