

EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

acc. to Article 19 of Regulation (EU) 2017/745 on Medical Devices

Name and Address of the Manufacturer: Maquet Critical Care AB
Röntgenvägen 2
SE-171 54 Solna, Sweden

Single Registration Number: SE-MF-000001264

On our sole responsibility, we hereby declare that the product(s)

Product / Trade Name: Servo-u Ventilator system

Product Identification: 6694800

System version: 4.6

Software version: 4.06.00

Description Critical Care Ventilator

Reference No.: See Annex I of this document

Basic UDI-DI (acc. To Part C of Annex VI): 7325710001117R

Classification (acc. To Annex VIII of MDR): Class IIb

comply with the relevant provisions of the following Regulation(s) and Directive(s):

Regulation (EU) 2017/745 on Medical Devices

Notified Body: TÜV SÜD Product Service GmbH
ID No. 0123

Conformity Assessment Procedure: Zertifizierstelle, Ridlerstraße 65
80339 München, Germany
acc. To Annex IX of Regulation (EU)
2017/745

EU QMS Certificate (MDR) No. G10 072017 0015 Rev. 04,
valid from **2025-02-17**
valid to **2030-02-16**

Common Specifications used N/A

Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment

This declaration of conformity is valid from date of issue until **2030-02-16**

For the signature of the Manager for Product Compliance on behalf of Maquet Critical Care AB see left corner of page.

ANNEX I

The following components are covered by the device's CE mark:

Reference No.	Product- / Trade Name / Description	Basic UDI-DI
6884598	Base SW Servo-u	N/A
6884599	Base SW Servo-u Adult	N/A
6884600	SW Pediatric patient category, Servo-u	N/A
6884601	SW BiVent/APRV, Servo-u	N/A
6884602	SW Volume Support, Servo-u	N/A
6884603	SW NAVA, Servo-u	N/A
6693655	SW Automode, Servo-u	N/A
6693680	SW CO ₂ analyzer, Servo-u	N/A
6880513	SW NIV, Servo-u	N/A
6880514	SW Neonatal option, Servo-u	N/A
6880515	SW Nasal CPAP, Servo-u	N/A
6880516	SW Alarm output, Servo-u	N/A
6880517	SW NIV NAVA, Servo-u	N/A
6880518	SW Y sensor, Servo-u	N/A
6885301	SW Servo Compass, Servo-u	N/A
6885303	SW High Flow Therapy, Servo-u	N/A
6887809	SW Open Lung Tool trends, Servo-u	N/A
6889017	SW Open Lung Tool Auto RM, Servo-u	N/A
6889019	SW Open Lung Tool Auto SRM, Servo-u	N/A
6889015	SW Transpulmonary pressure, Servo-u	N/A
6889886	SW Heliox, Servo-u	N/A
6889888	SW NPS, Servo-u	N/A
6889890	SW NIV NPS, Servo-u	N/A
6893037	SW option connectivity, Servo-u	N/A
6650118	O ₂ cell	N/A
6640044*		

Copies must not be used unless their validity has been verified.

6693752	Expiratory cassette, Servo-u	N/A
6670680	O ₂ sensor	N/A
6487180	Battery module, Servo ventilator	N/A
6487941	Test tube, grey	N/A
6038801	Clamp, rail 10x25 mm	N/A
9358193	Clamp, 1 slot	N/A
6693715	Support Arm 178	N/A
6693735	Humidifier Holder Servo-u/Servo-n	N/A
6693722	Waterbag/IV pole Servo-u/Servo-n	N/A
6880848	Thermoshell, Expiratory cassette Servo-u/Servo-n, 5 pcs/pkg	N/A
6693695	Mobile Cart Servo-u/Servo-n, flat pack	N/A
6880248	Handle, new Servo-u	N/A
6692510	Handle, Servo-u upgrade	N/A
6692675	Mounting kit for Compressor Mini on Mobile Cart Servo-u/Servo-n	N/A
6693747	Cable holder Servo-u/Servo-n	N/A
6693720	Gas cylinder restrainer kit, Servo-u/Servo-n	N/A
6890365	Drawer for Low Mobile Cart, Servo-u/Servo-n	N/A
6693712	Shelf Base, Servo-u/Servo-n	N/A
6693710	Pendant/bed holder, Servo-u/Servo-n	N/A
6880099	User interface holder, Servo-u/Servo-n	N/A
6887050	CO ₂ analyzer module Capnostat 5, Servo ventilators	N/A
6880104	CO ₂ /Y sensor adapter, 10 pcs disposable	N/A
6693662	Y sensor module, Servo-u/Servo-n	N/A
6693672	Y sensor Pressure line 1.8m, 10 pcs disposable	N/A
6880253	Y-piece 10 mm angled, sampling port, 5 pcs, 10 mm	N/A
6693667	Y Sensor neonatal 5 pcs, disposable	N/A
6880548	Y piece holder and hook, Servo-u/Servo-n	N/A
6889485	Heliox Servo adapter kit NIST/NIST	N/A
6889486	Heliox Servo adapter kit AGA/NIST	N/A

6889487	Heliox Servo adapter kit DISS	N/A
6672330	Edi module, Servo ventilator 50 Hz	N/A
6672332	Edi module, Servo ventilator 60 Hz	N/A
6006832	Test Lung 190, adult	N/A
6301720	Test Lung 191, neonatal	N/A

* Order number for exchange on installed Servo ventilators