Declaration of Conformity

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

Maker: (Name, Address)	Ustar Biotechnologies (Hangzhou) Ltd.	
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Authorized: (Name, Address)	Registration office:	Lotus NL B.V.
	Postal address:	Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
Medical device:	Product Name:	Disposable Sample Collector
	Classification of products according to directive:	Devices other than those covered by Directive 98/79/EC Annex II
	Batch/serial No. type, production term (if applicable):	U40033/U40035
Applicable coordination standards:	EN13612 :2002/AC :2002	EN ISO 14971:2012
	EN ISO 13485:2016	EN ISO 23640:2015
	EN13641:2002	EN ISO15223-1:2016
	BS EN ISO 18113-1:2011	BS EN ISO 18113-2:2011

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.

General Manager:

Hangzhou

March 20 2020

(place and date of issue)

YIZHI LIN

(name and signature or equivalent marking of authorized person)

USTAR BIOTECHNOLOGIES (HANGZHOU) LTD. 330108411005