Declaration of Conformity

CE according to Directive 98/79/EC, on *in vitro* diagnostic medical devices CE

Maker: (Name, Address)	Ustar Biotechnologies (Hangzhou) Ltd.	
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Authorized: (Name, Address)	Peter Wei	
	Postal address:	Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
	Registration office:	Lotus NL B.V.
Medical device:	Description:	Nucleic Acid Amplification and Detection Analyzer
	Classification of products according to directive:	Diagnostic reagent box others devices indicated in IVD ANNEX II
	Batch/serial No. type, production term (if applicable):	UC0102/U30003
Applicable coordination standards:	EN 13640:2002 EN ISO 13485:2016 EN 13975:2003 BS EN ISO 18113-2:2011	EN ISO 14971:2012 EN ISO 15223-1:2016 BS EN ISO 18113-3:2011

Signatory representative declares herein the above mentioned device meets the basic requirement of European *in vitro* diagnostic medical devices directive 98/79/EC Annex I.

This declaration of conformity is based on European *in vitro* diagnostic medical devices directive 98/79/EC Annex III. The compiled technical file and quality system are testified by the Annex III quality system certificate issued according to *in vitro* diagnostic medical devices directive by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager:

Hangzhou
March 20 2020
(place and date of issue)

YIZHI LIN
(name and signature or equivalent marking of authorized person)