



EU Declaration of Conformity

Manufacturer Name : Hunan Beyond Medical Technology Co., Ltd.
Manufacturer Address : Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, 410208 Changsha,
Hunan, China
Manufacturer SRN : CN-MF-000002143
Authorized Representative Name : WellKang Ltd.
Enterprise Hub, NW Business Complex,
Authorized Representative Address : 1 Beraghmore Road, Derry, BT48 8SE,
Northern Ireland, UK
Authorized Representative SRN : XI-AR-000001836
GMDN Code : Reference to Appendix
Product Name : Reference to Appendix
Product model(s) : Reference to Appendix
Classification : Reference to Appendix
Notified body : TÜV Rheinland LGA Products GmbH
Notified Body Address : Tillystraße 2, 90431, Nürnberg, Germany
Notified Body Identification Number : 
(EC) Certificate(s) : HD 601478010001
Start of CE-Marking : 2020-05-25
Hunan Beyond Medical Technology Co., Ltd. Uses the following
procedures for the CE-marking of their products according to the **Directive**
Conformity assessment route : **93/42/EEC**: Class IIa and IIb: EC conformity declaration according to
Annex II excluding section 4 Conformity assessment based on a quality
management system and assessment of the technical documentation.

This EU declaration of conformity is issued under the sole responsibility of Hunan Beyond Medical Technology Co., Ltd..
We hereby declare that the medical device(s) specified above meet the provision of the **Directive 93/42/EEC** for medical
devices. This declaration is supported by the Quality System approval to ISO13485 issued by **TÜV Rheinland LGA**
Products GmbH. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Ting Cheng, PRRC

Legally binding signature, Function

Place and date of issue:

Changsha, 2023. 2. 23

Change sha, MM-DD-YYYY

Appendix

Product Name	GMDN code	Product model(s)	Classification
Infusion Pumps	13215	BYS-820,BYS-820S,BYS-820D, Sunfusion Semi-2,Sunfusion Erch-6,Sunfusion Anim-8	Class IIb
Syringe Pumps	13217	BYZ-810, BYZ-810S, BYZ-810D, Sunfusion Semi-1,Sunfusion Erch-3,Sunfusion Anim-5	Class IIb
Sleep Apnoea Breathing Therapy Equipment	60711	BY-Dreamy-C00, BY-Dreamy-C01, BY-Dreamy-C02, BY-Dreamy-AC08, BY-Dreamy-AC09, C-20C, C-20A	Class IIb
Sleep Apnoea Breathing Therapy Equipment	60712	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	Class IIb
CPAP/BIPAP Masks	/	EaseFit NMI, EaseFit FMI, EaseFit NMI-NV, EaseFit FMI-NV	Class IIa

The end