DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 028817 0047 Rev. 00

Holder of Certificate: **MAQUET GmbH**
Kehler Straße 31
76437 Rastatt
GERMANY

Facility(ies): MAQUET GmbH
Kehler Straße 31, 76437 Rastatt, GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production, Sales and Service of Medical Devices including Patient Positioning Systems and associated accessories for Therapy and Diagnosis, Transport Devices, Operating Room Integration Systems (hardware / software), Sterilizers and associated accessories**

Digitally signed by Dubalari Pavel
Date: 2021.10.12 13:42:49 EET
Reason: MoldSign Signature
Location: Moldova

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713126733

Valid from: 2018-10-16
Valid until: 2021-10-15

Stefan Preiß

Date, 2018-10-16

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

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

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Medizinprodukten
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ZLG-BS-244.10.08

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

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