



FINESS HEALTHCARE GROUP CO.,LTD

Declaration of Conformity

EU Declaration of Conformity

Doc.No.:FN-QS9.3-UB0101-RB-IGF 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:	ZOUSTECH S.L. Pso. Castellana,141-Planta 19, 28046 Madrid, SPAIN	SRN No.:	ES-AR-000002008
Product Name:	Urine Bottle		
Brand Holder:	IGEFA Zentrallogistik GmbH & Co. KG Henry-Kruse-Straße 1 16356 Ahrensfelde / OT Blumberg		
Model Number:	FN-UB0101010102	Brand Model REF:	2067731
Basic UDI-DI:	697391169UB0101GK		

Classification (MDR, Annex VIII): Class I Non sterile,Rule1

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.

Harmonized Standards:

EN ISO13485:2016 EN ISO15223-1:2021

Start of CE Marking: 2020-01-01

Place,Date of Issue: Ningbo,2021-08-21

Signature:

Name: Michelle Zhang

Position: PRRC

Finess Healthcare Group Co.,Ltd
Quality/Regulatory Department.

Michelle.Z