



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

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 103335 0002 Rev. 00

Manufacturer

Dongguan Tondaus Meditech Co., Ltd.

3rd Floor, No.27, Rd. Guantai

Chiling Community, Houjie Town

523900 Dongguan, Guangdong

PEOPLE'S REPUBLIC OF CHINA

Product

Surgical Skin Marker

Category(ies):

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

GZ1938101

Valid from:

2019-11-11

Valid until:

2024-05-26

Date,

2019-11-11

Christoph Dicks

Head of Certification/Notified Body

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 103335 0002 Rev. 00

Facility(ies):

Dongguan Tondaus Meditech Co., Ltd.

3rd Floor, No.27, Rd. Guantai, Chiling Community, Houjie Town,
523900 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF
CHINA