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|                                                                                   | Document No.  | CE-UB-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

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 Name: MedPath GmbH

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 EN ISO 13485: 2016; EN ISO 14971: 2019;  
Specification/ EN ISO 15223-1: 2016; EN 1041: 2008/A1: 2013; ISO 8669-2:1996  
standard:

|                                                                                   |               |                           |         |     |                |             |
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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