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

Digitally signed by Iurchevici Valeriu
Date: 2020.08.18 12:56:50 EEST
Reason: MoldSign Signature
Location: Moldova

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 scaving 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

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

ZERTIFIKAT ■ CERTIFICATE ■ 認證證書 ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

TÜV SÜD 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**.

Product Compliance Management
Munich, 2018-01-09

IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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:

tuv-sud.com/ps-cert

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

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

DAkkS CRT2 / 10.13

Dräger

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference
–

Phone
+49 451 882-1602

Fax
+49 451 882-71602

E-mail
marianne.selent@draeger.com

Manufacturer's Authorization

April 9, 2020

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 24 "B", of. 80
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative 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 the 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 31.12.2020.

Duly authorized to sign this Authorization on behalf of:

Drägerwerk AG & Co. KGaA

ppa. Baumann

Claus Martin Baumann
Authorized representative

Kruse, Stephan Digital unterschrieben von Kruse, Stephan Datum: 2020.04.14 15:36:23 +02'00'

Stephan Kruse
Authorized representative

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
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:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner