



ENVELOPE HEALTH BIOTECHNOLOGY CO., LTD.

# EC Declaration of Conformity

We,

Manufacturer Name: ENVELOPE HEALTH BIOTECHNOLOGY CO., LTD.

Address: 1203, No. 7 Building, South Mingzhu apartment, No. 21 Hongan 3 Street, Donghai community, Yantian Street, Yantian District, Shenzhen, China

as the Manufacturer of  
Product Name:

Part Number	Product Name(s)
EH001C-50	DNA Methylation Detection Kit for Human SDC2
EH001C-200	ADHFE1 and PPP2R5C Genes (Real-Time PCR)

Analyte: Methylation status of Human DNA Syndecan 2(SDC2), Alcohol Dehydrogenase Iron Containing 1(ADHFE1) and Protein Phosphatase 2 Regulatory Subunit B'Gamma (PPP2R5C) genes.

Classification: other device not listed under Annex II and not for self-testing  
Conformity assessment: IVDD 98/79/EEC Annex III


herewith declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

The following standards were used to prove conformity:

- EN ISO 13485:2016
- EN ISO 14971:2012/2019
- EN ISO 18113-1:2011
- EN ISO 18113-2:2011
- EN ISO 18113-3:2011
- EN ISO 13612:2016
- EN ISO 15223-1:2012
- EN ISO 23640:2015
- EN ISO 62366-1:2015

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet GmbH  
Borkstrasse 10, 48163 Muenster, Germany



*Wang Yuying*  
Name, Position: Wang Yuying/ GM



Date: 2021.03.23  
Place, City: Shenzhen/ China