EC Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Name: Hangzhou Primecare Medical Co., Ltd. Add: Room 408-409, Zancheng Center West, Shangcheng District, 310008 Hangzhou, PEOPLE'S REPUBLIC OF CHINA
SRN:	Not available yet
European Representative:	Name: MedPath GmbH Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN:	DE-AR-000000087
Product Name:	Leg Bag Sleeve
Trade name:	Primecare

Product REF

Primecare Product REF	GHC Product REF
8102301	05/02/13/S/GHC
8102302	05/02/13/M/GHC
8102303	05/02/13/L/GHC
8102304	05/02/12/M/GHC
8102305	05/02/12/L/GHC
8102306	05/02/12/XL/GHC
8102307	05/03/10/M/GHC
8102308	05/03/10/L/GHC
8102309	05/03/10/XL/GHC
8102310	04/99/01/945/GHC

Basic UDI	697236069UB05KV
Intended purpose	Used to securely fix common urine leg bags to the leg.
Classification acc. to MDR Ax. VIII:	Class I, Rule 1
Applied Common Specification/ standard:	EN ISO 13485: 2016; EN ISO 14971: 2019; ISO 10993-1: 2018; EN ISO 10993-5: 2009; EN ISO 10993-10: 2013; EN ISO 15223-1: 2016; EN 1041: 2008/A1: 2013;
Conformity Assessment Procedure:	MDR Annex II + Annex III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

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Place of Issue: Hangzhou, CHINA

Date of Issue: 2021-03-11

Signature: Yan Xueqing

Yan Xueqing

Position: Management Representative

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