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 101180 0002 Rev. 00

Manufacturer: **Zhejiang CuraWay Medical Technology Co., Ltd.**
Room 106, Building 1, #600 21st Street
Economic & Technological Development Area
310018 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, GERMANY

Product Category(ies): **Cura RF Electrode,**
Breast Lesion Localization Wire,
Disposable Biopsy Needle,
Disposable Coaxial Biopsy Needle,
Semi-Automatic Core Biopsy Instrument,
Automatic Core Biopsy Instrument

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.: SH18140101

Valid from: 2019-05-10
Valid until: 2024-05-09

Date, 2019-05-10

Stefan Preiß

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
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Facility(ies): **Zhejiang CuraWay Medical Technology Co., Ltd.
Room 106, Building 1, #600 21st Street, Economic & Technological Development Area, 310018
Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA**

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