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

Digitally signed by Dubalari Pavel
Date: 2021.12.29 18:38:52 EET
Reason: MoldSign Signature
Location: Moldova

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

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

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

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

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

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

Revision status of the annex: 1 dated 2020-07-07

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:
  - 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
- 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: 1 dated 2020-07-07

Devices/device categories included in the certificate:

Class II b:

- Hemoconcentrators
- ROTAFLOW Console
- ROTAFLOW Drive Unit
- 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
- Heart-Lung Machine HL 20
- Pump modules for Heart-Lung Machine HL 20, Types TPM, RPM
- 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: 1 dated 2020-07-07

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
  - Adult
  - 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
- 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

DEKRA Certification GmbH, Stuttgart, Handwerkstraße 15, D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-07-07
Notified Body ID-number: 0124

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Maquet Cardiopulmonary GmbH

Scope of certification:

Design, manufacturing, distribution and service of medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine

Certified location:

Kehler Straße 31, 76437 Rastatt, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50008-Z7-00.

Certificate registration no.:	50008-14-01	Certificate valid from:	2020-03-03
Validity of previous certificate:	2020-03-02	Certificate valid to:	2023-03-02

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-03

Annex to the Certificate No. 50008-14-01

Revision status: 0

valid from 2020-03-03 to 2023-03-02

The following locations belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Maquet Cardiopulmonary GmbH	Kehler Straße 31 D-76437 Rastatt	Design, manufacturing, distribution and service of medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
	Subsidiaries	**Certified locations**	**Scope of certification**
1.	Maquet Cardiopulmonary GmbH	Kehler Straße 31 D-76437 Rastatt	Design, manufacturing, distribution and service of active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine Distribution of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
2.	Maquet Cardiopulmonary GmbH	Neue Rottenburger Straße 37 D-72379 Hechingen	Design and manufacturing of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
3.	Maquet Cardiopulmonary GmbH	Grabenstraße 25 D-72411 Bodelshausen	Design of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine

DEKRA Certification GmbH, D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-03

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service

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

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

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