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	Document No.	CE-LS-02-01	Version	V01	Effective Date	2021-03-11

## 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 Straps

**Trade name:** Primecare

Product REF	Primecare Product REF	GHC Product REF
	8102201	05/01/BKL/Uni/GHC
	8102202	05/01/BKL/PRE/GHC
	8102203	05/01/BKL/PRE/SET
	8102204	05/01/BKL/PRE/03

**Basic UDI** 697236069UB04KT

**Intended purpose** Used to securely and comfortably attach common urine leg bag straps 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.

**Place of Issue:** Hangzhou, CHINA

**Date of Issue:** 2021-03-11

**Signature:**   
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 Mr. Xueqing Yan

**Position:** Management Representative