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 Representative:	**Name:** MedPath GmbH **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 MDR Ax. VIII:	Class Is, Rule 1
Applied Common Specification/ standard:	ENISO 13485: 2016; ENISO 14971: 2019; ENISO 15223-1: 2021; 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 Procedure:	MDR Annex XI Part A

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

Li Xuedong

Position: Management Representative

Heruntergeladen von Gast (IP 216.73.217.85) am 24.10.2026 um 22:50 Uhr · sana.swiss