EC Certificate

TÜVRheinland®

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

Registration No.: HD 2183512-1

Manufacturer: Shenzhen Hawk Medical Instrument Co., Ltd.
1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China

Products:
- Infusion Pumps
- Syringe Pumps
- Enteral Feeding Pumps
- Fluid Warmers
- Infusion Pump Management Units

Digitally signed by Botnaru Andrei
Date: 2022.06.17 18:03:21 EEST
Reason: MoldSign Signature
Location: Moldova

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.

Report No.: 10918567-100

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Shengkui Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

TÜVRheinland®

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

Registration No.: HD 2183512-1

Manufacturer: Shenzhen Hawk Medical Instrument Co., Ltd.
1st Floor, Building C, Jianyetai Industrial Zone, No. 11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China

The scope of certification includes the following manufacturing site:

No.	Location	Product groups manufactured
/01	Shenzhen Hawk Medical Instrument Co., Ltd. 2nd-4th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen, 518109 Guangdong P.R. China	Infusion Pumps, Syringe Pumps, Enteral Feeding Pumps, Fluid Warmers and Infusion Pump Management Units

Report No.: 10918567-100

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Shengkui Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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