

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: 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:

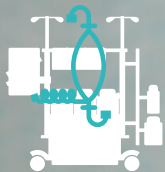
For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

- 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



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Machine sets



Table sets



Cardioplegia sets



Hemoconcentrator sets



Additional components and lines



Perfusion simplified

with the modular tubing set approach
by Getinge

This document is intended to provide information to an international audience outside of the US.

GETINGE 

Combined expertise

to make perfusion simpler

The combined expertise of perfusionists and Getinge is the basis for creation of the modular tubing sets. These sets comply with international standards of practice, adhering to minimum safety considerations for the safe conduct of surgical perfusion. Modular tubing sets are the first step to make perfusion easier, faster and safer.

Modular tubing sets ensure a quality standard in production, configuration and validation

The various modules have been intensively tested and validated at Getinge. Drawing approvals, documentation or verification for quality assurance are now a thing of the past.

In addition, Getinge ensures that the modular tubing sets comply with the guidelines for minimum system requirements and risk analysis for the Getinge Heart-Lung Machine HL 40. These guidelines have been developed by perfusionists and aligned with international perfusion recommendations in Europe, North America and Asia.

Modular tubing sets are pre-produced and available from stock

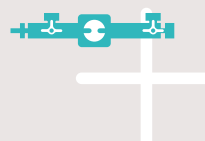
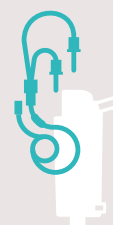
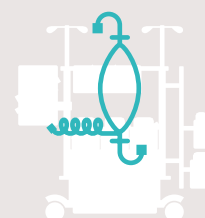
A further advantage of modular tubing sets is the continuous availability. Availability is normally given within two working days. This facilitates sustainable planning and inventory management.

When selecting modules, the new digital product catalog for modular tubing sets is available to help. The e-catalog contains a detailed overview of the individual modules and customized configuration of these modules is possible. Various calculators, such as priming volume or surface area in contact with blood, are also available.

Stay flexible with modular tubing sets

The modules contain all the essential components you need for an extra-corporeal circuit. The combination of modules is completely customizable.

Modules consists of table sets, machine sets, hemoconcentrator sets, cardioplegia sets and additional components and lines. Uncoated versions or with Softline Coating are available for adults and small adult patients.



Machine sets

Machine set consists of the disposables and the tubing, which are assembled on the heart-lung machine and carry the perfused blood between the table lines and reservoir, pump, oxygenator.

Main components include the reservoir, the oxygenator with integrated arterial filter and pump lines. Several variations are available as well as additional components and lines.



Table sets

Table set consists of lines, which are connected between the patient and the heart-lung machine lines.

Main components include arterial line, venous line, suction lines, vent lines and pre-bypass filter, if needed. Several variations as well as additional components and lines are available in different lengths depending on where the heart-lung machine is located.



Cardioplegia sets

Cardioplegia set includes the tubing lines and disposable components, which are used for carrying the cardioplegia solution to the heart for myocardial protection.

Getinge has cardioplegia sets for standard cardioplegia solution delivery methods, like blood cardioplegia or crystalloid cardioplegia.



Hemoconcentrator sets

Hemoconcentrator set consists of the inlet and outlet tubing lines, a waste bag and the hemoconcentrator. Several variations are available as well as additional components and lines.



Additional components and lines

Additional components and lines are available for all modules and include accessories and lines such as a Rotaflow Centrifugal Pump RF-32, gas lines, suction lines, pre-bypass filter, pressure dome. Several variations are available depending on size / weight of the patient (tubing diameter).



Learn more about modular tubing sets

The digital product catalog makes it easier for you to get an overview

Here you will find essential data and information about the respective set itself, including the technical drawing. You can also download this as a PDF.

In addition, the digital catalog also offers the possibility to compile your configuration from the various modules and to automatically calculate the priming volume and the surface area. Save valuable time by simply placing the required selection in the shopping cart and submitting it by pressing one button. You will immediately receive a quote for your modular tubing sets.



Discover the new digital catalog for modular tubing sets

by simply following the link in the QR code or directly via the catalog website. Register to get full access to the content or ask your Getinge representative for more information.

catalog.getinge.com



With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

Modular Tubing Sets may be pending regulatory approvals to be marketed in your country. Contact your Getinge representative for more information. All images used are for illustrative purposes only and may not accurately represent the product or its use. Copyright 2021 · All rights not expressly granted are reserved.

This document is intended to provide information to an international audience outside of the US.

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www.getinge.com