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EC Declaration of Conformity

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

Name: Hangzhou Primecare Medical Co., Ltd.
Manufacturer: 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