



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

Date, 2015-01-16

Hans-Heiner Junker



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

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Product Service

CERTIFICATE

No. Q5 17 11 10578 031

Holder of Certificate: **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



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



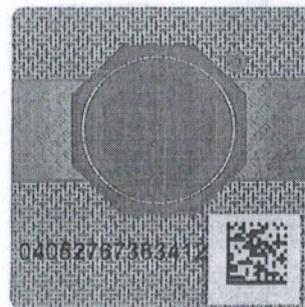
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

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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CERTIFICAT

CERTIFICADO

CЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that



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**



M. Wegner

Product Compliance Management
Munich, 2018-01-09



Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference

DW-legal / ew-ro / 119/13

Phone

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Erika.Wagner@draeger.com

December 7, 2018

Manufacturer's Authorization

We, Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23558 Lübeck, Germany, who is an established and reputable manufacturer of medical equipment, having factories at Lübeck (Germany), Telford (United States), Andover (United States) and Shanghai (China), do hereby declare that

Echipamed Plus SRL
Valea Trandafirilor, 24B, of. 80
MD-2001 Chisinau
Republic of Moldova

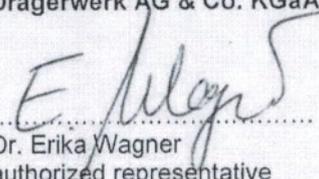
is an official distributor for Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights of Drägerwerk AG & Co. KGaA in the territory of the Republic of Moldova.

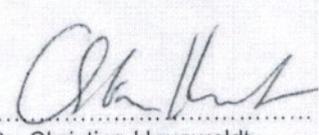
We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights manufactured by us in their own name and on their own account.

This authorization letter will remain valid until 31.12.2019.

Duly authorized to sign this Authorization on behalf of:

Drägerwerk AG & Co. KGaA


Dr. Erika Wagner
authorized representative


Dr. Christian Hauswaldt
authorized representative



Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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info@draeger.com
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VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Prof. Dr. Nikolaus Schweickart
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner