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 086467 0010 Rev. 02

Signature Not Verified
Dokument podpisany przez Beata Kolan
Data: 2022.08.01 14:48:50 CEST
Powód: Zatwierdzam dokument

Manufacturer:

Leo Medical Co., Ltd.
1st and 2nd Floor, No. 10 Building, 18 Huashan Road
213022 Changzhou City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Single-use Stone Extraction Catheter,
Single-use Balloon Dilatation Catheter,
Single-use Stone Retrieval Basket,
Single-use Biliary Draining Tubing,
Ligation Device, Sphincterotome,
Polypectomy Snares,
Single-use Nitinol Stone Retrieval Basket,
Single-use Nasal Biliary Drainage Catheter,
Single-use Guidewire,
Single-use Snare Probe,
PTA Balloon Dilatation Catheter,
Single-use Billary Drainage Catheter,
Single-use Injection Therapy Needle Catheter

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.: SH19843EXT01

Valid from: 2019-07-25
Valid until: 2024-05-26

Date, 2019-07-25

Stefan Preiß
Head of Certification/Notified Body

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

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

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Facility(ies):

Leo Medical Co., Ltd.
1st and 2nd Floor, No. 10 Building, 18 Huashan Road, 213022 Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

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