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 086239 0016 Rev. 03

Manufacturer: **Anrei Medical (HZ) Co., Ltd.**
No. 3, Ave. 8
Hangzhou Economic Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Single-use Biopsy Forceps, Single-use Grasping Forceps, Single-use Guide Wire,Single-use Stone Retrieval Balloon Catheter, Polypectomy Snare, Sphincterotome, Sclerotherapy Needle,Single Use Stone Retrieval Basket,Single Use Hemoclip, Single-use Balloon Dilator Catheter, Bronchial Stent System, Biliary Stent System, Intestinal Stent System,Esophageal Stent System, Single-use Biliary Drainage Catheter, Hot Biopsy Forceps,Single Use Urinary Guidewire, Single Use Rotatable and Repositionable Hemoclip, Single Use Retrieval Net, Single Use Electrosurgical Knife, Rescue Single-Use Grasping Forceps, Rescue Pulmonary Grasping Forceps, Single Use Bougie Dilator, Single-use Cold Snare**

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.: SH1949901

Valid from: 2020-03-12
Valid until: 2024-05-26

Date, 2020-03-12

Christoph Dicks
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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17