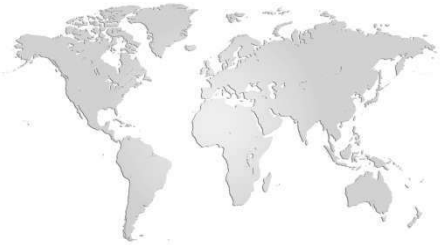
EC CERTIFICATE

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

Digitally signed by Dubalari Pavel
Date: 2022.11.15 10:27:35 EET
Reason: MoldSign Signature
Location: Moldova

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

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

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

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

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

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-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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
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ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 104155 0003 Rev. 01

Manufacturer:

Datascope Corp
15 Law Drive
Fairfield NJ 07004
USA

Product:

Guidewires
Guidewires for Cardiology

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713171530

Valid from: 2020-02-17
Valid until: 2024-05-26

Date, 2021-02-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 104155 0003 Rev. 01

Model(s):

Guidewires for 7.5 Fr or 8 Fr IAB Catheters

PTFE Stainless Steel Guidewire (Box of 5)

Size	Catalogue Numbers
0.025"x 145cm	0684-00-0254-09
0.025" x 175cm	0684-00-0254-14
0.025" x 260cm	0684-00-0254-15

Guidewires for 7 Fr IAB Catheters

PTFE Stainless Steel Guidewire (Box of 5)

Size	Catalogue Numbers
0.018" x 145cm	0684-00-0254-16

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 102541 0003 Rev. 00

Manufacturer: **Datascope Corp.**
1300 MacArthur Blvd
Mahwah NJ 07430
USA

Product Category(ies): **Intra-Aortic Balloon Pumps and accessories.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72155863

Valid from: 2020-05-28
Valid until: 2024-05-26

Date, 2020-05-28

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS2 102541 0002 Rev. 01

Certificate Holder:

Datascope Corp.
1300 MacArthur Blvd
Mahwah NJ 07430
USA

Certification Mark:

Scope of Certificate:

Design, Development, Manufacturing, Service, Installation and Distribution of Intra-Aortic Balloon-Pumps and Accessories; Design and Development of Heart and Lung Machine Therapy Device; Production of Collagen Raw Material for use in Vascular Closure Application

Standard: **ISO 13485:2016**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **72159139**

Effective Date: **2020-10-21**

Expiry Date: **2023-10-20**

Page 1 of 1
Date of Issue: 2020-11-05

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

Manufacturer: **Maquet Cardiopulmonary GmbH**

Address: **Kehler Str. 31**
76437 Rastatt
Germany

Product name: **BMU Sensor**
BMU Cell

Classification: Class IIa
see attached Product List

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
2020-07-08	Nursel Boelens (Director Regulatory Affairs/Safety Officer)	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}		
701040804	70104.0804	BMU Cell 1/2"
701040844	70104.0844	BMU Cell 3/8"
701040845	70104.0845	BMU Cell 1/4"
701040849	70104.0849	BMU Sensor 3/8"
701040850	70104.0850	BMU Sensor 1/4"
701040851	70104.0851	BMU Sensor 3/16"

Manufacturer:	**Maquet Cardiopulmonary GmbH**
Address:	**Kehler Str. 31** **76437 Rastatt** **Germany**
Product name:	**Capacitive Level Sensor (CLS) with the accessories Level Sensor Pad (LSP)**
Products and Accessories:	see attached Product List
Classification:	Class IIb

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
2021-05-21	Dr. Nico (Andreas) Braunegger (Teamlead 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 IIb		
701010855	701010855	CLS 20-535 Capacitive Level Sensor
701049252	701049252	CLS L2.0 Capacitive Level Sensor

Accessories covered:

REF no.	Article no.	Product description
Class IIb		
701022208	701022208	Level-Sensor Pads Pack 100 pcs