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:	Urine Bag
Trade name:	Primecare

Product REF

Primecare Product REF	GHC Product REF
8101101	04/01/500US/10/GHC
8101102	04/01/500US/30/GHC
8101103	04/01/500US/50/GHC
8101504	04/01/750UF/50/GHC
8101501	04/01/750US/10/GHC
8101502	04/01/750US/30/GHC
8101503	04/01/750US/50/GHC
8101702	04/06/2000/90/GHC
8101705	04/06/2000/130/GHC
8101701	04/07/2000/90/GHC
8101602	04/07/1500/90/00
8101601	04/07/1500/90/01
8101402	04/01/750USE/12/GHC
8101707	04/CH/2000US/90/GHC
8101708	04/CH/1500USo/90/GHC
8101709	04/CH/2000USo/90/GHC
8101603	04/07/1500/10/01
8101602	04/CH/1500/90/00/GHC

Basic UDI	697236069UB01KM
Intended purpose	This product is used for draining accumulated urine.
Classification acc. to MDR Ax. VIII:	Class I, Rule 1
Applied Common Specification/ standard:	EN ISO 13485: 2016; EN ISO 14971: 2019; EN ISO 15223-1: 2016; EN 1041: 2008/A1: 2013; ISO 8669-2:1996

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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: 2024-10-17

Signature: Li Xuedong

Li Xuedong

Position: Management Representative

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