



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

C. Dicks

Christoph Dicks
Head of Certification/Notified Body



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
Mölsinger 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

./.



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



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

