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 4.4

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, Ridlerstraβe 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 16 09 72017 009, dated 2016-11-04, valid to 2021-12-29) 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
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Product(s) Covered:

Trade Name	Article No.
Base unit	
FLOW-i Anesthesia System C20	66 77 200
FLOW-i Anesthesia System C30	66 77 300
FLOW-i Anesthesia System C40	66 77 400
Additional ventilation modes	
PRVC	66 88 202
PS with backup	66 88 200
SIMV (VC) and SIMV (PC)	66 88 197
Extended ventilation package	66 88 205
Additional options	
AGC (Automatic Gas Control)	68 81 990
Recruitment Maneuvers	68 86 518
Optional module, Additional Fresh Gas Outlet (AFGO)	66 81 887
AFGO adapter kit, onsite upgrade	66 86 860
Absorber	
CO2 Absorber Disposable	66 77 845
CO2 Absorber Reusable	66 92 582
Dust Filter for CO2 Absorber Reusable	68 80 430
Alternative mains power cable	
Mains Power cable, 3.5 m, Great Britain, UK BS 1363	66 70 310
Mains Power cable, 3.5 m, Europe, EU CEE 7	64 24 329
Mains Power cable 3,5m North America	66 83 275

Maquet Critical Care AB
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Email: Regulatory.Affairs@maquet.com
www.getinge.com

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Gas outlet connector	
Gas Outlets, O2 and Air, AGA	66 80 312
Gas Outlets, O2 and Air, NIST	66 81 890
Gas Outlets, O2 and Air, French	66 81 892
Gas outlets, O2 and Air, DISS	66 81 895
Vaporizer	
Vaporizer Sevoflurane, QUIK FIL	66 82 285
Vaporizer Desflurane, Saf-T-Fil	66 82 287
Vaporizer Isoflurane, Maquet filling	66 82 280
Vaporizer Sevoflurane, Maquet filling (Abbott, Baxter)	66 82 282
Vaporizer Sevoflurane Maquet filling	68 86 601
Vaporizer Sevoflurane QUIK FIL	68 86 611
Vaporizer Isoflurane Maquet filling	68 86 621
Vaporizer Desflurane SAF-FIL	68 86 631
Vaporizer Sevoflurane SAFE-T-SEAL	68 87 135
MAQUET filling adapter tube for isoflurane bottle	66 82 290
MAQUET filling adapter tube for sevoflurane bottle (Abbott, Baxter)	66 82 292
Cover for vaporizer slot	68 80 158
Vaporizer holder	68 80 155
O2 flowmeter / suction equipment	
Suction and Auxiliary O2 Flow module	66 79 847
Gas hose kit O2 + Air AGA/ISO color	66 82 170
Gas hose kit O2 + Air NIST/ISO color	66 82 172
Gas hose kit O2+ Air French std/ISO color	66 82 175
Gas hose kit O2 + Air DISS/US color	66 88 892

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Gas hose kit O2 + Air NIST/UK color	66 89 867
Angled adapter for sterile water container	66 81 900
Bacterial Filter (5 pcs)	68 87 498
Backup gas supply	
Back up gas trolley 1 x O2 + 1 x Air	66 79 842
Back up gas trolley 1 x O2 + 1 x N2O	66 80 165
Gas Backup Rack O2/N2O	68 81 266
Gas Backup Rack O2/AIR	68 81 267
Backup Gas Holder N2O	66 86 587
Backup Gas Holder O2	66 92 630
Hose O2, gas backup, ISO color (for gas cylinder)	66 83 602
Hose O2, gas backup, US color (for gas cylinder)	66 88 897
Hose N2O, gas backup ISO/US color	66 83 607
Hose Air, gas backup, ISO color	66 83 605
Hose Air, gas backup, US color	66 88 895
Hose Air, gas backup, UK color	66 89 870
EVAC outlet Connections	
EVAC Restrictor	68 80 156
22 mm out. Diam. Connector	66 92 740
30 mm out. Diam. ISO taper connection	66 73 980
12.7 mm/½” in house Barb connector	66 79 627
25 mm/1” in house Barb connector	66 79 630
AGA EVAC connector	66 79 645
WAGD-to-Vacuum connector	66 92 742
Connection tube 22 int. diam, (disposable), 50 m	61 89 646
DISS EVAC connector	66 79 647

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Gas analyzer accessories	
Sampling line 25 pcs/pkg	66 92 212
Water trap Dryline A, 10 pcs	65 22 747
Extra breathing system parts	
Patient cassette complete, extra	66 80 325
Volume reflector, extra, incl. reflector socket	66 80 327
Volume reflector (PEI)	68 87 831
Reusable accessories	
Tube joint/adapter 22 mm	64 25 581
Mounting kits	
Mounting kit for two pin interface	66 80 315
Mounting kit, slide plate horizontal	66 87 692
Mounting kit for T8	66 86 635
Mounting kit for T5	66 86 637
Mounting kit for VESA 75/100	66 86 577
Mounting kit for Pick & Go	66 87 472
Mounting kit, slide plate vertical	66 87 695
Adjustable arm for patient monitor parameter modules	66 76 960
Top Shelf	66 88 207
Mounting kit, Schiller Argus Pro SL	66 81 902
Mounting kit, Siemens/Infinity SC 7000, Siemens/Infinity SC 9000XL	66 81 905
Universal bracket for C20	66 87 457
Universal bracket for C30	66 87 932
Universal bracket for C20 right side	68 81 339
Pendant mounting kit, Trumpf/Dräger	66 89 200

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FOR MEDICAL DEVICES

Pendant mounting kit, M-Lifting	66 89 202
Interface height 560 mm	66 89 207
Interface height 645 mm	66 89 210
Interface height 778 mm	66 89 212
Hardware accessories	
Adapter kit	66 86 585
Additional arm	66 86 225
Cable Support arm	66 87 487
Manual Breathing bag support arm	66 80 597
Manual Breathing bag support arm, rigid	68 80 157
Additional table	66 76 962
Rear handle	66 81 907
Hook and hook holder	93 68 952
Clamp, 1 slot	93 58 193
Vertical Rail Converter	66 89 740
Left side Duoflex rail (10 x 30 mm)	66 79 537
Right side Duoflex rail (10 x 30 mm)	66 79 542
Clamp, for Duoflex rail, 10 x30 mm	60 38 819
DIN rail (10x25mm), left side	66 78 570
DIN rail (10x25mm), right side	66 78 572
Clamp, for DIN rails, 10 x 25 mm	60 38 801
For upgrade of installed FLOW-i	
Upgrade via freight, FLOW-i	66 86 900
Upgrade via E-delivery, FLOW-i	66 87 590
MAQUET USB stick, (empty)	66 87 615

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MCARE SERVICES	
FLOW-i remote services adapter	66 96 757
Cleaning adapter	
Cleaning adapter kit	66 81 910
DIN adapters and Connections	
DIN 6 Connection	68 83 761
DIN 9 Connection	68 83 762
DIN 12 Connection	68 83 771
DIN 13 Connection	68 83 774
DIN adapter O_2 for Backup Gas Rack and trolley	68 84 098
DIN adapter N_2O for Backup Gas Rack and trolley	68 84 099
DIN adapter Air for Backup Gas Rack and trolley	68 84 100
DIN adapter O_2 for Backup Gas Holder	68 84 101
DIN adapter N_2O DIN 6/12/13 for Backup Gas Holder	68 84 102
DIN adapter N_2O DIN 9 for Backup Gas Holder	68 84 368

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Mm-0340, ver 15

PULSION
Medical Systems

Declaration of Conformity

PULSION Medical Systems SE
Hans-Riedl-Straße 17
85622 Feldkirchen, Germany

Declares under our sole responsibility that the product:

Product Name:	$PiCCO_2$
Product Model Number:	PC8500
Device Classification:	IIb according Annex IX, Rule 10.
Global Medical Device Nomenclature Code (GMDN):	42873, Invasive arterial pressure cardiac output/oximetry monitor

to which this Declaration relates is in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive).

PULSION Medical Systems SE is assessed to EN ISO 13485:2012+AC:2012 and MDD, Annex II-Section 3 MDD by:

DEKRA Certification GmbH (CE 0124)
Handwerksstraße 15
70565 Stuttgart

This declaration of conformity is valid in combination with the DEKRA certificates No. 50215-11-01 and No. 50215-16-07 which are valid until May 24th, 2018.

PULSION Medical Systems SE

Feldkirchen, March 10th, 2016

Mikael Johansson

Managing Director

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 075182 0005 Rev. 00

Holder of Certificate: **PULSION Medical Systems SE**
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies): PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, manufacturing, packaging, marketing, sales and servicing of patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables**

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). See also notes overleaf.

Report No.: 713153619

Valid from: 2019-05-17
Valid until: 2021-05-24

Stefan Preiß

Date, 2019-05-17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Manufacturer:	**Maquet Cardiopulmonary GmbH**
Address:	**Kehler Str. 31** **76437 Rastatt** **Germany**
Product name:	**CARDIOHELP System**
Products and Accessories:	see attached Product List
Classification:	see attached Product List

We, Maquet Cardiopulmonary GmbH, hereby declare under our sole responsibility that the mentioned devices comply with the provisions of:

European Medical Device Directive 93/42/EEC

Conformity Assessment:	Annex II of Directive 93/42/EEC
Notified Body:	DEKRA Certification GmbH Handwerkstr. 15, 70565 Stuttgart, Germany (Notified Body ID-no. 0124)

For and on behalf of Maquet Cardiopulmonary GmbH, Rastatt,

Date	Name	Signature
2019-05-27	Nursel Boelens (Director Regulatory Affairs)	

Product List

This product list specifies the products covered by the Declaration of Conformity.

Products covered:

REF no.	Article no.	Product description
Class IIb		
70104.8012	70104.8012	CARDIOHELP-i
70104.7999	70104.7999	CARDIOHELP Base Unit