

此为证书 CN23/00004607 译本

下述组织

苏州金唯智生物科技有限公司

中国（江苏）自由贸易试验区苏州片区苏州工业园区酝慧路8号安升达总部大楼1层和2层
的管理体系已经过审核，并被证明符合下述要求

ISO 13485:2016

EN ISO 13485:2016

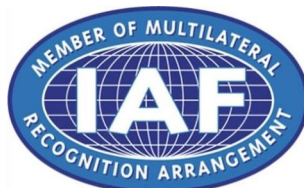
所涉及的活动范围覆盖
用于体外诊断试剂的核酸引物和探针的研发和生产

该证书的有效期自 2025 年 08 月 16 日 至 2026 年 08 月 28 日 并须经过符合要求的监督审核保持有效
版本号 4. 初始注册日期 2023 年 08 月 29 日
在此范围内出具了多张证书，主证书编号为 CN23/00004607
在其它场所实施的认证活动在后续页面上列出

L. Moran

签署
Liz Moran
Business Manager

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com



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此为证书 CN23/00004607 译本，续

苏州金唯智生物科技有限公司

ISO 13485:2016

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版本号 4

场所

苏州金唯智生物科技有限公司
中国（江苏）自由贸易试验区苏州片区苏州工业园区酝慧路8号安升达总部大楼1层和2层
用于体外诊断试剂的核酸引物和探针的研发和生产

安升达（天津）生物科技有限公司
中国天津市武清开发区福源道北侧创业总部基地 B06 栋 5 层，B22 栋 9 层
用于体外诊断试剂的核酸引物和探针的研发



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Certificate CN23/00004607

The management system of

GENEWIZ INC., Suzhou

SGS

1st & 2nd Floor of AZENTA Building, No. 8, Yunhui Road, Suzhou Industrial Park, Suzhou Area, China (Jiangsu) Pilot Free Trade Zone

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design and Development, Manufacture of Nucleic Acid Primers and Probes used for In Vitro Diagnostic Reagents

This certificate is valid from 16 August 2025 until 28 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 29 August 2023

Multiple certificates have been issued for this scope, the main certificate is numbered CN23/00004607

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

Liz Moran

Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



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Certificate CN23/00004607, continued
GENEWIZ INC., Suzhou

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ISO 13485:2016

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Issue 4

Sites

GENEWIZ INC., Suzhou

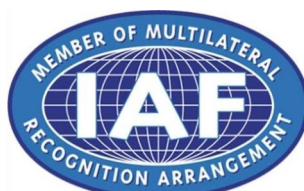
1st & 2nd Floor of AZENTA Building, No. 8, Yunhui Road, Suzhou Industrial Park, Suzhou Area, China (Jiangsu) Pilot Free Trade Zone

Design and Development, Manufacture of Nucleic Acid Primers and Probes used for In Vitro Diagnostic Reagents

Azenta (Tianjin) Biotechnology Co.,Ltd.

5th Floor of Building B06 and 9th Floor of B22, North of Fuyuan Road, Venture Headquarter Base, Wuqing Development Area, Tianjin, P.R. China

Design and Development of Nucleic Acid Primers and Probes used for In Vitro Diagnostic Reagents



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