EU 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:	Pre-filled Syringe
Product Photograph:	
Product REF	See Annex 1
Basic UDI	Pre-filled Syringes with sterile water:697236069PS01M7 Pre-filled Syringes with 10% Glycerin Solution:697236069PS04MD
Intended purpose	The Pre-filled Syringe is intended to be used for foley catheter balloon inflation after insertion during catheterization procedure.
Classification acc. to MDR Ax. VIII:	Class Is, Rule 1
Applied Standard:	See Annex 2
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
(EU) Certificate(s):	G21 005225 0005 Rev.01
Expire date of the Certificate:	2028-07-17
Start of CE Marking:	2024-12-01
Place of Issue:	Hangzhou, CHINA
Date of Issue:	2026-04-16
Signature:	Yan Xueqing

Position: Person responsible for regulatory compliance

Annex 1

No.	Primecare Model	**Description**	**Packaging**	Product REF
1	PCAA02	10 ml syringes, pre-filled with 10 ml 10% Glycerin Solution	Blister packaging	623002B
2	PCAA04	10 ml syringes, pre-filled with 10 ml Sterile water	Blister packaging	623001B

Annex 2

S/ N	Name of document
1	ENISO13485:2016 Quality system - Medical devices -Particular requirements
2	Regulation (EU) 2017/745 on Medical Devices
3	EN ISO14971:2019 Medical Device - Application of risk management
4	ENISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	ENISO 10993-5:2009 Biological Evaluation of Medical Device-Part 5: Test for in vitro Cytotoxicity
6	ENISO10993-10:2023 Biological Evaluation of Medical Devices- Part 10: Tests for irritation and delayed-type hypersensitivity
7	ENISO10993-12:2021 Biological Evaluation of Medical Devices- Part 12:Sample preparation and reference materials
8	ENISO 10993-23-2021 Biological evaluation of medical devices —Part 23 Tests for irritation
9	ISO 15223-1:2021/Amd:2025 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
10	ENISO 20417:2021Medical devices — Information to be supplied by the manufacturer
11	EN 62366-1:2020 Medical devices-- Part 1: Application of usability engineering to medical devices
12	MEDDEV. 2.7.1 Rev.4 June. 2016 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
13	EN ISO 11137-1 2015+A2 2019 Sterilization of health care products — Radiation — Part1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO11137-1:2006, including Amd 1:2013)
14	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (IS0 11737-2:2019)
15	ASTM F1980-2021 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
16	ASTM F88-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
17	ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
18	ISTA 3A：2018 Packaged-products for parcel delivery system shipment 70kg or less
19	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
20	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
21	EN ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
22	EN ISO 14644-2:2015 Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
23	EN 17141:2020 Cleanrooms and associated controlled environments -Biocontamination control
24	EN ISO 7886-1:2018 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
25	ISO 11040-8:2016 Requirements and test method for finished pre-filled syringe
26	EN ISO 80369-7:2018 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2016)