

EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A



Registration No.: DZ 2318749-1

Manufacturer: **GENMED ENTERPRISES INTERNATIONAL LTD**
Fountain House, Fountain Lane, St Mellons,
Cardiff,
CF3 0FB
United Kingdom

EUDAMED Single
Registration No.: GB-MF-000010687

Products: Products of Class IIa:
K010101 ENDOTHERAPY TROCARS, SINGLE-USE
- Sterile Trocars for Single Use,
K010190 ENDOTHERAPY DEVICES - VARIOUS
- Sterile Insufflation Needles for Single Use,
K010201 ENDOTHERAPY, SINGLE-USE SURGICAL INSTRUMENTARY
- Sterile Suction Irrigations for Single Use,
- Sterile Specimen Retrieval Bags for Single Use,
G030801 GASTROINTESTINAL ENDOSCOPY, FORCEPS, SINGLE-USE
- Sterile Laparoscopic Forceps for Single Use,

Authorised
representative(s): Genmed Enterprises Medical Ltd
30 Botanic Avenue, Drumcondra, Dublin, Ireland

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-02-09

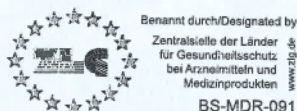
The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 244325322-200

Effective date: 2022-02-09

Expiry date: 2027-01-20

Issue date: 2022-02-09



Fuxiu Sheng
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.