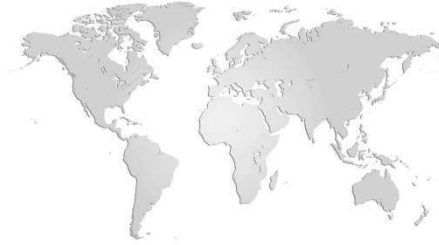


EC CERTIFICATE

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

HLS Set Advanced

Integration meets innovation

MAQUET
GETINGE GROUP



HLS Set Advanced

Integration meets innovation

The HLS Set Advanced provides complete monitoring and is specially developed for veno-venous or veno-arterial extracorporeal support for up to 30 days continuous use.* Powered by CARDIOHELP, the world's smallest heart-lung machine, the system combines user-friendliness and patient safety. The system also has all the necessary approvals for the transport of patients on extracorporeal support within or between hospitals.

The HLS Set Advanced is available in two versions: HLS Set Advanced 5.0 with a blood flow of up to 5 l/min and HLS Set Advanced 7.0 with a blood flow of up to 7 l/min. Both sets have a biocompatible BIOLINE Coating. The HIT Set Advanced with SOFTLINE Coating is available for patients who are susceptible to heparin-induced thrombocytopenia.



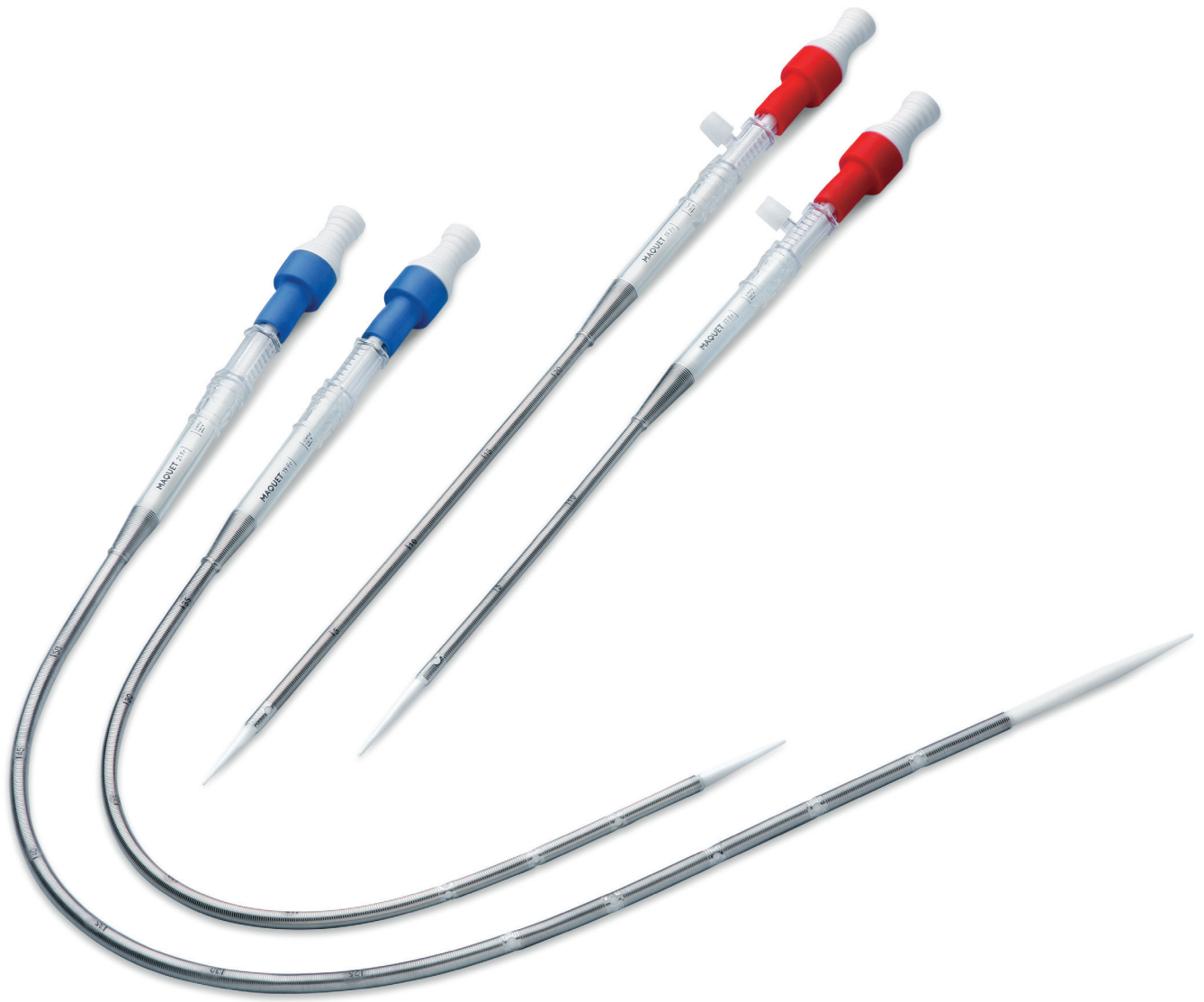
HLS Module Advanced mounted on the CARDIOHELP

The core of the HLS Set Advanced, the HLS Module Advanced, is the world's first oxygenator with an incorporated low-trauma centrifugal pump and an infrared sensor to measure venous oxygen saturation (SvO₂), hematocrit (Hct), hemoglobin (Hb) and venous temperature (TVen). Previously these parameters could only be measured using an external blood gas analyzer or a sensor in the venous blood line. Sensors to measure three pressures and the arterial temperature are also integrated into the module, thus avoiding the need for external measurements, improving accuracy and reducing the risk of air emboli and thrombus formation.



HLS Module Advanced

*When used with HLS Cannulae with BIOLINE Coating.



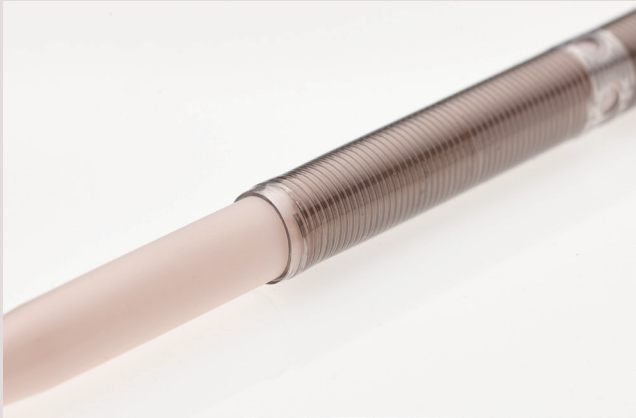
HLS Cannulae

Solutions from tip-to-tip

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

GETINGE 

Smooth transition between introducer and cannula tip



Stop ring defines maximum insertion depth



HLS Cannulae

Trusted vessel access

The HLS Cannulae are indicated for cannulation of all suitable vessels (e.g. femoral vessels) and can be inserted percutaneously, using the Seldinger technique, or under visual control into the previously exposed vessel.

An excellent flow performance, a wide range of cannulae sizes and different coating options make it one of the most popular peripheral cannulae - the perfect choice for vessel access during extracorporeal circulation.

Performance characteristics:

- Thin cannula walls support an excellent pressure/flow performance
- Reinforced side holes help reduce the risk of kinking
- Versions with Bioline Coating for extended respiratory and / or circulatory support
- Duration of use from 6 hours up to 30 days*

Easy to use:

- Locking mechanism keeps introducer in position during insertion
- Smooth transition from introducer to cannula to support a safe cannula insertion
- Depth marks to control insertion depth, a stop ring to define maximum insertion depth
- Selectively hardened proximal cannula body, reduces the risk of kinking after insertion

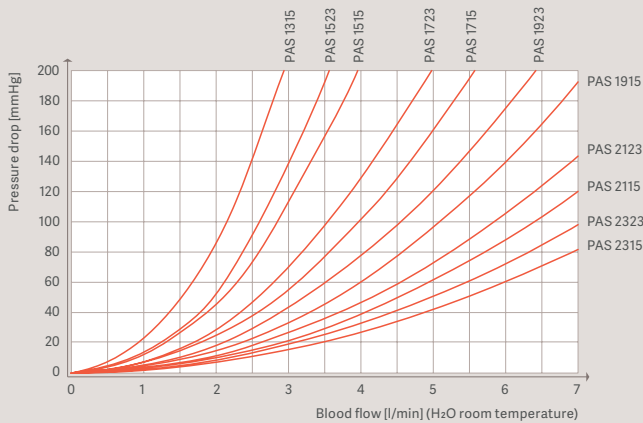


A pair of side holes on every arterial tip

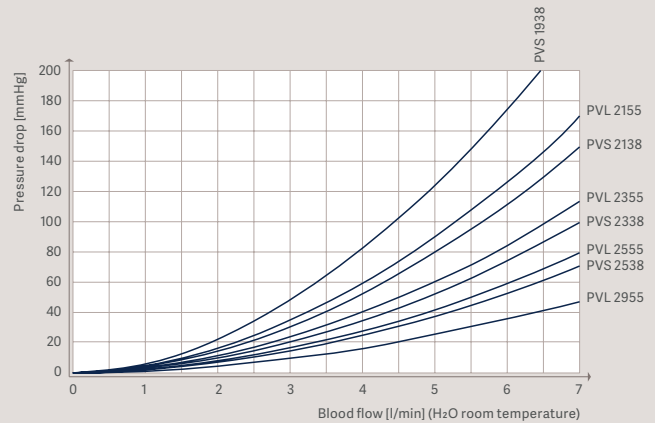


Multiple drainage openings on every venous cannula

Pressure drop for all arterial HLS Cannulae 3/8"



Pressure drop for all venous HLS Cannulae 3/8"



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
Lot 1.5 PAL 1923	19 Fr (6.3 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1923
Lot 1.6 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
Lot 1.7 PVL 2355	23 Fr (7.7 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2355
Lot 1.8 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

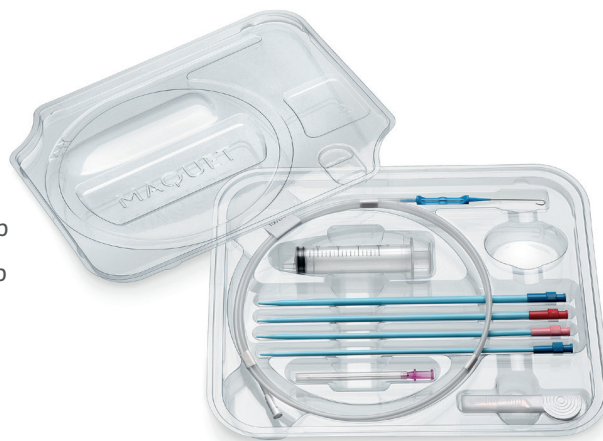
One cannula per carton

Percutaneous Insertion Kit

Kit to prepare for arterial or venous peripheral cannulation of vessels for extracorporeal circulation.

The kit includes:

- 4 vessel dilators: 10/12 Fr., 12/14 Fr., 14/16 Fr., 16/18 Fr.
- Guide wire for arterial cannulae 0.038" (0.097 cm) x 100 cm, J-tip
- Guide wire for venous cannulae 0.038" (0.097 cm) x 150 cm, J-tip
- Guidewire advancer
- 18 Ga (1.27 mm) puncture needle
- Mini scalpel
- 10 ml (10 cc) syringe
- Additional dilator sizes and guidewires available



Order details percutaneous insertion kits and cannulae accessories

	Article No.	Guide wire length	Description
Lot 1.4	PIK 100*	100 cm	Percutaneous insertion kit for arterial HLS cannulae
Lot 1.3	PIK 150*	150 cm	Percutaneous insertion kit for venous HLS cannulae
	PIK dilator set L**		Cannulae accessories: 3 multi-step dilators, dilator sizes 18/20 Fr., 20/22 Fr., 22/24 Fr.
	PIK dilator S**		Cannulae accessories: 1 multi-step dilator, dilator size 08/10 Fr.
	PIK guidewire 100**	100 cm	Cannulae accessories: separate guidewires for arterial cannulae
	PIK guidewire 150**	150 cm	Cannulae accessories: separate guidewires for venous cannulae

*One kit per carton, sterile packed

**5 pcs. per carton, sterile packed

Note

All information presented in this brochure is either referenced by the below publications or is on file at Getinge.

HLS Cannulae Set - Instructions for Use · 70104.8192 · G-139 · Version 05 · NONUS · 2021-04

Percutaneous Insertion Kit - Instructions for Use · 70104.8194 · G-137 · Version 06 · GLOBAL · 2020-06

This document is intended to provide information to an international audience outside of the US. The products in this brochure may be pending regulatory approvals to be marketed in your country. Contact your Getinge representative for more information. Refer to Instructions for Use for current indications, warnings, contraindications and precautions.

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Manufacturer · Maquet Cardiopulmonary GmbH · Kehler Str. 31 · 76437 Rastatt · Germany · +49 7222 932-0

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HLS Set Advanced & CARDIOHELP device

Technical data

	Lot 1.2	Lot 1.1
Technical Data	HLS Set Advanced 5.0	HLS Set Advanced 7.0
Flow rates	0.5–5l/min	0.5–7l/min
Gas exchange surface area	1.3m ²	1.8m ²
Heat exchange surface area	0.3m ²	0.4m ²
Priming volume HLS Module Advanced	240ml	273ml
Priming volume HLS Set Advanced with 2x 2.3m tubing length	570ml	600ml
Gas exchange fibers	Diffusion membrane (PMP)	Diffusion membrane (PMP)
Duration of use with BIOLINE Coating	Max. 30 days	Max. 30 days
Duration of use with SOFTLINE Coating	Max. 5 days	Max. 5 days
Integrated venous measuring cell	<ul style="list-style-type: none"> – oxygen saturation SvO₂ – hemoglobin (Hb) – hematocrit (Hct) – temperature 	<ul style="list-style-type: none"> – oxygen saturation SvO₂ – hemoglobin (Hb) – hematocrit (Hct) – temperature
Integrated sensors	<ul style="list-style-type: none"> – 3 pressures (venous, arterial, internal) – arterial temperature 	<ul style="list-style-type: none"> – 3 pressures (venous, arterial, internal) – arterial temperature
	70106.9076	70106.9073

Technical Data	CARDIOHELP-i
Dimensions (HxWxD) with guard closed	315 x 255 x 427 mm (without holder/disposable)
Weight	Approx. 10kg
Display	5.7" LCD touchscreen
Sensors	<ul style="list-style-type: none"> 4 x External pressures 3 x Internal pressures 2 x External temperatures 2 x Internal temperatures 1 x Venous oxygen saturation 1 x Hemoglobin 1 x Hematocrit 1 x Flow/Bubble sensor 1 x Bubble sensor 1 x Level sensor
Operating voltage range	<ul style="list-style-type: none"> 11–28 Volt DC 100–240 Volt AC/50–60Hz
Interfaces for	<ul style="list-style-type: none"> 1 x USB port type A (for data export on USB stick) 1 x USB port type B (for data recording system and service purposes) 1 x Connection for alarm output (ward call)
Battery operating time	Min. 90 min (fully charged batteries)