



# FINESS HEALTHCARE GROUP CO.,LTD

## Declaration of Conformity

## EU Declaration of Conformity

Doc.No.:FN-QS9.3-FGT0101-R-LCH Rev.01

<b>Manufacturer:</b>	<b>Finess Healthcare Group Co.,Ltd</b> No.1503 A1 Block,No.203 Lantian Road 315000 Ningbo PEOPLE'S REPUBLIC OF CHINA	<b>SRN No.:</b>	CN-MF-000004124
<b>European Representative:</b>	<b>ZOUSTECH S.L.</b> Pso. Castellana,141-Planta 19, 28046 Madrid, SPAIN	<b>SRN No.:</b>	ES-AR-000002008
<b>Product Name:</b>	PE Fingerstalls		
<b>Brand Holder</b>	LCH medical products, 12-14, rue Sarah Bernhardt, 92600 Asnières-sur-Seine, FRANCE		
<b>Model Number:</b>	FN-FGT0101010101	<b>Brand REF:</b>	DGL-03 (71030)
<b>Basic UDI-DI:</b>	FN-FGT0101010201 697391169FGT0101Q6		DGL-01 (71029)

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.

Harmonized Standards:

EN ISO10993-5:2009 EN ISO10993-10:2013

Start of CE Marking: 2022-03-02

Place,Date of Issue: Ningbo,2022-04-11

Signature:

Name: Michelle Zhang

Position: PRRC

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

Michelle Zhang