

## Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ICU Medical, Inc.
Manufacturer address and contact details	951 Calle Amanecer San Clemente CA 92673 USA
Single Registration Number (SRN) (if available)	US-MF-000009764

Authorised Representative name (if applicable)	Medical Device Safety Service GmbH
Authorised Representative address and contact details	Schiffgraben 41 D-30175 Hannover, Germany
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	NSAI
Notified body number (if applicable)	0050
Directive Certificate number(s) to which this confirmation is made (if applicable)	252.129 252.602 252.631 252.702 252.714 252.998 252.1002
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	See attached Schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met  
and
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule:

- Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
- A formal application to a notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment was made before 26 May 2024 for the devices listed in the attached schedule and a signed written agreement was in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

➤ **Device(s) as listed in the attached schedule**

- The devices continue to comply with MDD.
- There have been no significant changes to the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:** ICU Medical Inc.

Date: 13 May 2024



Jennifer Cooke  
Senior Manager, Regulatory Affairs  
jennifer.cooke@icumed.com

## Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	Directive Certificate numbers to which this confirmation is made	Original expiry date as indicated on the Directive Certificates prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Critical Care Catheters, - Advanced Sensor Catheters (TriOx/TDM)	252.129	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2027
Critical Care Catheters, - Central Venous Catheters	252.129	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2027
Critical Care Catheters, - Central Venous Oximetry Catheters (TriOx/CVOC)	252.129	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2027
Critical Care Catheters, - Thermodilution (TD) Catheters	252.129	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2027
Tego Connector	252.631	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
SwabCap	252.998	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Administration sets	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Extension sets	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Bag Spikes	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028

Stopcocks and Manifolds	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Neutron Connector	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Clave Needlefree Connectors	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Nuitiv Connector	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Administration/Extension Kits	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Transfer Sets	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
ChemoClave CSTDs: Connectors, Administration Sets, Extension Sets, Transfer Sets, Oncology Kits, Bag spikes	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
ChemoLock CSTDs: Connectors, Administration Sets, Extension Sets, Transfer Sets, Oncology Kits, Bag spikes	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Spiros Administration Sets, Extension Sets, Transfer Sets, Oncology Kits	252.602	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Spiros Connectors	252.714	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Vented and Non Vented Vial Adapters	252.1002	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Vented and Non Vented Vial Adapters with Clave Connector	252.1002	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
ChemoClave Closed Vial Adapters	252.1002	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
ChemoLock Closed Vial Adapters	252.1002	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028

Accudynamic	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Basic Monitoring Set Devices (Pressure Tubing, Flushes, Stopcocks, Extension Sets, Luers/ Caps/ Connectors/ Valves)	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
SafeSet Kits	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Cardiac Catheterization Kits	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Transducer Monitoring Kits	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Intracranial Transducer Monitoring Kits	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Transducer SafeSet Kits	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Transducer Cardiac Catheterization Kits	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028
Thermoset injectate delivery system	252.702	26 May 2024	NSAI (0050)	BSI Group, The Netherlands B.V. (2797)	31 December 2028