

EU Declaration of Conformity

Manufacturer: Foshan Hongfeng Co., Ltd
No.4-2 Leqiang Road, Leping Sanshui, Foshan, 528100, Guangdong, China

SRN:

EC Representative: **MedNet EC-REP GmbH**
Borkstrasse 10 48163 Muenster Germany

Product Name: Medical air mattress with pump

Models: HF6001, HF6002, HF600
2U, HF6005, HF6006, HF
6008, HF601, HF608, HF
609, HF6P01, HF62012,
HF-1

BASIC UDI-DI 06971066420009

Classification (According to the Annex VIII of MDR): Class I, Rule 1

Conformity Assessment Route: Annex II and III of MDR

We, the manufacturer herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EU regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Regulation:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Standards:

EN ISO 13485: 2016, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC60601-9, IEC60601-11
EN10993-5, EN10993-10, EN ISO15223-1:2012, EN1041:2008, ISO14971:2012

Start of CE Marking: 2019.03.06

Place, Date of Issue: Foshan, China 2019.3.6

Signature: *Tina Zhao*

Name: Tina Zhao

Position: General Manager

Place: foshan, China

Date of issue: 2020-3-6

