

## Declaration of Conformity

Manufacturer: Foshan Hongfeng Co., Ltd  
No.4-2, Leqiang Road ,Leping Town, Sanshui District , Foshan  
City , Guangdong province , 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 cushion

Models: HF2002,HF2005,HF2006,HF2007,HF2008

HF2002 BASIC UDI-DI: 697106642HF200257

HF2005 BASIC UDI-DI: 697106642HF20055D

HF2006 BASIC UDI-DI: 697106642HF20065F

HF2007 BASIC UDI-DI: 697106642HF20075H

HF2008 BASIC UDI-DI: 697106642HF20085K

Classification (According to the Annex VIII of MDR): Class I, Rule 13  
Conformity Assessment Route: Annex II Annex III 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

Applied standards :

EN ISO 13485: 2016, ISO 15223:2021, ISO 14971:2019

EN10993-5: 2009,EN10993-10: 2010, MEDDEV 2.7/1 rev 4, MEDDEV 2.12/1 rev 8

Start of CE Marking: 2019.03.06  
Place, Date of Issue: Foshan,China 2021.8.5

Signature: *Tina Zhao*

Name: Tina Zhao  
Position: General Manager  
Place: foshan , China  
Date of issue:2021-8-5

