



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 003076 0006 Rev. 01

Manufacturer:

Shinva Medical Instrument Co., Ltd.

Xinhua Medical Scientific Zone

Zibo New & Hi-Tech Industrial Development Zone

255086 Zibo

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): H2O2 Low Temperature Plasma Sterilizer

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.:

BJ19501033

Valid from:

2019-12-09

Valid until:

2024-05-26

Date,

2019-12-09

Christoph Dicks

Head of Certification/Notified Body



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 003076 0006 Rev. 01

Facility(ies):

Shinva Medical Instrument Co., Ltd.

No. 99 Beixin Road, Zibo New & Hi-Tech Zone, 255086 Zibo,
PEOPLE'S REPUBLIC OF CHINA

Shinva Medical Instrument Co., Ltd.

Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial
Development Zone, 255086 Zibo, PEOPLE'S REPUBLIC OF
CHINA

Shinva Medical Instrument Co., Ltd.

No. 2009 Xinhua Ave, Zhoucun, 255300 Zibo, PEOPLE'S
REPUBLIC OF CHINA