

Certificate CN22/42004

The management system of

NANJING VAZYME BIOTECH CO., LTD.

Business Registration Address: No. 1-6 Floor Eastern sector, Building C1-2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 7 January 2022 until 6 January 2025 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date.

Issue 1. Certified since 7 January 2022

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This is a multi-site certification.

Additional site details are listed on subsequent pages.

Authorised by



21HC 13485 2016 0421 M2

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MANAGEMENT





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Certificate CN22/42004, continued

NANJING VAZYME BIOTECH CO., LTD.

ISO 13485:2016 EN ISO 13485:2016



Issue 1

Detailed scope

Manufacture of molecular enzymes and premixes used in PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms

Additional facilities

Business Operation Address: No. 5 Runhua Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

Business Operation Address: No. 9, Daoqianghe Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

