

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4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**

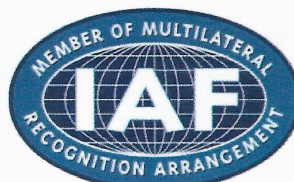
所涉及的活动范围覆盖  
用于体外诊断试剂的核酸引物和探针的研发和生产

该证书的有效期自 2024年08月12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 3. 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

签署

Jonathan Hall  
Global Head -  
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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  
EN ISO 13485:2016

版本号 3

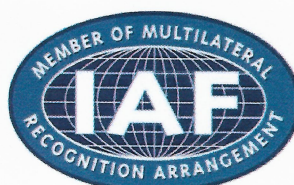
场所

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4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

4<sup>th</sup> 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 12 August 2024 until 28 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 29 August 2023

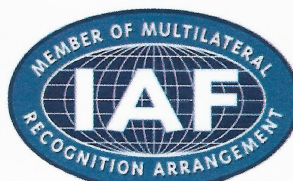
Multiple certificates have been issued for this scope, the main certificate is numbered CN23/00004607

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

Authorised by

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Certificate CN23/00004607, continued  
**GENEWIZ INC., Suzhou**



**ISO 13485:2016**  
**EN ISO 13485:2016**

Issue 3

**Sites**

GENEWIZ INC., Suzhou

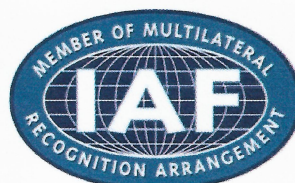
4<sup>th</sup> Floor of AZENTA Building, No. 8, Yunhui Road, Suzhou Industrial Park, Suzhou Area, China (Jiangsu) Pilot Free Trade Zone

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

Azenta (Tianjin) Biotechnology Co., Ltd.

5<sup>th</sup> Floor of Building B06 and 9<sup>th</sup> 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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