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

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 17 04 79270 007

Facility(ies):

Beijing Eternity Electronic Technology Co.,Ltd.
F2-3,Building 2, No.17, Xijing Road, Shijingshan District, 100043
Beijing, PEOPLE'S REPUBLIC OF CHINA

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-13321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 079270 0008 Rev. 00

Holder of Certificate: **Beijing Eternity Electronic Technology Co.,Ltd.**
F2-3, Building 2, No.17, Xijing Road
Shijingshan District
100043 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Beijing Eternity Electronic Technology Co.,Ltd.
F2-3, Building 2, No.17, Xijing Road, Shijingshan District, 100043
Beijing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Anaesthesia machines, Ventilators, Emergency and Transport Ventilators, Infusion Pumps, Medical Air Compressors, NCPAP System (Nasal Continuous Positive Airway Pressure System), Syringe Pump.**

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.: BJ1879704

Valid from: 2018-10-25
Valid until: 2021-07-16

Date, 2018-10-25

Stefan Preß

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

TÜV®

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

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

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 17 04 79270 007

Manufacturer:

Beijing Eternity Electronic Technology Co.,Ltd.
F2-3,Building 2, No.17, Xijing Road
Shijingshan District
100043 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Anaesthesia machines, Ventilators, Emergency and Transport Ventilators, Infusion Pumps, Medical Air Compressors, NCPAP System (Nasal Continuous Positive Airway Pressure System), Syringe Pump.

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.: BJ1779707

Valid from: 2017-07-17
Valid until: 2022-07-16

04052768716712

Date, 2017-05-08

Stefan Preiß

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

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