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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 109546 0006 Rev. 00

Manufacturer:

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
No.1 Baisheng Road Development Zone
212300 Danyang, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G2 055329 0025 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate MDD. It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply.

Report No.: SH2139201

Valid until: 2024-05-26

Issue Date: 2022-05-17

Christoph Dicks
Head of Certification/Notified Body

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Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 109546 0006 Rev. 00

Product Category(ies): **Electric Suction Apparatus,**
Oxygen Concentrator,
Air Compressive Nebulizer,
Electronic Blood Pressure Monitor,
Finger Pulse Oximeter, Non-contact Infrared Forehead Thermometer,
Portable Phlegm Suction Unit, Mesh Nebulizer

Description of Change: **Certificate Holder Address changed from " Yunyang Industrial Park, Danyang, 212300, Jiangsu, P.R. China" to " No.1 Baisheng Road, Development Zone, 212300 Danyang, Jiangsu, P. R. China"**

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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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 055329 0025 Rev. 00

Manufacturer:

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Yunyang Industrial Park
212300 Danyang, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Electric Suction Apparatus,
Oxygen Concentrator,
Air Compressive Nebulizer,
Electronic Blood Pressure Monitor,
Finger Pulse Oximeter, Non-contact Infrared Forehead Thermometer,
Portable Phlegm Suction Unit
Mesh Nebulizer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH2039201

Valid from: 2020-03-30
Valid until: 2024-05-26

Date, 2020-03-30

Christoph Dicks
Head of Certification/Notified Body

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