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 REF:

Primecare Device Model	Product REF
PCAA02	01/01/99/KB/10/GHC

Basic UDI: 697236069PS04MD

Intended purpose: The pre-filled syringe is intended to be used for catheter balloon inflation.

Classification acc. to MDR Ax. VIII: Class Is, Rule 1

Applied Standard: See Annex 1

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.00

Expire date of the Certificate: 2028-07-17

Start of CE Marking: 2024-12-01

Place of Issue: Hangzhou, CHINA

Date of Issue: 2025-12-17

Signature:

Yan Xueqing

Position: Person responsible for regulatory compliance

Annex 1

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)