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|----------------------------------------------------------------------------------|---------------|---------------------------|---------|-----|----------------|-------------|
|  | Document Name | Declaration of Conformity |         |     | Page           | Page 1 of 2 |
|                                                                                  | Document No.  | CE-CK-02-01-10            | Version | V01 | Effective Date | 2025.02.26  |

## 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: CN-MF-000011403

European **Name:** MedPath GmbH

Representative: **Add:** Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Product Name: Catheter Care Kit

Product REF

| Primecare device REF | Product Name      |
|----------------------|-------------------|
| 8202124              | 01/01/99/BS/GHC   |
| 8202125              | 01/01/99/BSKE/GHC |
| 8202126              | 01/01/99/BSK/GHC  |

Basic UDI 697236069CK01H4

Intended purpose Catheter Care kit is used to insert or change an indwelling catheter in a hygienic way, this device is sterile and for single use only.

Classification acc. to Class Is, Rule 1

MDR Ax. VIII:

Applied Common ENISO 13485: 2016; ENISO 14971: 2019; ENISO 15223-1: 2021;

Specification/ standard: ENISO 20417:2021; EN 455-1:2020+A1:2022; EN 455-2:2024;  
EN 455-3:2023; EN 455-4:2009; EN 14079:2003

Conformity Assessment MDR Annex XI Part A

Procedure:

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.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

Identification number: 0123

(EC) Certificate(s): G21 005225 0005 Rev.01

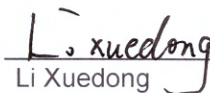
Expire date of the Certificate: 2028-07-17

Start of CE Marking: Not yet

Place of Issue: Hangzhou, CHINA

Date of Issue: 2025-02-26

Signature:

  
Li Xuedong

Position: Management Representative