

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Hunan Beyond Medical Technology Co., Ltd. Well Kang Ltd.

Beyond Zone, Lijiacun Rd, Xueshi Street,
Yuelu District, 410208 Changsha, Hunan,
PEOPLE'S REPUBLIC OF CHINA.

Enterprise Hub, NW Business Complex,
1 Beraghmore Rd., Derry, BT48 8SE,
Northern Ireland, UK

We, the manufacturer, herewith declare that the products

Infusion Pump

**(Model: BYS-820,BYS-820S,BYS-820D,
Sunfusion Semi-2,Sunfusion Erch-6,Sunfusion Anim-8)
GMDN-Code: 13215**

Syringe Pump

**(Model: BYZ-810, BYZ-810S, BYZ-810D,
Sunfusion Semi-1,Sunfusion Erch-3,Sunfusion Anim-5)
GMDN-Code: 13217**

Sleep Apnoea Breathing Therapy Equipment

**(BY-Dreamy-C00, BY-Dreamy-C01, BY-Dreamy-C02,
BY-Dreamy-AC08, BY-Dreamy-AC09, C-20C, C-20A)
GMDN Code: 60711**

**(BY-Dreamy-B17,BY-Dreamy-B18,BY-Dreamy-B19, B-20S,
B-25S, B-25A, B-25T, B-25P, B-30T, B-30P, B-30F)
GMDN Code: 60712**

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

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

CPAP/BIPAP Masks

(Model: EaseFit NMI, EaseFit FMI, EaseFit NMI-NV, EaseFit FMI-NV)

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 II 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.: HD601478010001

Issue date: 2020-05-25

Expiry date: 2024-05-26

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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

Company: Hunan Beyond Medical Technology Co., Ltd.

Address: Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, 410208 Changsha,
Hunan, PEOPLE'S REPUBLIC OF CHINA.

ChangSha 2/8/2022
Place, date

ChengTing MR
Legally binding signature, Function