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

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 098565 0007 Rev. 01

Manufacturer:

Suzhou Lantex Medical Technology Company Limited
Building 7, 58 Xinting Road, High-tech Industrial Zone
215151 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Single Use Intraluminal Circular Stapler,
Single Use Circular Stapler for Rectal Prolapse and Haemorrhoids,
Single Use Reloadable Linear Stapler and Reloads,
Single Use Reloadable Linear Cutter Stapler and Reloads,
Single Use Endoscopic Linear Cutter Stapler and Reloads,
Single Use Transverse Cutting Linear Stapler and Reloads,
Single Use Clipping Device, Single Use Snare,
Single Use Sphincterotome**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 098565 0007 Rev. 01

Report No.: SH211174EXT01

Valid from: 2021-04-28
Valid until: 2024-05-26

Date, 2021-04-28

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Perminov Andrei
Date: 2022.08.04 16:25:27 EEST
Reason: MoldSign Signature
Location: Moldova

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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