Declaration of Conformity

According to Art. 17 of Regulation 2017/746 (EU) on in vitro diagnostic medical devices

Manufacturer: HUNAN EHOME HEALTH TECHNOLOGY COMPANY LIMITED
Address: Room 103 and 104, No.13 Building, Country Garden Wisdom Garden, Xueshi Street, Yuelu District, Changsha, Hunan, P. R. China
Tel: 0731-89792690
Email: zuoan@ehomepoct.com

Authorised Representative: Riomavix S.L.
Address: Calle de Almansa 55, 1D, Madrid 28039 Spain
Tel.: +34 658 396 230
E-mail: riomavix@gmail.com
SRN: ES-AR-000001202

Product: Multi-functional Analyzer
Model: EHBT-50, EHBT-51
Basic UDI-DI: 697567949EHBT50WY
Intended Use: The analyzer is used for the detection of specific components in human whole blood, serum and plasma.
Classification: Class A, according to Rule 5 of IVDR Annex VIII
Intended use： The analyzer is used for the detection of specific components in human whole blood, serum and plasma.
Conformity Assessment Route： Annex IX, IVDR (EU) 2017/746

We, manufacturer, herewith declare under our sole responsibility that the above-mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

List of Directive and Standard Applied:

EN ISO 14971:2019	EN ISO 13485:2016	ISO 15223-1:2021
ISO 18113-1:2022	ISO 18113-2:2022	IEC61010-1: 2010
IEC 62366-1:2015	EN 13612:2002	IEC61010-2-101:2018

Signed this Day/10 of
Month/05 of Year/2024,
Place(Changsha Hunan),China
(Place and Date of Issue)

(Signature and Position)
Signed for and on behalf of the Manufacturer