Jiangsu Caina Medical Co., Ltd
No.23, Huanxi Rd. Zhutang Town,
214415 Jiangyin City, Jiangsu,China

EC Declaration of Conformity

Manufacturer:	Jiangsu Caina Medical Co., Ltd Add: No.23 Huanxi Rd, Zhutang Town, Jiangyin City, Jiangsu 214415, China
SRN:	CN-MF-000011217
Authorised representative:	Shanghai International Holding Corp.GmbH(Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001

We declare under our sole responsibility that

Basic UDI-DI:	69715644600340ZU, 69715644600341ZW, 6971564460034223
Medical Device:	Pre-filled Syringe with Saline
Medical Device Model	PP01, PP02, PP03
Risk class:	IIa according to Annex VIII rule 6 of Regulation (EU) 2017/745

meets the provisions of the EU Medical Regulation2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the final inspection report of the device.

Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX Chapter I, Section 2 and 3 and Chapter III (Quality Management System)
Notified Body	TÜV Rheinland LGA Products GmbH Tillystraße2, 90431 Nürnberg, Germany CE 0197
EU Certificate:	HZ 2016352-1
Effective date:	2024-07-22
Expiry date:	2029-07-21
CS reference:	EN ISO 14971:2019, EN ISO15223-1:2021, EN ISO 20417:2021, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015/A1:2023, EN ISO 17665-1:2006, EN ISO 11737-2:2019, EN ISO 11737-1:2018+A1:2021, EN ISO 10993-1:2020

Jiangyin/July 24,2024	Zhou Shangxiang, PRRC	Zhou Shangxiang
Place, date	Name and function	Signature

TD number: CNTCF-0034 Ver.B01