



Certificate

No. Q5 072017 0013 Rev. 01

Holder of Certificate:

GETINGE ✱

MAQUET CRITICAL CARE AB

Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):

MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

See Scope of Certificate

Certification Mark:**Scope of Certificate:**

**Design, development and manufacturing
of Anaesthesia, Monitoring, Ventilator
Systems and Perfusion Systems**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5 072017 0013 Rev. 01

Report No.:

713193727

Valid from:

2020-12-30

Valid until:

2023-12-29

Date,

2020-12-28

Christoph Dicks

Head of Certification/Notified Body

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

acc. to Directive 93/42/EEC on Medical Devices

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

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

Product Description: Anesthesia system

Product Identification: Flow-i Anesthesia System
C20, C30 and C40,
System Version 4.8.3

Product-No.: See Annex I of this document

Classification (acc. to Annex IX of MDD): Class IIb

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

Directive 93/42/EEC 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 II excluding (4) of
Directive 93/42/EEC

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

This declaration is valid until the next change of the product or until the expiration date of the Certificate (No. G1 072017 0014, dated **2020-01-22**, valid to **2024-05-26**) issued by the notified body. Any modification of the medical device not authorized by us will invalidate this declaration.

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

ANNEX I

TO THE EC DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

Product(s) Covered:

Trade Name	Article No.
Base unit	
FLOW-i Anesthesia System C20 (s/n > 20000)	6888520
FLOW-i Anesthesia System C30 (s/n > 20000)	6888530
FLOW-i Anesthesia System C40 (s/n > 20000)	6888540
Additional ventilation modes	
PRVC	6688202
PS with backup	6688200
SIMV (VC) and SIMV (PC)	6688197
Extended ventilation package	6688205
Additional options	
AGC (Automatic Gas Control)	6881990
Recruitment Maneuvers	6886518
Optional module, Additional Fresh Gas Outlet (AFGO)	6681887
AFGO adapter kit, onsite upgrade	6686860
O2 Only	6890455
Oxygen 93	6890925
Absorber	
CO2 Absorber Disposable	6677845
CO2 Absorber disposable 12 pcs	6887738
CO2 Absorber Reusable	6692582

ANNEX I

TO THE EC DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

Dust Filter for CO2 Absorber Reusable	6880430
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Alternative mains power cable

Mains Power cable, 3.5 m, Great Britain, UK BS 1363	6670310
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Mains Power cable, 3.5 m, Europe, EU CEE 7	6424329
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Mains Power cable 3,5m North America	6683275
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Vaporizer

Vaporizer Sevoflurane, QUIK FIL	6682285
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Vaporizer Desflurane, Saf-T-Fil	6682287
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Vaporizer Isoflurane, Maquet filling	6682280
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Vaporizer Sevoflurane, Maquet filling (Abbott, Baxter)	6682282
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Vaporizer Sevoflurane Maquet filling	6886601
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Vaporizer Sevoflurane QUIK FIL	6886611
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Vaporizer Isoflurane Maquet filling	6886621
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Vaporizer Desflurane SAF-FIL	6886631
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Vaporizer Sevoflurane SAFE-T-SEAL	6887135
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Vaporizer Sevoflurane SAFE-T-SEAL	6887523
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MAQUET filling adapter tube for isoflurane bottle	6682290
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MAQUET filling adapter tube for sevoflurane bottle (Abbott, Baxter)	6682292
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Cover for vaporizer slot	6880158
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Vaporizer holder	6880155
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O2 flowmeter / suction equipment

Suction and Auxiliary O2 Flow module	6679847
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Angled adapter for sterile water container	6681900
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Hydrofobic Bacterial Filter (5 pcs)	6887498
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ANNEX I

TO THE EC DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

Backup gas supply

Gas Backup Rack O2/N2O	6881266
Gas Backup Rack O2/AIR	6881267
Backup Gas Holder N2O	6686587
Backup Gas Holder O2	6692630

EVAC outlet Connections

EVAC Restrictor	6880156
22 mm out. Diam. Connector	6692740
30 mm out. Diam. ISO taper connection	6673980
12.7 mm/1/2" in house Barb connector	6679627
25 mm/1" in house Barb connector	6679630
AGA EVAC connector	6679645
WAGD-to-Vacuum connector	6692742
Connection tube 22 int. diam, (disposable), 50 m	6189646
DISS EVAC connector	6679647

Gas analyzer parts

Water trap Dryline A, 10 pcs	6522747
Water trap Dryline 1, 10 pcs	6889352

Extra breathing system parts

Patient cassette complete, extra	6680325
Volume Reflector Flow-i	(s/n > 20000) 6888985

Reusable parts

ANNEX I

TO THE EC DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

Tube joint/adapter 22 mm	6425581
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Mounting kits

Mounting kit for two pin interface	6680315
Mounting kit, slide plate horizontal	6687692
Mounting kit for T8	6686635
Mounting kit for T5	6686637
Mounting kit for VESA 75/100	6686577
Mounting kit for Pick & Go	6687472
Mounting kit, slide plate vertical	6687695
Adjustable arm for patient monitor parameter modules	6676960
Top Shelf	6688207
Universal bracket for C20	6687457
Universal bracket for C30	6687932
Universal bracket for C20 right side	6881339
Pendant mounting kit, Trumpf/Dräger	6689200
Pendant mounting kit, M-Lifting	6689202
Interface height 560 mm	6689207
Interface height 645 mm	6689210
Interface height 778 mm	6689212

Hardware parts

Adapter kit	6686585
Additional arm	6686225
Cable Support arm	6687487
Manual Breathing bag support arm	6680597

ANNEX I

TO THE EC DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

Manual Breathing bag support arm, rigid	6880157
Additional table	6676962
Rear handle	6681907
Hook and hook holder	9368952
Clamp, 1 slot	9358193
Vertical Rail Converter	6689740
Left side Duoflex rail (10 x 30 mm)	6679537
Right side Duoflex rail (10 x 30 mm)	6679542
Clamp, for Duoflex rail, 10 x30 mm	6038819
DIN rail (10x25mm), left side	6678570
DIN rail (10x25mm), right side	6678572
Clamp, for DIN rails, 10 x 25 mm	6038801
Flexible manual breathing bag arm	6887717
Tubing hook large	6887712
Tubing hook small	6887713
Suction tip holder	6887714

For upgrade of installed FLOW-i

SW Upgrade via freight, FLOW-i	(s/n > 20000)	6889612
SW Upgrade via E-delivery, FLOW-i	(s/n > 20000)	6889613
MAQUET USB stick, (empty)		6687615

MCARE SERVICES

FLOW-i remote services adapter	6696757
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Cleaning adapter

ANNEX I

TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Cleaning adapter kit	6681910
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DIN adapters and Connections

DIN 6 Connection	6883761
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DIN 9 Connection	6883762
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DIN 12 Connection	6883771
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DIN 13 Connection	6883774
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DIN adapter O ₂ for Backup Gas Rack and trolley	6884098
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DIN adapter N ₂ O for Backup Gas Rack and trolley	6884099
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DIN adapter Air for Backup Gas Rack and trolley	6884100
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DIN adapter O ₂ for Backup Gas Holder	6884101
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DIN adapter N ₂ O DIN 6/12/13 for Backup Gas Holder	6884102
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DIN adapter N ₂ O DIN 9 for Backup Gas Holder	6884368
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7. PREVENTIVE MAINTENANCE

Required equipment




- Standard service tools.
- Connector kit for pressure tester and Pressure gauge. See chapter Service procedures > Pressure regulators REG1–REG4.
- Calibration equipment. See chapter Service procedures > Calibrations – Service & Settings.
- Lubricants should normally not be used when servicing the unit. If lubricants must be used, use only very small amounts of grease with P/N 95 73 700. This special grease is O₂ compatible.
- If the silicon gaskets are difficult to mount, the gaskets can be lubricated with a small amount of clean water to help them in position.
- Gas evacuation system.
- Barometer (or information about the actual barometric pressure).
- Access to the Service & Settings (S&S) is required.
- Maintenance kits and spare parts required for the Preventive Maintenance to be performed.

Accessories, spare parts and maintenance kits

Only original parts from the manufacturer must be used. Accessories, spare parts and maintenance kits can be ordered from your local Getinge representative.

Maintenance kit FLOW-i 24 months

When performing **Preventive Maintenance Plus**, a 'Maintenance kit FLOW-i 24 months' should be used. The following parts must be replaced and they are included in the maintenance kit:

Fresh gas supply/Reflector gas supply		Qty
Filters for the gas modules		4
Nozzle units for the gas modules		4
O-ring in docking		4

7. PREVENTIVE MAINTENANCE

Patient cassette docking		Qty
Insp. sample filter holder, Version A		1
Insp. sample filter holder, Version B		1
Exp. sample filter holder		1
Gas analyzer section		
Sampling line Nafion		1
Fan		
Dust filter		1
Control Panel		
Rotary encoder including knob		1

7. PREVENTIVE MAINTENANCE

Maintenance kit FLOW-i cassette 24 months

When performing **Preventive Maintenance Plus**, a 'Maintenance kit FLOW-i cassette 24 months' should be used. Note that:

- One maintenance kit is required for each cassette used with the concerned system.
- One maintenance kit is included in the Maintenance kit FLOW-i 24 months.

The following parts must be replaced and they are included in the maintenance kit:

Patient cassette (parts for one cassette)		Qty
APL/PEEP valve membrane		1
Absorber valve		2
Valve seat for OV10 and OV11, including O-ring One extra O-ring is included if required during the valve seat replacement.		2
Valve cage for OV10 and OV11, including ceramic valve disc		2