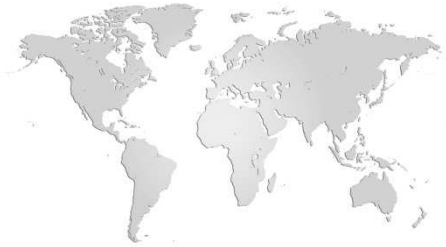
EC CERTIFICATE

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

Digitally signed by Dubalari Pavel
Date: 2022.03.21 10:17:05 EET
Reason: MoldSign Signature
Location: Moldova

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

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

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

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: 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

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-02-08
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

Manufacturer:	**Maquet Cardiopulmonary GmbH**
Address:	**Kehler Str. 31** **76437 Rastatt** **Germany**
Product name:	**HLS Cannulae** - **Arterial** - **Venous**
Optional:	With SOFTLINE Coating
Products:	see attached Product List
Classification:	Class IIa

We, Maquet Cardiopulmonary GmbH, hereby declare under our sole responsibility that the mentioned devices comply with the provisions of:

European Medical Device Directive 93/42/EEC

Conformity Assessment:	Annex II of Directive 93/42/EEC
Notified Body:	DEKRA Certification GmbH Handwerkstr. 15, 70565 Stuttgart, Germany (Notified Body ID-no. 0124)

For and on behalf of Maquet Cardiopulmonary GmbH, Rastatt,

Date	Name	Signature
2020-07-06	Nursel Boelens (Director Regulatory Affairs)	i.V. Nursel B.

Product List

This product list specifies the products {and accessories} covered by the Declaration of Conformity.

Products covered:

REF no.	Article no.	Product description
Class IIa		
PAL 1523 BO-PAL 1523	70104.7256 70105.3099	Art. HLS cannula OD = 15 Fr (5.0 mm) 3/8" connector with LL, insertion length 23 cm
PAL 1723 BO-PAL 1723	70104.7258 70105.3100	Art. HLS cannula OD = 17 Fr (5.7 mm) 3/8" connector with LL, insertion length 23 cm
PAL 1923 BO-PAL 1923	70104.7259 70105.3101	Art. HLS cannula OD = 19 Fr (6.3 mm) 3/8" connector with LL, insertion length 23 cm
PAL 2123 BO-PAL 2123	70104.7263 70105.3102	Art. HLS cannula OD = 21 Fr (7.0 mm) 3/8" connector with LL, insertion length 23 cm
PAL 2323 BO-PAL 2323	70104.7267 70105.3103	Art. HLS cannula OD = 23 Fr (7.7 mm) 3/8" connector with LL, insertion length 23 cm
PAS 1315 BO-PAS 1315	70105.3275 70105.3278	Art. HLS cannula OD = 13 Fr (4.3 mm) 3/8" connector with LL, insertion length 15 cm
PAS 1515 BO-PAS 1515	70104.7255 70105.0048	Art. HLS cannula OD = 15 Fr (5.0 mm) 3/8" connector with LL, insertion length 15 cm
PAS 1715 BO- PAS 1715	70104.7257 70105.3104	Art. HLS cannula OD = 17 Fr (5.7 mm) 3/8" connector with LL, insertion length 15 cm
PAS 1915 BO- PAS 1915	70104.7260 70105.3105	Art. HLS cannula OD = 19 Fr (6.3 mm) 3/8" connector with LL, insertion length 15 cm
PAS 2115 BO- PAS 2115	70104.7264 70105.3106	Art. HLS cannula OD = 21 Fr (7.0 mm) 3/8" connector with LL, insertion length 15 cm
PAS 2315 BO-PAS 2315	70104.7268 70105.3107	Art. HLS cannula OD = 23 Fr (7.7 mm) 3/8" connector with LL, insertion length 15 cm
PVL 2155 BO- PVL 2155	70104.7266 70105.3108	Venous HLS Cannula OD= 21Fr (7.0 mm) 3/8" connector without LL, insertion length 55 cm

REF no.	Article no.	Product description
PVL 2355 BO-PVL 2355	70104.7270 70105.3109	Venous HLS Cannula OD= 23Fr (7.7 mm) 3/8" connector without LL, insertion length 55 cm
PVL 2555 BO-PVL 2555	70104.7271 70105.3110	Venous HLS Cannula OD= 25Fr (8.3 mm) 3/8" connector without LL, insertion length 55 cm
PVL 2955 BO- PVL 2955	70104.7273 70105.3111	Venous HLS Cannula OD= 29Fr (9.7 mm) 3/8" connector without LL, insertion length 55 cm
PVS 1938 BO- PVS 1938	70104.7261 70105.3112	Venous HLS Cannula OD= 19Fr (6.3 mm) 3/8" connector without LL, insertion length 38 cm
PVS 2138 BO- PVS 2138	70104.7265 70105.3113	Venous HLS Cannula OD= 21Fr (7.0 mm) 3/8" connector without LL, insertion length 38 cm
PVS 2338 BO- PVS 2338	70104.7269 70105.3114	Venous HLS Cannula OD= 23Fr (7.7 mm) 3/8" connector without LL, insertion length 38 cm
PVS 2538 BO- PVS 2538	70104.7272 70105.3115	Venous HLS Cannula OD= 25Fr (8.3 mm) 3/8" connector without LL, insertion length 38 cm

SOFTLINE Coated variants are indicated by a BO (SOFTLINE) prefix in the ref number.

Manufacturer:	**Maquet Cardiopulmonary GmbH**
Address:	**Kehler Str. 31** **76437 Rastatt** **Germany**
Product name:	**Percutaneous Insertion Kit**
Products and Accessories:	see attached Product List
Classification:	Class IIa

We, Maquet Cardiopulmonary GmbH, hereby declare under our sole responsibility that the mentioned devices comply with the provisions of:

European Medical Device Directive 93/42/EEC

Conformity Assessment:	Annex II of Directive 93/42/EEC
Notified Body:	DEKRA Certification GmbH Handwerkstr. 15, 70565 Stuttgart, Germany (Notified Body ID-no. 0124)

For and on behalf of Maquet Cardiopulmonary GmbH, Rastatt,

Date	Name	Signature
2020-07-06	Nursel Boelens (Director Regulatory Affairs)	i.V.

Product List

This product list specifies the products and accessories covered by the Declaration of Conformity.

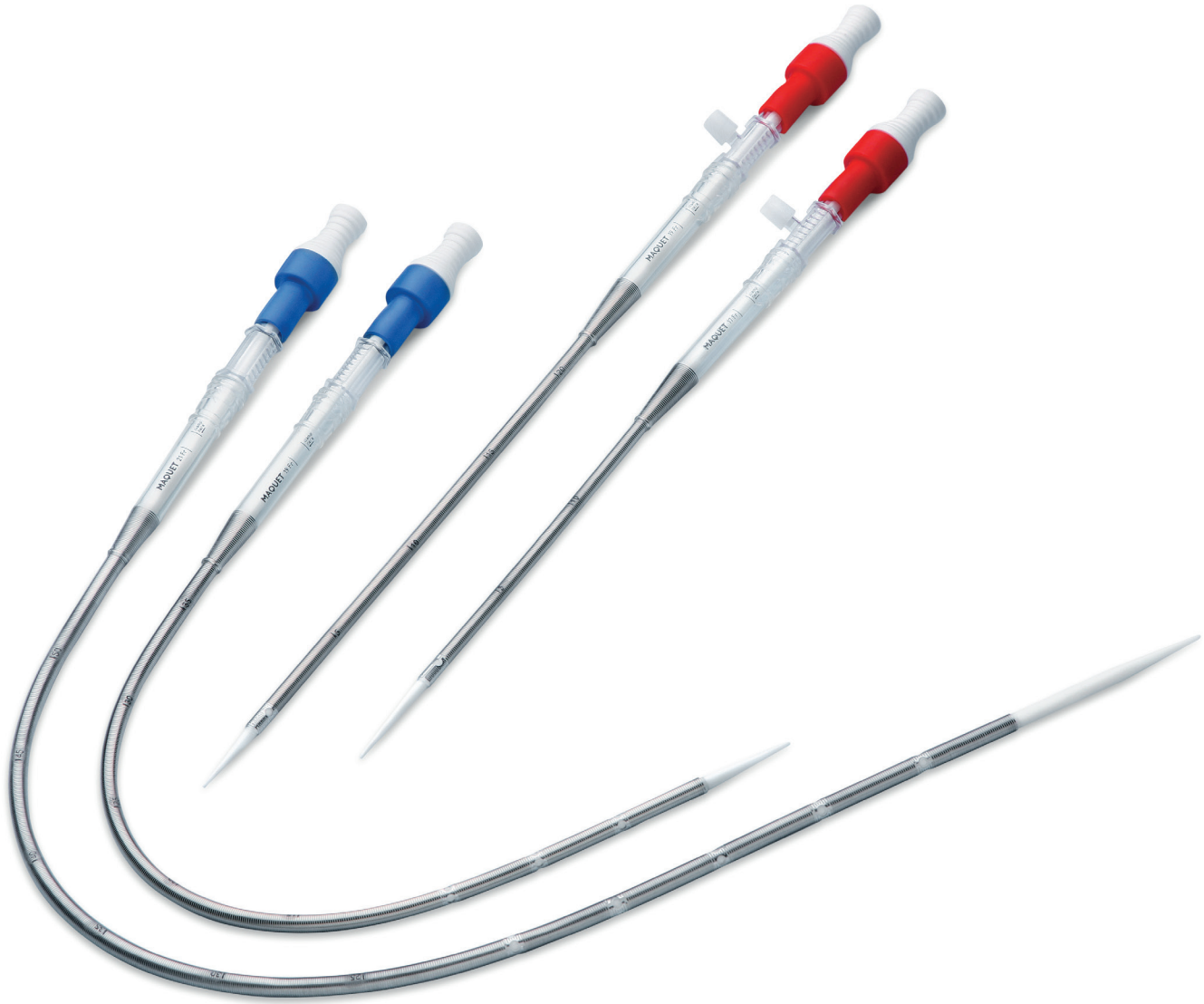
Products covered:

REF no.	Article no.	Product description
Class IIa		
PIK 100	70104.7384	Percutaneous Insertion Kit (scalpel, puncture needle, guidewire 100 cm, dilators, syringe)
PIK 150	70104.7385	Percutaneous Insertion Kit (scalpel, puncture needle, guidewire 150 cm, dilators, syringe)

Accessories covered:

REF no.	Article no.	Product description
Class IIa		
PIK dilator set L	70105.4427	PIK dilator set large 18/20 20/22 22/24 Fr
PIK dilator S	70105.4606	PIK dilator small 8/10Fr
PIK Guide wire 100	70105.5457	Guide wire set PIK 100 cm
PIK Guide wire 150	70105.5459	Guide wire set PIK 150 cm

Lot : 2; 3



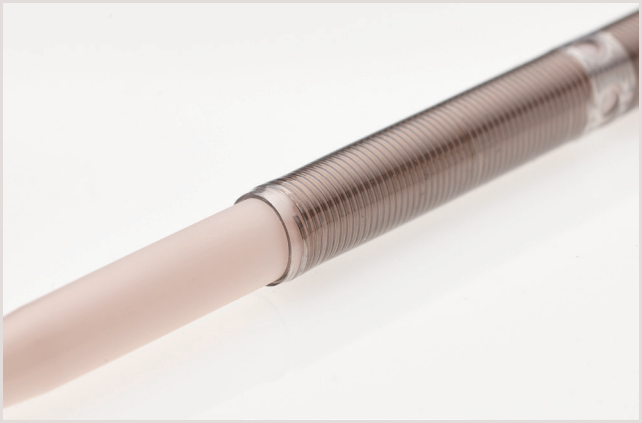
HLS Cannulae

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:

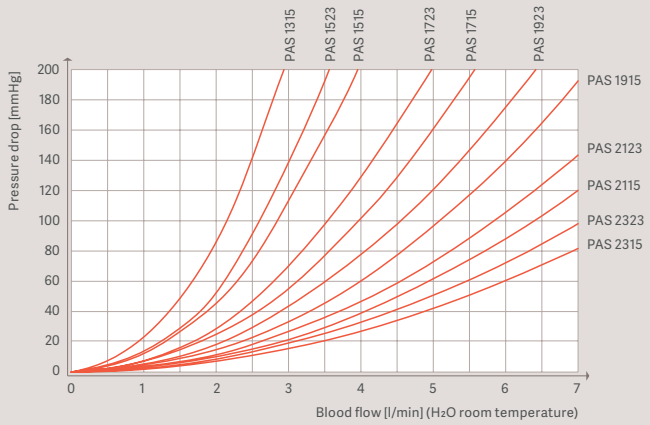
- Locking mechanism keeps introducer in position during insertion
- Smooth transition from introducer to cannula to support a safe cannula insertion
- Depth marks to control insertion depth, a stop ring to define maximum insertion depth
- Selectively hardened proximal cannula body, reduces the risk of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

A pair of side holes on every arterial tip

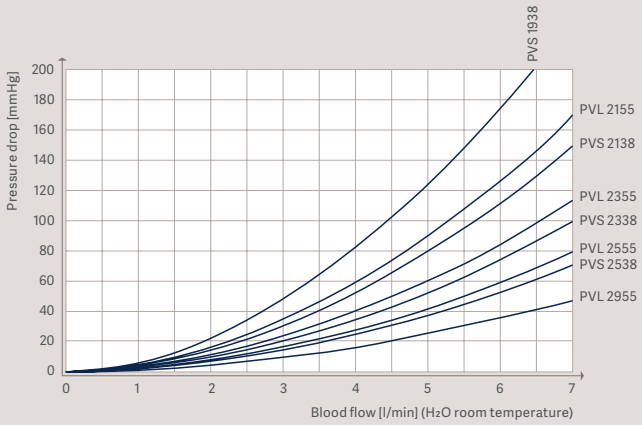
Multiple drainage openings on every venous cannula

* HLS cannulae with Bioline Coating in combination with PLS Set, PLS Set Plus or HLS Set Advanced (all with Bioline Coating) can be used for up to 30 days in CE region.

Pressure drop for all arterial HLS Cannulae ⅜"



Pressure drop for all venous HLS Cannulae ⅜"



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

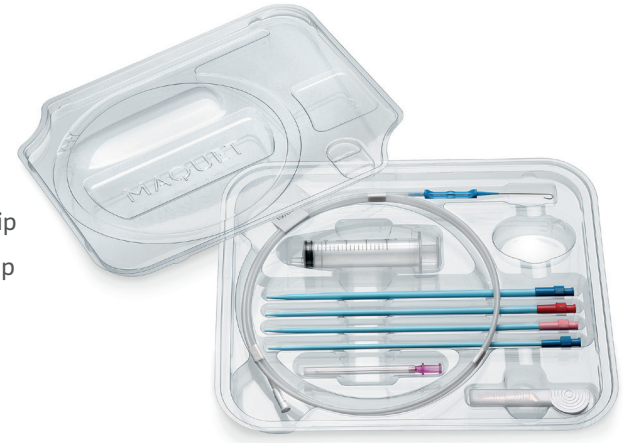
Product order details venous HLS cannulae

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

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
PIK 100*	100 cm	Percutaneous insertion kit for arterial HLS cannulae
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

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

www.getinge.com

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