

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 4.7

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

Base unit

FLOW-i Anesthesia System C20 (s/n < 20000)	6677200
FLOW-i Anesthesia System C30 (s/n < 20000)	6677300
FLOW-i Anesthesia System C40 (s/n < 20000)	6677400

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

Absorber

CO2 Absorber Disposable	6677845
CO2 Absorber disposable 12 pcs	6887738
CO2 Absorber Reusable	6692582
Dust Filter for CO2 Absorber Reusable	6880430

Alternative mains power cable

Maquet Critical Care AB
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www.getinge.com

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

Vaporizer

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

O2 flowmeter / suction equipment

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

Backup gas supply

Gas Backup Rack O2/N2O	6881266
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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, extra, incl. reflector socket	6680327
Volume reflector (PEI)	6887831

Reusable parts

Tube joint/adapter 22 mm	6425581
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ANNEX I

TO THE EC DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

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
Manual Breathing bag support arm, rigid	6880157

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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

For upgrade of installed FLOW-i

SW Upgrade via freight, FLOW-i (s/n < 20000)	6686900
SW Upgrade via E-delivery, FLOW-i (s/n < 20000)	6687590
MAQUET USB stick, (empty)	6687615

MCARE SERVICES

FLOW-i remote services adapter	6696757
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Cleaning adapter

Cleaning adapter kit	6681910
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DIN adapters and Connections

DIN 6 Connection	6883761
DIN 9 Connection	6883762
DIN 12 Connection	6883771

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DIN 13 Connection	6883774
DIN adapter O ₂ for Backup Gas Rack and trolley	6884098
DIN adapter N ₂ O for Backup Gas Rack and trolley	6884099
DIN adapter Air for Backup Gas Rack and trolley	6884100
DIN adapter O ₂ for Backup Gas Holder	6884101
DIN adapter N ₂ O DIN 6/12/13 for Backup Gas Holder	6884102
DIN adapter N ₂ O DIN 9 for Backup Gas Holder	6884368