



Certificate

No. Q5 028817 0047 Rev. 01

Holder of Certificate: **MAQUET GmbH**

Kehler Straße 31
76437 Rastatt
GERMANY

Facility(ies):

MAQUET GmbH
Kehler Straße 31, 76437 Rastatt, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design and Development, Production, Sales and Service of Medical Devices including Patient Positioning Systems and associated accessories for Therapy and Diagnosis, Transport Devices, Operating Room Integration Systems (hardware / software), Sterilizers and associated accessories

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 028817 0047 Rev. 01

Report No.: 713207081

Valid from: 2021-10-16

Valid until: 2024-10-15

Date, 2021-10-12

Christoph Dicks
Head of Certification/Notified Body

EC CERTIFICATE

for the Quality Assurance System



**according the Directive 93/42/EEC,
Annex II excluding section (4)**

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
Maquet Cardiopulmonary GmbH

Kehler Straße 31, 76437 Rastatt, Germany

Certified location:

Kehler Straße 31, 76437 Rastatt, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 5008-Z7-00, the decision dated 2020-03-03 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-03-03 to 2024-05-26

Registration No.: 50008-16-10



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-03-03
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50008-16-10

Valid from 2020-03-03 to 2024-05-26

Revision status of the annex: 3 dated 2021-02-08

Devices/device categories included in the certificate:

Class II a:

- Oxygenators with SOFTLINE Coating:
 - QUADROX-i
 - Adult / Small Adult, microporous membrane
 - Option: with integrated arterial filter
 - QUADROX-iD
 - Adult, diffusion membrane
 - Option: with integrated arterial filter
 - QUADROX-i
 - Neonatal, microporous membrane
 - Option: with integrated arterial filter
 - QUADROX-i
 - Pediatric, microporous membrane
 - Option: with integrated arterial filter
- Venous Hardshell Cardiotomy Reservoir with or without SOFTLINE Coating:
 - Pediatric
 - Neonatal
- Combination of Reservoir with Oxygenator with or without SOFTLINE Coating:
 - Adult
 - Pediatric
 - Neonatal
- Heat Exchanger PLEGIOX with or without SOFTLINE Coating
- Centrifugal Pump ROTAFLOW with or without SOFTLINE Coating
- HIT Set (Heparin-induced thrombocytopenia Set) Advanced 5.0 / 7.0 with SOFTLINE Coating
- HIT Set PLS Plus with SOFTLINE Coating
- Tubing Sets and components with or without SOFTLINE Coating
 - Optional including Venous Softbag Reservoir with or without SOFTLINE Coating
 - Optional including Arterial Filter QUART with SOFTLINE Coating
 - Optional including Transfer Bag with SOFTLINE Coating
 - Optional including Venous Hardshell Cardiotomy Reservoir Adult, Pediatric, Neonatal with or without SOFTLINE Coating
- Tubing Set with Centrifugal Pumps with or without SOFTLINE Coating
 - MECC Set with or without SOFTLINE Coating
 - Tubing Sets for CARDIOHELP-i with or without SOFTLINE Coating
 - Cardiac Intervention Set (CI Set)
 - Organ Donor Perfusion Set (ODP Set) with SOFTLINE Coating
- Transfer Bags
- AVALON ELITE Bi-Caval Dual Lumen Catheters
- HLS Cannulae with or without SOFTLINE Coating
- BMU Sensor
- BMU Cell
- Percutaneous Insertion Kits
- Guidewires
- Dilators

Annex to the EC Certificate No. 50008-16-10

Valid from 2020-03-03 to 2024-05-26

Revision status of the annex: 3 dated 2021-02-08

Devices/device categories included in the certificate:

Class II b:

- Hemoconcentrators
- ROTAFLOW Drive Unit
- ROTAFLOW II Base Unit
- ROTAFLOW II Drive (flex)
- ROTAFLOW II Drive (compact)
- CARDIOHELP Base Unit
- CARDIOHELP-i
- Capacitive Level Sensor CLS with accessory Level Sensor Pad LSP
- Flow-Bubble Sensor FBS
- Bubble Sensor BS
- Temperature Probe
- Venous Probe
- Heater Unit HU 35
- Heater-Cooler Unit HCU 40
- Blood Monitoring Unit BMU 40
- Tubing Set with Hemoconcentrators with or without SOFTLINE Coating

Annex to the EC Certificate No. 50008-16-10

Valid from 2020-03-03 to 2024-05-26

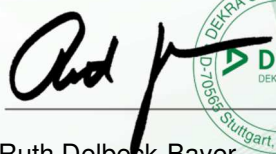
Revision status of the annex: 3 dated 2021-02-08

Devices/device categories included in the certificate:

Class III:

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

- Oxygenators with BIOLINE Coating:
 - QUADROX-i
 - Adult / Small Adult, microporous membrane
 - Option: with integrated arterial filter
 - QUADROX-iD
 - Adult, diffusion membrane
 - Option: with integrated arterial filter
 - QUADROX-i
 - Neonatal, microporous membrane
 - Option: with integrated arterial filter
 - QUADROX-i
 - Pediatric, microporous membrane
 - Option: with integrated arterial filter
 - QUADROX-iD
 - Pediatric, diffusion membrane
- Venous Hardshell Cardiotomy Reservoir with BIOLINE Coating
 - Pediatric
 - Neonatal
- Heat Exchanger PLEGIOX with BIOLINE Coating
- Tubing Sets and components with BIOLINE Coating
 - Optional including Venous Softbag Reservoir with BIOLINE Coating
 - Optional including Arterial Filter QUART with BIOLINE Coating
 - Optional including Venous Bubble Trap with BIOLINE Coating
 - Optimal including Venous Hardshell Cardiotomy Reservoir Adult with BIOLINE Coating
- Tubing Set with Hemoconcentrators with BIOLINE Coating
- Tubing Set with Centrifugal Pumps with BIOLINE Coating
 - MECC Set with BIOLINE Coating
 - Tubing Sets for CARDIOHELP-i with BIOLINE Coating
 - Organ Donor Perfusion Set (ODP Set) with BIOLINE Coating
 - Minimized Extra Corporeal Circulation Set (MECC-i Set) with BIOLINE Coating
- HLS Cannulae with BIOLINE Coating
- Centrifugal Pump ROTAFLOW with BIOLINE Coating
- PLS Set (Permanent Life Support Set) / PLS Set Plus with BIOLINE Coating
- HLS Set (Heart-Lung Support Set) Advanced 5.0 / 7.0 with BIOLINE Coating






Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-02-08
Notified Body ID-number: 0124

Lot : 63

Notes Help

2 Spare parts Fit To Window

Pictures



ID	Part-No	Description
1	2270294	Battery pack 10.8V/ 550 mAh
	11360499	Tallow-drop screw DIN7985-M3x20-A2-50-H
	98019444	Escutcheon
	115091CE	IR transmitter without charging unit
100		Wiring diagram
110		Circuit diagram
120		Hydraulic diagram
210		service manual customer
240		recycling manual

IR transmitter without charging unit

GETINGE

115091CE IR transmitter without charging unit