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

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 066149 0017 Rev. 01

Manufacturer:

HANGZHOU FUSHAN MEDICAL APPLIANCES CO., LTD.
No. 1288 South Jinxi Road
Linglong Industrial Park
Lin'an District
311301 Hangzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

HANGZHOU FUSHAN MEDICAL APPLIANCES CO., LTD.
No. 1288 South Jinxi Road, Linglong Industrial Park, Lin'an District, 311301 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Silicone Urethral Catheter, Trocar, Laryngeal Mask Airway, Nebulizer, Stomach Tube, Nasogastric Tube, Drainage Tube, Endotracheal Tube, Supra Laryngeal Airway, Mask, Suction Tube Kit, Rectal Tube, Oxygen Tube, Yankauer Handle, Drainage Kit, Resuscitator, Guedel/Oropharyngeal Airway, Intravenous Catheter, Infusion Access Adapter, Gastrostomy Tube, Pessary

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.: SH1951212

Valid from: 2019-10-28
Valid until: 2023-07-15

Date, 2019-10-28

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

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