

## **EC** Certificate

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

Registration No.:

HD 60147801 0001

Report No.:

17056867 007

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 60145709 0001

**Expiry Date:** 

2024-05-26

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:** 

Date:

2020-05-25

2020-05-25

**Notified Body** 

Jason Pan

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.