# FINESS HEALTHCARE GROUP CO.,LTD

**Declaration of Conformity**

## EU Declaration of Conformity

Doc.No.:FN-QS9.3-PS01-RB-ASI Rev.00

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|---|---|---|---|
| Manufacturer: | **Finess Healthcare Group Co.,Ltd**<br>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.**<br>Pso. Castellana,141–Planta 19, 28046 Madrid, SPAIN | SRN No.: | ES-AR-000002008 |
| Brand Holder | **ASID BONZ GmbH**<br>Hertzstraße 3, 71083 Herrenberg, Germany | | |

| Product Name: | Model Number: | Brand Name | Brand REF no.: |
|---|---|---|---|
| Protection/Examination Sheet | FN-PS01010101 | Protection examination sheet 2-Ply water resistant 210cmx80cm | 712020 |
| Protection/Examination Sheet | FN-PS01010102 | Protection examination sheet 2-Ply water resistant 180cmx80cm | 712010 |
| Protection/Examination Sheet | FN-PS01010103 | Protection examination sheet 2-Ply water resistant 200cmx100cm | 712030 |
| Basic UDI-DI: | 697391169PS01PY | | |

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:
ENISO13485:2016 ENISO14971:2019 EN ISO10993-5:2009 EN ISO10993-10:2013 ENISO 15223-1:2021

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Michelle·Z

Position: PRRC