EU declaration of conformity

CE

Manufacturer information:

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

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

SRN: Not applicable

Authorised representative information:

Name: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

Product covered by the EU declaration of conformity:

Product and trade name: Waterproof Cast & Bandage Protector

Model: KRP/FL - (1301, 1302, 1303, 1304, 1305, 1306, 1307, 1308, 1309, 1310, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1208, 1209, 1210,, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2208, 2209, 2310, 3301, 3302, 3303, 3304, 3305, 3306, 3307, 3308, 3309, 3310, 3201, 3202, 3203, 3204, 3205, 3206, 3207, 3208, 3209, 3210, 400, 401) - (30, 31, 32, 33, 34)

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

Basic UDI-DI: 697364188FL3W

CS: Not applicable

Applicable Standards: EN ISO 13485:2016+AC: 2018, EN ISO 14971: 2012, EN 1041: 2008 EN ISO 15223-1:2016, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2010 **Notified body:** Not applicable

Conformity Assessment Procedure: ANNEX II and ANNEX III

We herewith declare that the device is covered by the present declaration is in conformity with REGULATION (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices and the EU declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documentations are retained under the premises of the manufacturer.

Name(printed): 张培勇 **Function or Title: General Manager**

Signature: 张培勇

Place: Chengdu, China **Date (YYYY-MM-DD):** 2022.12.30

Issue on behalf of Chengdu Cryo-Push Medical Technology Co., Ltd.