EU Declaration of Conformity

Manufacturer:	Foshan Hongfeng Co., Ltd No.4-2 Leqiang Road, Leping Sanshui, Foshan, 528100, Guangdong, China
EC Representative:	MedNet EC-REP GmbH Borkstrasse 10 48163 Muenster Germany
Importatore:	RICANT S.r.l. Street Marie Curie, 5-5A 20018 Sedriano (MI) Italy
Product Name:	Medical air mattress with pump
Models:	SY200
BASIC UDI-DI	06971066420009

Classification (According to the Annex VIII of MDR): Class I.
Rule: According to rule 13, Annex VIII, Chapter III of Medical Device Regulation (UE)2017/745.
Conformity Assessment procedure: Annex II and 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. 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:2022-11-10