

# 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](http://www.dekra-certification.de)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://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

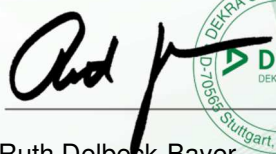
Revision status of the annex: 3 dated 2021-02-08

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