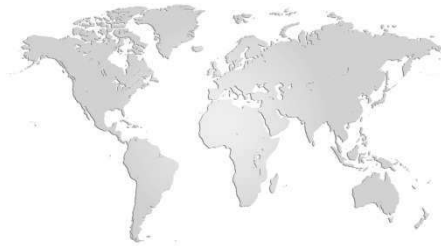


EC CERTIFICATE

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:

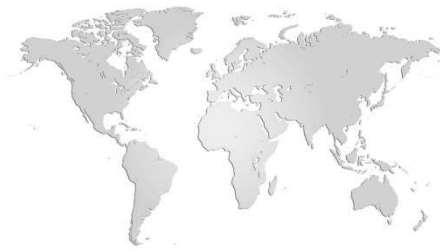
For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

- 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 Cardiomy 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



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-R1-00.

Certificate registration no.: 50008-14-02_EN

Certificate valid from: 2022-05-31

Validity of previous certificate: 2022-05-30

Certificate valid to: 2025-01-07

A handwritten signature in black ink over a circular DEKRA logo. The logo contains the text 'DEKRA Certification GmbH' and 'D-70565 Stuttgart, Handwerkstraße 15'.

Natascha Jezyschek
DEKRA Certification GmbH, Stuttgart, 2022-05-31



Annex to the Certificate No. 50008-14-02

valid from 2022-05-31 to 2025-01-07

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Maquet Cardiopulmonary GmbH	Kehler Straße 31 76437 Rastatt Germany	see page 1
	at the following locations/at the companies at the following locations		Scopes of certification
1.	Maquet Cardiopulmonary GmbH	Kehler Straße 31 76437 Rastatt Germany	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 72379 Hechingen Germany	Design and manufacturing of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
3.	Maquet Cardiopulmonary GmbH	Grabenstr. 25 72411 Bodelshausen Germany	Design of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine



Natascha Jezyschek
DEKRA Certification GmbH, Stuttgart, 2022-05-31

Sensation Plus Fiber-optic IAB Catheters

Give patients the clinical effectiveness of a larger volume IAB in an easy-to-use balloon.

Improve patient comfort and safety with the Sensation Plus IAB. Sensation Plus brings innovative fiber-optic technology and greater hemodynamic support to adult patients 5'0" (152 cm) and above. Advanced fiber-optic technology provides accurate and consistent blood pressure indices, faster time to therapy and automatic *in-vivo* calibration.

- Greater hemodynamic support for more systolic unloading and more augmentation.²
- Needle-free securement with the StatLock® IAB Stabilization Device improves patient comfort and safety.



Sensation Plus IAB catheters

Sensation Plus 7.5 Fr. and 8 Fr. Fiber-optic IAB Catheters³

IAB volume	Introducer sheath length	Catheter extender compatible with:	Part Number
50 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0576-01
40 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0568-01

³ Sensation Plus IAB catheters include Insertion Kits with Introducers and 2 StatLock® IAB devices.

Optional Accessories for Sensation Plus IAB Catheter Insertion Kit

Description	Part Number
Sensation Plus 8 Fr. 50 cc Insertion Kit only	0884-00-0019-23
Sensation Plus 7.5 Fr. 40 cc Insertion Kit only	0884-00-0019-22

Sensation Plus Insertion Kit includes:

- One 6" (15 cm) reinforced introducer sheath with hemostasis valve
- One introducer dilator
- One vessel dilator
- One 18 gauge angiographic needle
- One 0.025" x 145 cm 3 mm J PTFE stainless steel guidewire
- One male luer cap
- One three-way stopcock
- Two 4' pressure tubings
- One 6'0" catheter extender tubing (40 cc ONLY)
- One 5'7" catheter extender tubing (50 cc ONLY)

² Bench testing completed by Getinge. Data on file. Bench test results are not necessarily predictive of clinical results.

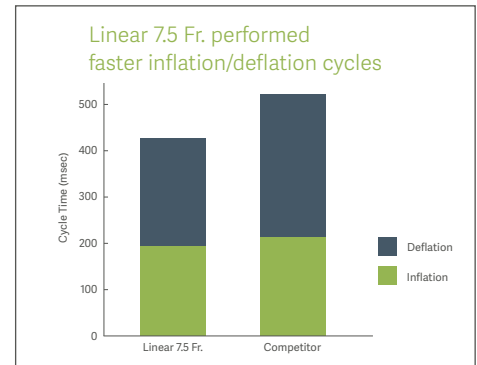
Linear IAB Catheters

Smaller profile, big performance⁷

In IAB therapy, proper timing of inflation and deflation within the cardiac cycle is critical to patient outcomes.

In bench testing, Linear 7.5 Fr. IAB catheters demonstrated faster inflation and deflation cycles than the competition.

- Linear has 19% faster cycle time in 80° bend test method compared to a competitor IAB catheter.
- Faster gas shuttle performance offers better support for rapid heart rates and arrhythmias.



Linear 7.5 Fr. IAB Catheters⁸

IAB Volume	Introducer sheath length	Catheter extender compatible with:	Part Number
40 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0480-01
34 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0479-01
25 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0478-01

⁸All Linear IAB catheters Include Insertion Kits with Introducers

IAB Volume	Introducer sheath length	Catheter extender compatible with:	Part Number
40 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0480-02
34 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0479-02
25 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0478-02

⁸All Linear IAB catheters include Insertion Kits with Introducers

Optional Accessories for Linear 7.5 Fr. IAB Catheters 40 cc and 34 cc Insertion Kit

Description	Part Number
Linear 7.5 Fr. 40 cc and 34 cc Insertion Kit for Sheathless/Sheathed Insertion	0884-00-0019-13

Linear 40 cc and 34 cc Insertion Kit includes:


- One 7.5 Fr. 6" (15 cm) reinforced introducer sheath with hemostasis valve
- One introducer dilator
- One vessel dilator
- One 18 gauge angiographic needle
- One 0.025" x 145 cm 3 mm J PTFE stainless steel guidewire
- One male luer cap
- One three-way stopcock
- Two 4' (122 cm) pressure tubings
- One 6' catheter extender tubing


⁷ Bench testing completed by Getinge. Data on file. Bench test results are not necessarily predictive of clinical results.

BMU Sensor and BMU cell

Lot : 10;11

With cuvettes already pre-connected

BMU Sensor (arterial),
 3/8" (10 pcs per box) 70104.0849
1/4" (5 pcs per box) 70104.0850
3/16" (5 pcs per box) 70104.0851
• To be ordered separately from Getinge.

BMU cell (venous)
 1/2" (10 pcs per box) 70104.0804
3/8" (5 pcs per box) 70104.0844
1/4" (5 pcs per box) 70104.0845
• To be ordered separately from Getinge.


Holder

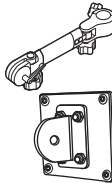
Attachment to slide rail 10 x 25 mm

 **Slide rail mount**
70104.6063

Attachment to mast Ø 38 mm

Attachment to mast Ø 33 mm
(Sorin and Terumo HLM)


 **Mast adapter for:**
- Sprinter Cart
- Sorin HLM
- Terumo HLM
70103.3314

 **Holder for BMU 40**
6 mm arm 70104.3406
100 mm arm 70104.3405
200 mm arm 70104.3404
• Including:
- Adapter plate.
- Screws for adapter plate.


Installation


 **Installation**
• The equipment must be installed by a Getinge certified technician.
• To be quoted separately.

Service

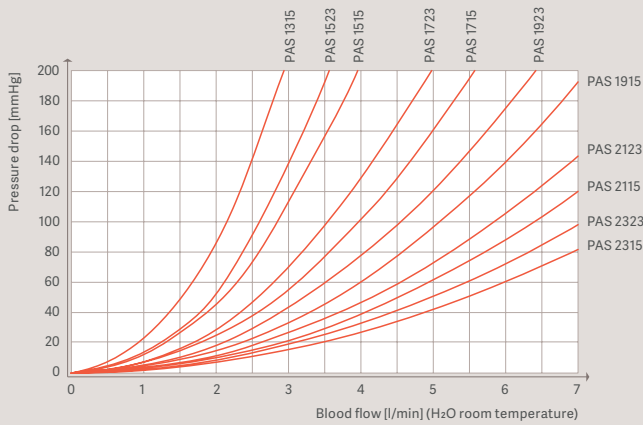
 **Service contract**
• To be specified by technical dept.

Training

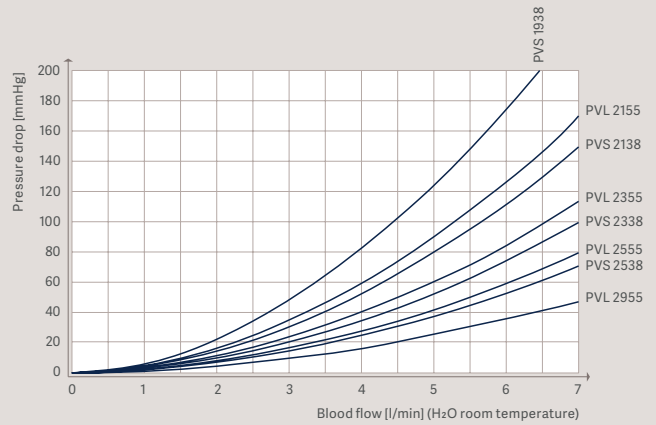
 **Technical training**
• For details contact your local representative.

 **Application training**
• For details contact your local representative.

Pressure drop for all arterial HLS Cannulae 3/8"



Pressure drop for all venous HLS Cannulae 3/8"



Lot : 5 ; 15

Product order details arterial HLS cannulae

Type	Outer diameter	Insertion length	Side holes	Perforation length	Connector	Bioline Coating
PAS 1315	13 Fr (4.3 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1315
PAS 1515	15 Fr (5.0 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1515
PAS 1715	17 Fr (5.7 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1715
PAS 1915	19 Fr (6.3 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1915
PAS 2115	21 Fr (7.0 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 2115
PAS 2315	23 Fr (7.7 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 2315
PAL 1523	15 Fr (5.0 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1523
PAL 1723	17 Fr (5.7 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1723
PAL 1923	19 Fr (6.3 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1923
PAL 2123	21 Fr (7.0 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 2123
PAL 2323	23 Fr (7.7 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 2323

One cannula per carton

Product order details venous HLS cannulae

Type	Outer diameter	Insertion length	Side holes	Perforation length	Connector	Bioline Coating
PVS 1938	19 Fr (6.3 mm)	38 cm	12	10 cm	3/8"	BE-PVS 1938
PVS 2138	21 Fr (7.0 mm)	38 cm	12	10 cm	3/8"	BE-PVS 2138
PVS 2338	23 Fr (7.7 mm)	38 cm	16	10 cm	3/8"	BE-PVS 2338
PVS 2538	25 Fr (8.3 mm)	38 cm	20	10 cm	3/8"	BE-PVS 2538
PVL 2155	21 Fr (7.0 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2155
PVL 2355	23 Fr (7.7 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2355
PVL 2555	25 Fr (8.3 mm)	55 cm	24	20 cm	3/8"	BE-PVL 2555
PVL 2955	29 Fr (9.7 mm)	55 cm	32	20 cm	3/8"	BE-PVL 2955

One cannula per carton

Lot : 6; 7

The Quadrox-i product design

4 variants to cover all patient sizes



Neonatal

HMO 10000 / HMO 11000 (w. filter)

Pediatric

HMO 30000 / HMO 31000 (w. filter)

Small Adult

HMO 50000 / HMO 51000 (w. filter)

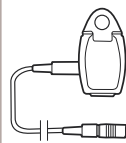
Adult

HMO 70000 / HMO 71000 (w. filter)

	Neonatal	Pediatric	Small Adult	Adult
Edge length	45 mm	55 mm	90 mm	90 mm
Maximum blood flow	1.5 l/min	2.8 l/min	5.0 l/min	7.0 l/min
Gas transfer surface area	0.38 m ²	0.8 m ²	1.3 m ²	1.8 m ²
Heat exchanger surface area	0.07 m ²	0.15 m ²	0.3 m ²	0.4 m ²
Fiber diameter	300 μm	380 μm	380 μm	380 μm
Priming volume without filter	<41 ml	<190 ml	*181 ± 3 ml	*232 ± 4 ml
Priming volume with Filter	<43 ml	<107 ml	*303 ± 3 ml	*344 ± 5 ml

* Has been updated in IFU accordingly.

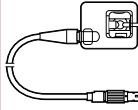
Venous bubble sensor



- BS 3/8x3/32 L1.7**
Bubble Sensor for 3/8" x 3/32" tubing
70105.5720
- Length: 1.7 m.
 - For use with HLS Set Advanced and sets with Quadrox-iR.
 - Coded with blue spout.

Pressure transducer

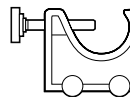
Four pressures



- Medex Transducer Kit 960 LogiCal**
70104.9184
- Includes:
 - Transducer cable 1.8 m, for pressure module connection.
 - Pressure transducer with transducer plate.
 - Marker kit 4 colours.

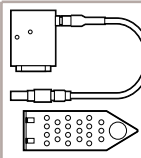


- Medex MX 960 LogiCal pressure dome**
70102.2744
- Disposable.



- Medex MX 960 LogiCal transducer holder**
70102.0721
- Pole mount.
 - Holds 4 Medex LogiCal transducers.

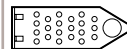
Air emboli protection



- CLS Capacitive level sensor kit**
70104.9490
- Includes:
 - Capacitive level sensor with cable 2 m.
 - Level sensor pad, 100 pcs.

Lot: 8

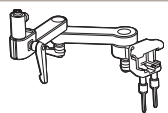
Extra sensor pads



- Level sensor pad, 100 pcs**
70102.2208
- Disposable.
 - To be attached to the venous bubble trap / reservoir at the chosen level.

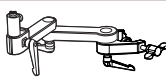
Emergency Drive holder

Rail holder



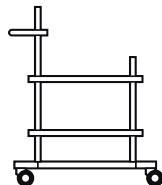
- HKH 9101-R Cardiohelp Emergency Drive holder for standard rail 10 x 25 mm**
70104.9304

Mast holder



- HKH 9101-M Cardiohelp Emergency Drive holder for mast**
70104.8006

Sprinter Cart / Sprinter Cart XL



- Sprinter Cart / Sprinter Cart XL**
- Note: If you use Cardiohelp-i on the Sprinter Cart / Sprinter Cart XL, the Cardiohelp Emergency Drive has to be mounted on a Cardiohelp Emergency Drive holder.
- See separate system flowchart, which also includes Gas Control Equipment.

Heater Unit HU 35



- Heater Unit HU 35**
See separate system flowchart.

- During patient transportation, environmental influences and supply sources for the system change. This can lead to infections and inadequate patient support.
 - Take the CARDIOHELP Emergency Drive and the power supply cable for the CARDIOHELP-i with you.
 - Prevent the patient from cooling down during transportation.
 - Make sure that there is sufficient oxygen in the gas bottle and that the batteries of the CARDIOHELP-i are charged.
 - Connect a pressure reducer when using gas bottles.
 - Protect the patient, devices and system from environmental influences such as rain and dust.
- During inter-hospital patient transportation, the atmospheric pressure on the patient and system can change. This can lead to a reduced gas transfer rate and changed display values on the CARDIOHELP-i.
 - Please note that when using the system at increasing altitudes without equalizing the pressure, the gas transfer rate decreases as a result of the lower atmospheric pressure.
 - Take great care when making settings on the CARDIOHELP-i and take the changed ambient pressure into account.

Lot :4

6 Product Information

6.1 Technical data

Device version	HLS Set Advanced 5.0 / HIT Set Advanced 5.0	HLS Set Advanced 7.0 / HIT Set Advanced 7.0
Blood flow	0.5 – 5 l/min	0.5 – 7 l/min
Gas flow	max. 10 l/min	max. 14 l/min
Recommended ratio of gas flow to blood flow	0.5:1 – 2:1	0.5:1 – 2:1
Tube size (inside diameter x wall thickness)	3/8" x 3/32" (9.53 mm x 2.38 mm)	3/8" x 3/32" (9.53 mm x 2.38 mm)
Centrifugal pump speed	0 – 5000 rpm	0 – 5000 rpm
Oxygenation membrane surface area	1.3 m ²	1.8 m ²
Heat exchanger surface area	0.3 m ²	0.4 m ²
Priming volume of the HLS Set Advanced for 2 x 2.2 m tube length	570 ml	600 ml
Priming volume of the HLS Module Advanced	240 ml	273 ml
Residual blood volume of the HLS Module Advanced	130 ml	175 ml
Sterilization method	Ethylene oxide	Ethylene oxide
Maximum permissible values	HLS Set Advanced 5.0 / HIT Set Advanced 5.0	HLS Set Advanced 7.0 / HIT Set Advanced 7.0
Pressure on blood side	Max. 0.533 bar (400 mmHg)	Max. 0.533 bar (400 mmHg)
Pressure on gas side	Max. 12 mbar (9 mmHg)	Max. 15 mbar (11.25 mmHg)
Water/blood temperature difference	Max. 8°C (14.4°F)	Max. 8°C (14.4°F)
Water pressure (heat exchanger inlet)	Max. 1 bar (750 mmHg)	Max. 1 bar (750 mmHg)
Water temperature (heat exchanger inlet)	Max. 41°C (105.8°F)	Max. 41°C (105.8°F)