

GCMEDICA ENTERPRISE LTD., (WUXI) CE Technology Documents for Product	Chapter No.: GC/CE-12-002	
	Edition: A.3	Version No.: 2019
EC Declaration of Conformity	The Chapter Page 1 of 1	

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Date	2019-05-30	Date	2019-05-30	Date	2019-05-30

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

GCMEDICA ENTERPRISE LTD., (WUXI)
Loujin Industrial Park, Shuofang, Wuxi, Jiangsu, CHINA

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

We, the manufacturer, herewith declare that the products

Yankauer Handles

(Type: Y1200 Y1201 Y1500 Y1501 Y1800 Y1801 Y2200 Y2201 Y2800 Y2801 Y20PS Y2400 Y240B Y240FB Y240FS P2000 P20FT YORTH0 Y80 Y82 GC1202E4N1 GC1202F6N2 GC1223G1W GC1257N1N GC1244E1W GC1248J1N GC1245E1W GC1200H02)

GMDN-Code: 35917

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

The medical device has been assigned to class *I/a* according to Rule 6 of Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC 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 IV of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

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

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

Wuxi, 2019-05-30

Place, Date

无锡卓九龙医疗器械有限公司
GCMEDICA ENTERPRISE
Legally-binding signature, Function