



EC Declaration of Conformity

**Manufacturer:**

Name: Hunan Ehome Health Technology Co., Ltd.
Address: Room 103 and 104, No.13 Building,
 Country Garden Wisdom Garden, Xueshi Street, Yuelu
 District, Changsha, Hunan, P. R. China

Whose Authorized Representative:

Name: MedUnion S.L. (ES-AR-000019366)
Address: Carrer de Tapioles, 33, 2-1, 08004,
 Barcelona, Spain
Tel: +0034-644173535

We, Hunan Ehome Health Technology Co., Ltd. (Manufacturer), here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them. The declaration of conformity is exclusively under the responsibility of Hunan Ehome Health Technology Co., Ltd. (Manufacturer).

Product Name: GLU/HDL-C /TC/TG Combo test kit

Classification: Others

Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding section 6).

Applicable Standards:

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|----------------------------|----------------------------|--------------------------|
| <i>EN ISO 13485:2016</i> | <i>EN ISO 18113-2:2011</i> | <i>EN 13612:2002</i> |
| <i>EN ISO 14971:2019</i> | <i>EN 13641:2002</i> | <i>EN ISO 23640:2015</i> |
| <i>EN ISO 18113-1:2011</i> | <i>EN ISO 15223-1:2016</i> | <i>IEC 62366-1:2015</i> |

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| Name of Authorized Signatory | Shuang Hu |
| Position | CEO |
| Signature |  |
| Date | 2022.4.26 |
| Place | Changsha Hunan, China |

