

EC DECLARATION OF CONFORMITY

Doc: HK-100QPCE-06 Rev.: A3 Date: 2021-01-19



EC DECLARATION OF CONFORMITY

Name and address of the 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

Name and address of the European

Representative:

WellKang Ltd
The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

We declare under our sole responsibility that

the medical device: Infusion Pump

Model: HK-100, HK-100I, HK-100II

GMDN Code: 13215

of class: Rule 11(3.2/7), IIb

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: Directive 93/42/EEC Annex II, excluding Section 4

Registration No.: HD 2183512-1

Notified Body: TÜV Rheinland LGA Products GmbH

Tillystraße 2 90431 Nürnberg Deutschland CE 0197

The expiry date of the above mentioned declaration of conformity is May 26, 2024.

Shenzhen, 2021-01-19

Place, date

Name and function

General Manager