Declaration of Conformity

1. Manufacturer:

Name: Jiangsu Embrace Science & Technology Development Co., Ltd.

Address: 29-2 Yingbin Road, Huai'an Economic and Technological Development Zone, 223005, Huai'an City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

SRN: CN-MF-000020321

2. European representative:

Name: MedPath GmbH

Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

3. Notified Body:

Name: TüV SüD Product Service GmbH

Address: Ridlerstr, 65, 80339 München, Germany

Identification number: 0123

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability:

	Variants list	**Sterile**	**size**	**Model number**
1	Pre-filled flush syringe, 3ml-YY, Basic UDI-DI: 697191102PS0000001JD	Sterile fluid path	3ml	3ml-YY
2	Pre-filled flush syringe, 5ml-YY, Basic UDI-DI: 697191102PS0000001JD	Sterile fluid path	5ml	5ml-YY
3	Pre-filled flush syringe, 10ml-YY, Basic UDI-DI: 697191102PS0000001JD	Sterile fluid path	10ml	10ml-YY
4	Pre-filled flush syringe, 3ml-ZT, Basic UDI-DI: 697191102PS0000002JF	Sterile field ready	3ml	3ml-ZT
5	Pre-filled flush syringe, 5ml-ZT, Basic UDI-DI: 697191102PS0000002JF	Sterile field ready	5ml	5ml-ZT

6	Pre-filled flush syringe, 10ml-ZT, Basic UDI-DI: 697191102PS0000002JF	Sterile field ready	10ml	10ml-ZT

5. **EMDN Code:** A02010701-PREFILLED SYRINGES WITH STERILE PHYSIOLOGICAL SOLUTION

6. **Intended Use:** Pre-filled flush syringe is used for flushing only of peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs) and implanted venous access ports.

7. **Classification:** IIb

Based on MDR EU2017/745 Annex VIII Rule 6

The specific sentence is:

All surgically invasive devices intended for transient use are classified as class IIa unless they:

-have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb.

8. **Conformity Assessment Route:**

EU MDR 2017/745 Annex IX

9. **Statement:**

We hereby declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

The EU declaration of conformity shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

10. **CS: N/A**

11. **Standard Applied:**

EN ISO 15223-1:2021 EN ISO 13485:2016 EN ISO 14971:2019

EN ISO 7886-1:2018

12. (EC) Certificate(s):

Number of the Certificate: G15 102433 0006 Rev. 00

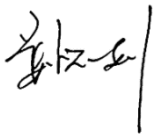
Expire date of the Certificate: 2031-06-07

Place, Issue date of the certificate: 2026-06-08

Declaration issue place: Huai'an, China

Declaration issue date: 2026-08-18

Name and position: Jiang Huaili, Quality Manager and Management Representative

Signature: 

Product List

S/N	REF	Product Description
1	CATHEFLUSH3ML	Pre-filled flush syringe 3ml Sterile fluid path
2	CATHEFLUSH5ML	Pre-filled flush syringe 5ml Sterile fluid path
3	CATHEFLUSH10ML	Pre-filled flush syringe 10ml Sterile fluid path
4	SPSM03012	Pre-filled flush syringe 3ml Sterile field ready
5	SPSM05013	Pre-filled flush syringe 5ml Sterile field ready
6	SPSM10014	Pre-filled flush syringe 10ml Sterile field ready