

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 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

医疗器械-质量管理体系-用于法规的要求

所涉及的活动范围覆盖

用于体外诊断试剂的 sgRNA 合成产品的研发和生产

用于体外诊断试剂的核酸引物和探针的研发

该证书的有效期自 2026 年 08 月 29 日 至 2029 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 6. 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

医疗器械-质量管理体系-用于法规的要求

版本号 6

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1层和2层
用于体外诊断试剂的 sgRNA 合成产品的研发和生产

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, 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

Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

Design and Development, Manufacture of sgRNA products used for In Vitro Diagnostic Reagents

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

This certificate is valid from 29 August 2026 until 28 August 2029 and remains valid subject to satisfactory surveillance audits.

Issue 6. 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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ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 6

Sites

GENEWIZ INC., Suzhou

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

Design and Development, Manufacture of sgRNA products 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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