MHRA
ERA2 4th floor Yellow,
151 Buckingham Palace Road
Victoria
London SW1W 9SZ
United Kingdom

Our Ref: IVD000682

Dr Edward Wang
Wellkang Ltd
Suite B
29 Harley Street
London
W1G 9QR
United Kingdom

14 June 2013

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:- Taizhou Runlab Labware Manufacturing Co Ltd** located at **Manufacturers Address:- No 32 Jinchuan Rd, West Industrial Zone Huangyan Taizhou, Zhejiang China 318020** 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 taking into account 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. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG3 form and means that you should now be operating under the In Vitro Diagnostic Medical Devices Directive and the 2002 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

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 changes to:

- 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

Please use RG3, the Registration form, to tell us about any of these changes. A fee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices

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:
Sterile Urine Containers
SP Hardware + accessories + consumables + software
Other Hardware + accessories + consumables + software

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

Angela Bartley
ERA2 Office Manager
Email angela.bartley@mhra.gsi.gov

Our Case Ref.:
#AR-Zhejiang-Runlab_IVDothers_PK-RW171205#
Ph: +86(576)84351955 Fx: +86(576)84351911

Your Ref./Contact Persons:
Manager / 秦旺仁增 Qin Wang Ren Zeng
E: runlab@runlab.com

To:
邮编 **318020** 浙江省 台州市
黄岩区 新前街道明辉路 **6** 号
浙江润兰科技有限公司
秦旺仁增 **Qin Wang Ren Zeng** (电话: **0576-84351955**)
Zhejiang Runlab Technology Co., Ltd.
Taizhou, Zhejiang 318020
China. PR

CE
European Authorised Representative
For Medical Devices

Auth Rep Certificate

No. **ARMDD121145A180116SZRW**
(Valid until: **4 Dec 2022**)

This is to certify that **Wellkang Ltd** has formally accepted the renewed appointment as the European Authorised Representative (EC Rep) for manufacturer- **Zhejiang Runlab Technology Co., Ltd.,** located at: **No.6 Minghui Road, Xinqian Street, Huangyan District, Taizhou, Zhejiang 318020, P.R. China,** as required by the EU Directive 98/79/EC of 27 October 1998 on In-Vitro Diagnostic medical devices. The manufacturer may use Wellkang's name/address as the EC Rep for the CE-marked products represented by Wellkang. The examples of use of Wellkang's name/address can be found at:
http://www.ce-marking.com/ec-rep.html

This representation including the information on the products represented is subject to the terms and conditions stated in the Authorised Representative Agreement signed between our two companies, and has been published online for verification by third parties at -
http://www.cemark.info/mdd/runlab.html

When you start to place the above-mentioned product(s) on the EEA Market, please make sure to properly affix the CE Marking on the product(s), the labelling, packaging, and/or other accompanying materials according to the related EU directives and guidelines which have already been provided to you by us.

Please be advised that Wellkang is NOT involved in the Design, Manufacture and/or Marketing, Distribution, Sales, Supply, Installation of your products, it is therefore your responsibility to provide the Instruction For Use (IFU), if applicable and required by the legislation of the EEA member state(s), in the official language(s) of the EEA member state(s) in which the products are placed on the market. You need to provide us with the true, accurate and most updated Technical Documentation (Technical Files) including IFU, per EU Decision No. 768/2008/EC, prior to any shipment of your products, which carry the name of Wellkang Ltd as the Authorised Representative, to the EEA market.

Please inform us immediately whenever there is a change about either the above-mentioned product(s) or your company details. So we can update your CE Marking documentation promptly and properly.

London/UK, 16th Jan 2018.

For and on behalf of
WELLKANG LIMITED

Authorized Signature(s)

Signature of Responsible
Wellkang Ltd

CE Marking
Authorized Representative for
Zhejiang Runlab Technology Co., Ltd.
(Former name: Taizhou Runlab Labware Manufacturing Co., Ltd.)
IVD Medical Devices

(Service renewal needed by: 5 September 2022)

| Products | CE Marking | Authorized Representative | Manufacturer |

Products

Product List

(No. MDD-SZ-PK-RW171205)

编号 No.	产品名称（中英文） Product Name	型号 Types/Models	EC-指令 Directive	CE 类别 Classification
1	离心管 Centrifuge Tubes	To Be Provided Separately 后续提供	IVDD 98/79/EC	other
2	样本杯 Specimen Containers	To Be Provided Separately 后续提供	IVDD 98/79/EC	other
3	采样棒 Loops	To Be Provided Separately 后续提供	IVDD 98/79/EC	other
4	吸管 Transport Pipettes	To Be Provided Separately 后续提供	IVDD 98/79/EC	other
5	血清管 Serological Pipette	To Be Provided Separately 后续提供	IVDD 98/79/EC	other
6	试剂槽 Solution Reservoir	To Be Provided Separately 后续提供	IVDD 98/79/EC	other

Please learn more about the products at
http://www.runlab.com

CE Marking

Represented by Wellkang since:	**5 December 2012**
Wellkang Auth Rep Certificates no.:	**ARMDD121145A180116SZRW** (Valid until: 4 Dec 2022) **ARMDD121145A121210SZ** (Valid until: 4 December 2017)
Product Classification:	In Vitro Diagnostic Medical Devices
Category:	**Common/Other** IVD
Conformity Module:	Module **A** (EC declaration of conformity) (Annex III, except point 6, Directive 98/79/EC)
Lead Competent Authority:	UK Medicines & Healthcare Products Regulatory Agency
Product Registration (Per Article 10, Directive 98/79/ec.)	Ref. No.: **GB/CA01/IVD000682** Click here to view the registration certificate.

Manufacturer

Zhejiang Runlab Technology Co., Ltd.
No.6 Minghui Road, Xinqian Street,
Huangyan District,
Taizhou, Zhejiang 318020,
China PR
Tel: +86(576)84351955
Fax: +86(576)84351911
Website: www.runlab.com
Email: (available but not published here)

Former name & address:
Taizhou Runlab Labware Manufacturing Co., Ltd.
No.32 Jinchuan Rd,
West Industrial Huangyan,
Taizhou, Zhejiang 318020,
PR China
Tel: +86-576-84351988
Fax: +86-576-84351977
Website: www.runlab.com

Authorized Representative

in the European Economic Area (incl. European Union and EFTA member states):

Wellkang Ltd
29 Harley Street, LONDON, W1G 9QR, England, United Kingdom
16 Castle Street, Dover, CT16 1PW, England, United Kingdom
Tels: +44(20)30869438/32876300 Fax: +44(20)76811874
Web: www.CE-marking.eu www.CE-marking.com www.wellkang.ltd.uk