EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145709 0001

Report No.: 17056867 004

Manufacturer:

Hunan Beyond Medical
Technology Co., Ltd.
Beyond Zone,Lijiacun Rd,
Xueshi Street,Yuelu District
410208 Changsha
P.R. China

Products:

- Infusion Pumps
- Syringe Pumps
- Sleep Apnoea Breathing Therapy Equipment
- CPAP/BIPAP Masks

Replaces Approval, Registration No.: HD 60121761 0001

Expiry Date: 2022-06-07

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-03-03

Date: 2020-03-03

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.