



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 14 12 10578 004

Manufacturer:

Drägerwerk AG & Co. KGaA

Moislinger Allee 53-55
23542 Lübeck
GERMANY

Facility(ies):

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

Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 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

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.:

713052642

Valid from:

2015-01-15

Valid until:

2020-01-14

Hans-Heiner Junker

Date, 2015-01-16



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

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CERTIFICAT

CERTIFICADO

CERTИФИКАТ

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

has established and applies
a Quality Management System for

**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.**

An audit was performed, Report No. 707037695.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2018-01-15** until **2021-01-14**.

Certificate Registration No.: **12 100 49423/01 TMS**.



[Handwritten signature]

M. Wegner

Product Compliance Management
Munich, 2018-01-09





Product Service

CERTIFICATE

No. Q5 17 11 10578 031

Holder of Certificate: **Drägerwerk AG & Co. KGaA**
Dräger

 Moislinger Allee 53-55
 23542 Lübeck
 GERMANY

Facility(ies):

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

 Drägerwerk AG & Co. KGaA
 Revalstraße 1, 23560 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

Applied Standard(s):

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

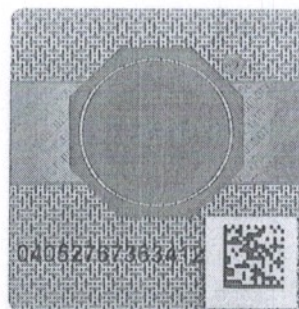

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713113147
Valid from: 2018-01-14
Valid until: 2021-01-13

Date, 2017-12-27

S. Preiß

Stefan Preiß



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DAKKS

 Deutsche
 Akkreditierungsstelle
 D-ZM-11321-01-00