



## EC Declaration of Conformity



### Regarding Medical Device Regulation(EU 2017/745)

#### Manufacturer

Name: Chengdu Cryo-Push Medical Technology Co.,Ltd.

Address: 2, Zone 9 and 102,105,Zone 20、Huayin Industrial Port、No.618,KeXing Road(West),  
Wenjiang District, Chengdu 611137 Sichuan P.R. China

SRN of Manufacturer: CN-MF-000019527

#### European Authorized Representative:



SRN of Authorized Representative: DE-AR-000000002

Product Name: Waterproof Cast & Bandage Protector

#### Product Model:

KRP/FL-(220230、220231、220232、220530、220531、220532、230131、230231、230232、  
230331、230431、230433、230531、230532、230533、230631、231030、231032、330130、  
330131、330230、330231、330232、330330、330331、330430、330431、330433、330530、  
330531、330532、330533、330630、330631、420230、420231、420232、420530、420531、  
420532、430131、430231、430232、430331、430431、430433、430531、430532、430533、  
430631、431030、431032)

**Classification:** Class I (according to Rule 4 of ANNEX VIII of REGULATION (EU) 2017/745)

**Conformity Assessment Route:** Annex II&III in Medical Device Regulation (EU2017/745)

**Basic UDI-DI:** 697364188FL3W

We、the manufacturer herewith declare in sole responsibility that the above mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 13485:2016    EN ISO 14971: 2019    EN 1041: 2008    EN ISO 15223-1:2021

EN ISO 10993-1:2018    EN ISO 10993-5:2009    EN ISO 10993-10:2010

All supporting documentations are retained under the premises of the manufacturer. We、the manufacturer are exclusively responsible for the declaration of conformity.

Signature: 张培勇

Date: August 27<sup>th</sup> 2024

Name/ Position: Zhang Peiyong/ GM

Place: Chengdu/ China