ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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 090358 0005 Rev. 03

Manufacturer:

Beijing HangTian KaDi Technology R&D Institute
Room 301, Third floor, Building No.13
No.15 Jing Sheng Nan Er Street
Tongzhou District
101102 Beijing
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Soft Tissue Retractor, Access System, Heart Stabilizer, Stabilizer Foot, Uterine Manipulator/Injector, Uterine Cup, Cyst Suction Needle, Blower/Mister, Specimen Retrieval Bag, Ring Retractor System, Suture Grasper Closure Device, Obstetric Suction Cup.**

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.: BJ19701021

Valid from: 2020-02-11
Valid until: 2024-05-26

Date, 2020-02-11

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

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Facility(ies):

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