EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of **NOT Annex II and NOT self-test***)*

Manufacturer:	Jiangsu Huaxia Ruitai Plastic Industry Co. Ltd.
Address:	Modem technology industry Zone, Jiangyan District,Taizhou,City. Jiangsu,China
EC Representative:	Wellkang Ltd 16 Castle Street, Dover, CT16 1PW, England, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Disposable Sampler
	Type/model, identification of product allowing traceability (Where applicable)	A：1 piece / bag,100 pieces / bag,200 pieces / bag,500 pieces / bag. B-1：1 piece / bag,100 pieces / bag, 200 pieces / bag, 500 pieces / bag. B-2：1 piece / bag,100 pieces / bag, 200 pieces / bag, 500 pieces / bag.
of Category	: **Common/Others IVD** (Devices of **NOT Annex II** and **NOT self-test**)	

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN ISO 15223-1:2016 EN 1041:2008 EN ISO 14971:2012 EN ISO 10993-1:2009 EN ISO 10993-5:2009 ISO 10993-10:2010
Conformity assessment procedure	**Module A (EC Declaration of Conformity) (Annex III, except point 6)**
Notified Body (name & number)	**NOT applicable**
Certificate & number	

Signed on: 22 April 2020. Place: Taizhou, Jiangsu, Country

Signature (on behalf of the manufacturer)

Name of authorized signatory: Chen Chunhua

Position held in the company: General Manager

Company Seal/Stamp:

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Our Ref:IVD001156

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW
United Kingdom

05 May 2020

Dear Dr Wang

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2002: REGULATION 44

Registration of manufacturers of *In-Vitro Diagnostic* Medical Devices and devices for Performance Evaluation

Thank you for informing the Competent Authority of the details of ***Manufacturers* Name:- Jiangsu Huaxia Ruitai Plastic Industry Co., Ltd.** located at **Manufacturers Address:- Modern Technology Industry Zone, Jiangyan District, Taizhou City, Jiangsu, China 225300** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified it/them correctly considering the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations.

Please note this letter does not represent any form of accreditation, certifcation or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any of the following changes;

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

You should submit your change of registration via DORS with the required statutory fee, which should be accompanied with the information when it is supplied, (the fee is payable for each record notified, and you may place multiple changes on one record).

Thank you for registering the following generic groups of devices

1. ***Part 5: IVDs which are not Annex II and not self-test devices***

For reagnets, reagent products, calibration and control materials:
group by common technological characteristics and/or analytes

New products:
None

For performance evaluation:
None

Neither:
Other containers for samples of human origin
Other Instruments - Spare parts

For other IVDs, group by appropriate indications

New products:
None

For performance evaluation:
None

Neither:
None

Part 6: IVDs which are Annex II or self-test devices

For reagnets, reagent products, calibration and control materials:
group by common technological characteristics and/or analytes

New products:
None

For performance evaluation:
None

Neither:
None

For other IVDs, group by appropriate indications

New products:
None

For performance evaluation:
None

Neither:
None

If you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely

Medicines & Healthcare products Regulatory Agency

MHRA

Malcolm Ridgway
Data Integrity Support Officer