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|---|---------------------------|-----------------|
| GCMEDICA ENTERPRISE LTD.(WUXI)<br>CE Technology Documents for product | Chapters No. GC/CE-32-001 |                 |
|   | Edition: B                | Version NO:2019 |
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|--------|-----------|-------|-----------|---------|-----------|
| Writer | Ying Wu   | Check | Stephen   | Confirm | Sharon    |
| Date   | 2019-5-25 | Date  | 2019-5-25 | Date    | 2019-5-25 |

## EC Declaration of Conformity

*Manufacturer:*

Gcmedica Enterprise Ltd.(WUXI)  
Loujin Industrial Park, Shuofang, Wuxi.  
214143,CHINA

*whose single Authorized Representative:*

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

We, the manufacturer, herewith declare that the products

**Bacterial /Viral Filter**

*Type: /*

**UMDNS-Code: 11712**

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

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: 2019-5-24

Expiry date: 2024-2-7

following the procedure relating to the EC Declaration of Conformity set out in 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 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. 214143, CHINA

Wuxi, 2019.5.25  
\_\_\_\_\_  
*Place, date*

  
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*Legally binding signature, Function*