# EC Declaration of Conformity

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

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|---|---|
| Manufacturer: | Name: Hangzhou Primecare Medical Co., Ltd.<br>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<br>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 |

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|---|---|
| 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;<br>EN ISO 15223-1: 2016; EN 1041: 2008/A1: 2013; ISO 8669-2:1996 |

Heruntergeladen von Gast (IP 216.73.217.10) am 23.11.2026 um 05:16 Uhr · sana.swiss

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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