EC Declaration of Conformity

Manufacturer:

GCMEDICA ENTERPRISE LTD. (WUXI)
Loujin Industrial Park, Shuofang, Wuxi, 214143, CHINA
Adam Jiang
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whose single Authorized Representative:

Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherland
SRN: NL-AR-000002066
Kun Yan
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We, the manufacturer, herewith declare that the products

Suction Specimen Traps

Type: See Appendix
GMDN-Code: 62853

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

Compliance of the designated product with the Directive 93/42/EEC aspects of manufacture concerned with securing and maintaining sterile conditions has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 60138811 0001
Issue date: 2019-05-24
Expiry date: 2024-02-07

following the procedure relating to the EC Declaration of Conformity set out in Annex VII and Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: GCMedica Enterprise Ltd. (WUXI)
Address: Loujin Industrial Park, Shuofang, Wuxi, 214143, CHINA

2022.2.11 Wuxi Jiangsu

Place, Date

Adam Jiang

Legally binding signature, Quality Manager

GCMEDICA CONFIDENTIAL

Appendix:

Product name	GC code	Cust code	Description
Suction Specimen Traps	GC8054E10	17000128	MUCUS SINGLE, CH 10, Funnel, 53 cm
Suction Specimen Traps	GC8054E12	17000228	MUCUS SINGLE, CH 12 catheter, FUN, 53 cm
Suction Specimen Traps	GC8054E14	17000328	MUCUS SINGLE, CH 14 catheter, FUN, 53 cm
Suction Specimen Traps	GC8054E00	17000428	MUCUS SINGLE, Male Cone, FUN

WWW.GCMEDICA.COM
受控文件