

## Declaration of Conformity

*Manufacturer:*

Excellentcare Medical (Huizhou) Ltd.

Add.: Shatou Industrial Zone, Yuanzhou Town, Boluo  
County, Huizhou, 516123, Guangdong, China

*whose single Authorized Representative:*

Share Info Consultant Service LLC

Repräsentanzbüro

Add.: Heerdter Lohweg 83, 40549 Düsseldorf

We, the manufacturer, hereby declare that the products

### **Anaesthetic Face Masks**

*UMDNS-Code: 12453; UMDNS TERM: Masks, Anesthesia*

### **Breathing Circuits**

*UMDNS-Code: 15562; UMDNS TERM: Breathing Circuits*

### **Breathing System Filters**

*UMDNS-Code: 11711; UMDNS TERM: Filters, Air*

### **Laryngeal Mask Airways**

*UMDNS-Code: 10059; UMDNS TERM: Airways, Oropharyngeal*

### **Nebulizers**

*UMDNS-Code: 12712; UMDNS TERM: Nebulizers*

### **Oxygen Masks**

*UMDNS-Code: 12448; UMDNS TERM: Masks, Air-Oxygen*

### **Suction Tubes**

*UMDNS-Code: 10749; UMDNS TERM: Catheters, Suction*

### **Nasal Cannulas**

*UMDNS-Code: 12700; UMDNS TERM: Cannulae, Nasal Oxygen*

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 (including 2007/47/EC). It bears the mark

**CE 0197**

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

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**

**Tillystraße 2, 90431 Nürnberg**

Certificate No.: HD 60144935 0001

Issue date: 2020-06-05

Expiry date: 2023-12-24

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

And herewith declare that the products

**Anesthesia Unit Carbon Dioxide Absorbents**

*UMDNS-Code: 17509; UMDNS TERM: Anesthesia Unit Carbon Dioxide Absorbents*

**Urine Drainage Bags**

*UMDNS-Code: 10944; UMDNS TERM: Collectors, Urine*

**Manual Wheelchairs**

*UMDNS-Code: 14449; UMDNS TERM: Wheelchairs*

**Air Compressor for Nebulizer**

*UMDNS-Code: 10972; UMDNS TERM: Compressors, Medical-Air*

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

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC (including 2007/47/EC). It bears the mark



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

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**

**Tillystraße 2, 90431 Nürnberg**

Certificate No.: SX 2164436-1

Effective date: 2021-12-25

Expiry date: 2024-12-24

Issue date: 2021-12-22

*For Class Is/Im product only:* Application of the abovementioned Annexes and the intervention by the Notified Body is limited to:

the aspects of manufacture concerned with securing and maintaining sterile conditions. **ISO 11135-2014 Sterilization of health-care products–Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical devices**

*or*

manufacture concerned with the conformity of the products with the metrological requirements.

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

**EXCELLNETCARE MEDICAL(HUIZHOU) LTD.**

Huizhou, 2021.12.30

*Place, date*



*Legally binding signature, CEO*