



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Dräger

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck
Germany

for the Scope of application

Design and development, production and distribution of
diagnostic and therapeutic medical devices and installations
as well as consulting and services
in the field of medical technology

Revalstraße 1, 23560 Lübeck
Germany

for the Scope of application

**Production and distribution of diagnostic
and therapeutic medical devices and installations**

has established and applies
a Quality Management System.

An audit was performed, Order No. **707037695**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2021-01-15** until **2024-01-14**.

Certificate Registration No.: **12 100 49423 TMS**.

Head of Certification Body
Munich, 2021-01-13



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Product Service

Certificate

No. Q5 010578 0031 Rev. 01

Holder of Certificate: **Drägerwerk AG & Co. KGaA**
 Moislinger Allee 53-55
 23542 Lübeck
 GERMANY

Certification Mark:



Scope of Certificate: **Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights**

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 010578 0031 Rev. 01

Report No.: 713193628
Valid from: 2021-01-18
Valid until: 2024-01-13

Date, 2021-01-18

Christoph Dicks
 Head of Certification/Notified Body





Product Service

Certificate

No. Q5 010578 0031 Rev. 01

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

Facility(ies): Drägerwerk AG & Co. KGaA
 Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

Drägerwerk AG & Co. KGaA
 Revalstraße 1, 23560 Lübeck, GERMANY

Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

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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

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 010578 0037 Rev. 01

Manufacturer: **Drägerwerk AG & Co. KGaA**
Moislinger Allee 53-55
23542 Lübeck
GERMANY

Facility(ies): Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 Lübeck, GERMANY

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Product Category(ies): Anaesthetic equipment with standard accessories,
Infusion equipment with standard accessories,
Pediatric equipment with standard accessories,
Lung ventilator equipment with standard accessories,
Monitoring equipment with standard accessories,
Equipment for suction, breathing-, inhalation-, oxygen-
and aerosol-therapy with standard accessories,
Medical supply units and terminal units for pressurized
medical gases and vacuum,
Pipelines for compressed medical gases and vacuum,
Anaesthetic gas scavenging systems, Components for
medical gas management systems, Software for diagnosis based on clinical
data Incl. patient data, monitoring and device parameter, Visualization,
diagnostic and therapeutic software for anesthesia and respiratory devices

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.: 713162398

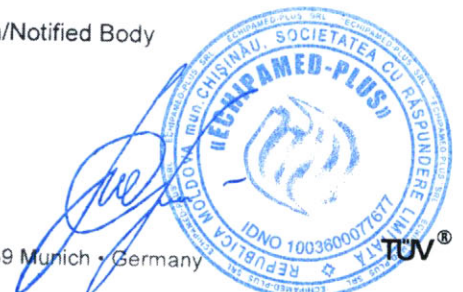
Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

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

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



TÜV SÜD
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFICADO ♦ CERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT