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www.zlg.de
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 072017 0014 Rev. 01

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):

MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

Product Category(ies): **Anaesthesia, Monitoring, Ventilator and Perfusion Systems**

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.: 713161324

Valid from: 2020-01-22
Valid until: 2024-05-26

Date, 2020-01-22

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 072017 0013 Rev. 01

Holder of Certificate: **MAQUET CRITICAL CARE AB**
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):
MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

See Scope of Certificate

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, development and manufacturing of Anaesthesia, Monitoring, Ventilator Systems and Perfusion Systems**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 072017 0013 Rev. 01

Report No.: 713193727

Valid from: 2020-12-30

Valid until: 2023-12-29

Date, 2020-12-28

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 072017 0015 Rev. 00

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713170827

Preceding certificate No.: This certificate is issued for the first time

Valid from: 2020-02-17
Valid until: 2025-02-16

Date of initial issuance / Rev.00: 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-02-17

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 072017 0015 Rev. 00

Device(s):	Risk classification	CND Code	Intended Purpose
INSTRUMENTS FOR ANESTHESIA AND PULMONARY VENTILATION SUPPORT	IIb	Z120301	Intended for respiratory support, administration of anesthetic and treatment of neonatal, pediatric and adult patients.

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History including Changes:

Revision / Issue Date / Report
Rev. 00 / 2020-02-17 / 713170827

Digitally signed by Ghereg Victor
Date: 2024.04.26 14:09:34 EEST
Reason: MoldSign Signature
Location: Moldova

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