EC Declaration of Conformity

Manufacturer:

GCMEDICA ENTERPRISE LTD., (WUXI)
Loujin Industrial Park, Shuofang, Wuxi, Jiangsu, CHINA
Adam Jiang
Tel: 86 510 85300900
E-mail: adam@gcmedica.com

whose single Authorized Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
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Lin Sun
Tel: 0049-1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Suction Connecting Tubes with and without Yankauer

(Type: 7.5×5.0mm, 9.0×6.0mm, 9.6×6.0mm, 9.8×6.0mm, 10.0×7.0mm, 11.3×7.1mm, 12×8mm)

UMDNS-Code: 14188

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: GC Medica Enterprise Ltd.(WUXI)
Address: Loujin Industrial Park, Shuofang, Wuxi, Jiangsu, CHINA

2019.06.04, Wuxi

Place, Date

Legally binding signature, Quality Manager