ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 04 80430 009

Manufacturer:

Changzhou Kanghui Medical Innovation Co., Ltd.
No. 11, North Changjiang Road
Xinbei Zone
213022 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Sterile and Non-Sterile Lockable Intramedullary Nails, Bone Plates, Bone Screws, General Spine System, Drill Bits, Metal Bone Pins, Ballon Tube, Vertebroplasty Instrument Kits

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.: SH1710814

Valid from: 2017-07-05
Valid until: 2020-07-26

Date, 2017-07-05

Stefan Preiß

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

Digitally signed by Axentii Olga
Date: 2019.04.16 20:02:21 EEST
Reason: MoldSign Signature
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Facility(ies):

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No. 11, North Changjiang Road, Xinbei Zone,
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