EU Declaration of Conformity

Manufacturer:	Foshan Hongfeng Co., Ltd No.4-2 Leqiang Road, Leping Sanshui, Foshan, 528100, Guangdong, China
SRN:	CN-MF-000016042
EC Representative:	**MedNet EC-REP GmbH** **Borkstrasse 10 48163 Muenster Germany** **EC-REP SRN：DE-AR-000000002**
Product Name:	Medical air mattress with pump
Models:	HF6001,HF6002,HF6002U,HF6005,HF6006,HF6008,HF601,HF608,HF609, HF6P01,HF62012,HF-A,HF806
BASIC UDI-DI	06971066420009

Classification (According to the Annex VIII of MDR): Class I, Rule 13

Conformity Assessment Route: Annex II Annex III and Annex IV of MDR

We , the manufacture 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 2021.5.25

Signature: Tina Zhao

Name: Tina Zhao

Position: General Manager

Place: foshan , China

Date of issue:2021-5-25

FOSHAN HONGFENG CO.,LTD 佛山鸿沣医疗科技有限公司