



# FINESS HEALTHCARE GROUP CO.,LTD

## Declaration of Conformity

## EU Declaration of Conformity

Doc.No.:FN-QS9.3-UB0101-RB-COM Rev.00

Manufacturer:	<b>Finess Healthcare Group Co.,Ltd</b> No.1503 A1 Block,No.203 Lantian Road 315000 Ningbo PEOPLE'S REPUBLIC OF CHINA	SRN No.:	CN-MF-000004124
European Representative:	<b>ZOUSTECH S.L.</b> Pso. Castellana,141-Planta 19, 28046 Madrid, SPAIN	SRN No.:	ES-AR-000002008
Product Name:	Urine Bottle		
Brand Holder:	<b>COMED</b> PARC DES FORGES,8 RUE LOUISE MICHEL,FR - 67200 STRASBOURG ,FRANCE		
Model Number:	FN-UB0101010103 FN-UB0101020102	Brand Model REF:	1620022C 1620023
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,2021-08-31

Signature:

Name: Michelle Zhang

Position: PRRC

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

Michelle Zhang