EC Declaration of Conformity

No.:QC-20240329-001,Version:12.0

Manufacturer:
Shenzhen Hawk Medical Instrument Co., Ltd
1st-4th Floor, Building C, Jianyetai Industrial Zone,
No.11 Minhuan Road, Fukang Community,
Longhua Street, Longhua District, Shenzhen,
518109 Guangdong, P.R.China
SRN: CN-MF-000013071

Whose Authorized Representative:
Umedwings Netherlands B.V.
Treubstraat 1,2288EG,
Rijswijk,The Netherlands
SRN: NL-AR-000000444

We, the manufacturer, herewith declare that the products

A. Infusion Pump (HK-100, HK-100I, HK-100II, hawk-i1)
Class IIb, Rule 11, GMDN Code: 13215

B. Enteral Feeding Pump (HK-300)
Class IIa, Rule 11,GMDN Code: 13209

C. Syringe Pump (HK-400, HK-400I, HK-400II, HK-400III, hawk-s1)
Class IIb, Rule 11,GMDN Code: 13217

D. Fluid Warmer (Hawk-fw1)
Class IIb, Rule 9, GMDN Code: 47616

E. Infusion Pump Management Units (HAWK-WS1, HAWK-WS2)
Class IIb, Rule 11, GMDN Code: 36179

meet the provisions of Directive 93/42/EEC of 14 June,1993 concerning medical devices amended by council directive 2007/47/EEC and Regulation (EU) 2023/607 amending Regulations (EU) 2017/745.

The classification of the medical devices has been assigned according to Annex IX of the Directive 93/42/EEC.
It bears the mark

CE 0197

Compliance of the designated products with the Directive 93/42/EEC **Annex II**,**excluding Section 4** has been assessed and certified by the Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2-90431 Nürnberg Deutschland
Registration No.: HD 2183512-1
Report No.:10918567-100
Effective date: 2021-05-25
Expiry date: 2028-12-31 under (EU) 2023/607

The above mentioned declaration of conformity is exclusively under the responsibility of

Shenzhen Hawk Medical Instrument Co.,Ltd

Shenzhen, March 29, 2024
Place, Date

Legally binding signature
Name:Chengliang Yan Function:General Manager

The above-mentioned products are in conformity with the following standards:

No.	Standard No.	Standard Description
1	ISO 13485:2016	Medical devices - Quality management systems – Requirements for regulatory purposes
2	IEC 60601-1:2006+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
4	IEC 60601-1-6:2010/AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
5	IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
6	IEC 60601-1-8:2006+A1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
7	IEC 60601-2-24:2012 (Not applies to Fluid Warmer)	Medical electrical equipment - Part 2-24: Particular requirements for basic safety and essential performance of infusion pumps and controllers; German version
8	IEC 62304:2006+A1:2015	Medical device software-Software life cycle processes
9	ISO 14971:2019	Medical devices - Application of risk management to medical devices
10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
11	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements