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
Tel: +31(0)646571005
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We, the manufacturer, herewith declare that the products

Uterine Aspiration Curettes/Uterine Aspiration Tubes

Type: See Appendix
GMDN-Code: 47341

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

Appendix

Curette	Code	Description
UCS06	GC7049A06	straight, 6mm
UCS08	GC7049A08	straight, 8mm
UCS09	GC7049A09	straight, 9mm
UCS10	GC7049A10	straight, 10mm
UCS11	GC7049A11	straight, 11mm
UCS12	GC7049A12	straight, 12mm
UCS14	GC7049A14	straight, 14mm
UCS16	GC7049D16	straight, 6mm
UCC06	GC7049B06	curve, 16mm
UCC08	GC7049B08	curve, 8mm
UCC09	GC7049B09	curve, 9mm
UCC10	GC7049B10	curve, 10mm
UCC11	GC7049B11	curve, 11mm
UCC12	GC7049B12	curve, 12mm
UCC14	GC7049B14	curve, 14mm
UCC16	GC7049E16	curve, 16mm