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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
Name: MedPath GmbH

European Representative: 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

Position: Management Representative