



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlgf.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 102689 0002 Rev. 00

Manufacturer: **CHANGZHOU INNOVATE MEDICAL
 INSTRUMENT
 AND TECHNOLOGY CO.,LTD**
 Floor 4th, Buliding 4B
 No.128, Mingxin West Road, Wujin Area
 213161 Changzhou, Jiangsu Province
 PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
 Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): Sterile Electrosurgical Pencils

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.: SH19144501

Valid from: 2019-08-01
Valid until: 2024-05-26

Date, 2019-08-01

Stefan Preiß
 Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ 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 102689 0002 Rev. 00

Facility(ies):

CHANGZHOU INNOVATE MEDICAL INSTRUMENT AND
 TECHNOLOGY CO.,LTD
 Floor 4th, Buliding 4B, No.128, Mingxin West Road, Wujin Area,
 213161 Changzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF
 CHINA

TÜV SÜD
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT