



FINESS HEALTHCARE GROUP CO.,LTD

Declaration of Conformity

EU Declaration of Conformity

Doc.No.:FN-QS9.3-IRS01-R-FN Rev.00

Manufacturer:	Finess Healthcare Group Co.,Ltd No.1503 A1 Block,No.203 Lantian Road 315000 Ningbo PEOPLE'S REPUBLIC OF CHINA	SRN No.:	CN-MF-000004124
European Representative:	SUNGO Cert GmbH Harffstr. 47,40591 Düsseldorf, Germany	SRN No.:	DE-AR-000010869
Product Name:	Irrigation Set		
Product Code:	FN-IRS0101,FN-IRS0102		
Basic UDI-DI:	697391169IRS01QE		

Classification (MDR, Annex VIII): Class I Non sterile,Rule 5

Conformity Assessment Route: Article 19+Annex II+Annex III

We herewith declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.The products above are in conformity with the Medical Device Regulation (EU) 2017/745.All supporting documentation is retained under the premises of the manufacturer.

General Applicable Regulation:

Medical Device Regulation (EU) 2017/745 and other applicable EU standards and MDCG Guidance.

Place,Date of Issue: Ningbo,2024-06-21

Signature:

Name: Michelle Zhang

Finess Healthcare Group Co.,Ltd

Quality/Regulatory Department:

Position: PRRC

Michelle-Z