

EC Declaration of Conformity

Manufacturer:

Name: Ustar Biotechnologies (Hangzhou) Ltd.
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Province, PEOPLE'S REPUBLIC OF CHINA
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SRN: CN-MF-000014615

Whose Europe Authorized Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the product(s)

Product Name	Nucleic Acid Amplification and Detection Analyzer	Model	UC0216/UC0208/ UC0204
Basic UDI-DI	Model Basic UDI-DI UC0216 697349224U3000064A000FE UC0208 697349224U3000054A000EZ UC0204 697349224U3000044A000EL	EMDN	W02050301
Intended Use	The Nucleic Acid Amplification and Detection Analyzer is used together with matched test kits for qualitative <i>in vitro</i> diagnosis of the nucleic acid sequence in samples of human pathogens based on three-stage magnetic conductivity extraction technology and fluorescence polymerase chain reaction (PCR), this product is an <i>in vitro</i> diagnostic medical device, and is used for the qualitative detection of pathogen nucleic acid sequences in human samples		
Classification	Class A (IVDR, Annex VIII Rule 5)		

meet(s) the provisions of the REGULATION (EU) 2017/746 which apply to them.

Conformity Assessment Route: Article 48-10, of REGULATION (EU) 2017/746.

Applicable Standards and CS:

EN ISO 13485:2016 EN ISO 18113-1:2011 EN 13612:2002 ISO 16142-2:2017
EN ISO 14971:2019 EN ISO 18113-3:2011 ISO 15223-1:2021 EN ISO 23640:2015
EN/IEC 61326-1:2021 EN/IEC 61326-2-6:2021 EN/IEC 61010-1

The aforementioned device has been assigned to class A according to Appendix VIII of the Regulation (EU) 2017/746, which means it bears the CE mark



We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/746.

The above-mentioned declaration of conformity is exclusively under the responsibility of
Ustar Biotechnologies (Hangzhou) Ltd.

Name of General Manager	Yizhi Lin
Signature	
Date	2023/02/28
Place	Hangzhou, Zhejiang Province, China
Seal (Manufacturer)	Ustar Biotechnologies (Hangzhou) Ltd.