



# 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](http://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

