



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 16 09 86467 009

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



**EC-Representative:** **Lotus Global Co., Ltd.**  
 1 Four Seasons Terrace  
 West Drayton, Middlesex  
 London  
 UB7 9GG  
 UNITED KINGDOM

**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**

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.:** SH1684307  
**Valid from:** 2017-01-10  
**Valid until:** 2019-12-29



**Date,** 2017-01-10  
  
 Stefan Preiß

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

Page 1 of 2



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 16 09 86467 009

**Facility(ies):**

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