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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 103622 0002 Rev. 00

Manufacturer:

JiangSu Celtics MediTech Co., Ltd.

3 Wujin Road West
Wujin High-Tech Industrial Park
213167 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

JiangSu Celtics MediTech Co., Ltd.
3 Wujin Road West, Wujin High-Tech Industrial Park, 213167
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Disposable Circular Stapler, Disposable Anorectal
Stapler, Disposable Linear Cutter and its Stapler
Auxiliary, Disposable Endo Cutting Stapler and
Loading Unit

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.

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Valid from: 2019-12-10

Valid until: 2024-05-26

Date, 2019-12-10

Christoph Dicks
Head of Certification/Notified Body