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 IIa, IIb or III)

No. G2 101512 0001 Rev. 00

Manufacturer:

Suzhou GZM Medical Co., Ltd.
Room 1612, Building 8
Shi Shan Tian Jie Living Plaza
New District
215011 Suzhou, Jiang Su
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Single Use Endoscopy Tubing Set (Contains Air/Water Source Tubing, Irrigation Tubing and Auxiliary Water Connector), Single Use Ophthalmic Surgical Procedure Packs (Contains Ophthalmic Forceps, Scissor, Iris Scissors, Phaco Chopper, Iris Hook, Lens Manipulating Hook, Curette, Peeler, Chalazion Clamp, Wire and Adjustable Speculum, Punctal Dilator, Caliper, Needle Holder, Fixing Ring, Cannulas and Irrigation/Aspiration Cannulas), Single Use Suction Cannulas, Single Use ENT Procedure Packs (Contains Bite Block, Forceps, Nasal Speculum, Aural Speculum, Aural Hook, Tongue Depressor, Probe, Suction Cannulas, Larynges Scissors, Elastic Incision Expending Hook), Disposable Digestive Endoscopy Dilator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH18140901

Valid from: 2019-02-27
Valid until: 2024-02-26

Date, 2019-02-27

I. Preiß

Stefan Preiß

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

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Facility(ies):

Suzhou GZM Medical Co., Ltd.
Room 1612, Building 8, Shi Shan Tian Jie Living Plaza, New District, 215011 Suzhou, Jiang Su, PEOPLE'S REPUBLIC OF CHINA

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