

EC DECLARATION OF CONFORMITY

Digitally signed by Botnaru Andrei
Date: 2022.06.23 15:14:25 EEST
Reason: MoldSign Signature
Location: Moldova



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**