



FINESS HEALTHCARE GROUP CO.,LTD

Declaration of Conformity

EU Declaration of Conformity

Doc.No.:FN-QS9.3-TNQ02-RB-COM 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:	Tourniquet		
Brand Holder:	COMED PARC DES FORGES,8 RUE LOUISE MICHEL,FR - 67200 STRASBOURG ,FRANCE		
Model Number:	FN-TNQ020101	Brand Model REF:	4290125
Basic UDI-DI:	697391169TNQ02T3		

Classification (MDR, Annex VIII): Class I Non sterile,Rule 1
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:

ENISO 14971:2019 EN ISO 15223-1:2021 EN ISO10993-1:2020

Place,Date of Issue: Ningbo,2022-08-15

Signature:

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Position: PRRC

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

Michelle Zhang