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

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 079078 0014 Rev. 01

Manufacturer:

Hangzhou Formed Medical Devices Co., Ltd.
Building 3, No. 292 Gonghe North Road, Xindeng Town
Fuyang District
311404 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Laryngeal Mask, Tracheal Tube Introducer, Catheter Mount, Endotracheal Tube, Feeding Tube, Oxygen Mask with Reservoir Bag, Nasal Cannula, Oxygen Mask, Nebulizer kit, Suction Tubing with Yankauer Handle, Venturi Mask, Anaesthetic Mask, Gastric Calibration Tube, Nelaton Catheter, Hydrophilic Urinary Catheter, Catheterization Kit, Suction Catheter, Foley Catheter, Breathing System Filter, Disposable Breathing Circuit, Drainage Tube, Wound Drainage System, Stomach Tube, Heat and Moisture Exchanger, Hydrophilic Urinary Catheter Kit

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.: SH19104104

Valid from: 2019-09-23
Valid until: 2024-05-26

Digitally signed by Jighili Tatiana
Date: 2023.09.16 12:49:21 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2019-09-23

Stefan Preiß
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

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 079078 0014 Rev. 01

Facility(ies):

Hangzhou Formed Medical Devices Co., Ltd.
Building 3, No. 292 Gonghe North Road, Xindeng Town, Fuyang District, 311404 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

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

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

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

A4 / 07.17