

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-n Ventilator system

Product Identification: 6688600

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

Zertifizierstelle, Ridlerstraße 65
80339 München, Germany

Conformity Assessment Procedure: 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
6885682	Base SW Servo-n	N/A
6880539	SW Automode Servo-n	N/A
6880540	SW NIV, Servo-n	N/A
6880541	SW BiVent/APRV, Servo-n	N/A
6880542	SW Alarm output, Servo-n	N/A
6880544	SW CO ₂ analyzer, Servo-n	N/A
6885302	SW Servo Compass, Servo-n	N/A
6885304	SW High Flow Therapy, Servo-n	N/A
6887810	SW Open Lung Tool trends, Servo-n	N/A
6888011	SW HFO, Servo-n	N/A
6889018	SW Open Lung Tool Auto RM, Servo-n	N/A
6889016	SW Transpulmonary pressure, Servo-n	N/A
6889887	SW Heliox, Servo-n	N/A
6889889	SW NPS, Servo-n	N/A
6889891	SW NIV NPS, Servo-n	N/A
6893038	SW option connectivity, Servo-n	N/A
6693750	Expiratory cassette, Servo-n	N/A
6650118	O ₂ cell	N/A
6640044*		
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

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6693722	Waterbag/IV pole Servo-u/Servo-n	N/A
6880848	Thermoshell, Expiratory cassette chamber. Servo-u/Servo-n, 5 pcs/pkg	N/A
6693695	Mobile Cart Servo-u/Servo-n, flat pack	N/A
6880247	Handle, new Servo-n	N/A
6690937	Handle, Servo-n 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
6301720	Test Lung 191, neonatal	N/A

* Order number for exchange on installed Servo ventilators.