

	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

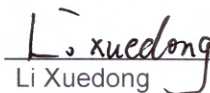
Expire date of the Certificate: 2028-07-17

Start of CE Marking: Not yet

Place of Issue: Hangzhou, CHINA

Date of Issue: 2025-02-26

Signature:


Li Xuedong

Position: Management Representative