

Certificate CN22/42004

The management system of

Nanjing Vazyme Biotech Co., Ltd.

SGS

Building D2, Red Maple Park, Kechuang Road, Economic 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

Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms and injection parts used for in vitro diagnostic medical devices

This certificate is valid from 07 January 2025 until 06 January 2028 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 07 January 2022

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

L. Moran

Authorised by

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Certificate CN22/42004, continued
Nanjing Vazyme Biotech Co., Ltd.

SGS

ISO 13485:2016
EN ISO 13485:2016

Issue 5

Sites

Nanjing Vazyme Biotech Co., Ltd.

Building D2, Red Maple Park, Kechuang Road, Economic and Technological Development Zone, Nanjing City,
Jiangsu Province, P.R. China

Human resources, purchasing and sales management in support of Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms and injection parts used for in vitro diagnostic medical devices

Nanjing Vazyme Biotech Co., Ltd.

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

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

Nanjing Vazyme Biotech Co., Ltd.

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

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

Nanjing Vazyme Material Technology Co., Ltd.

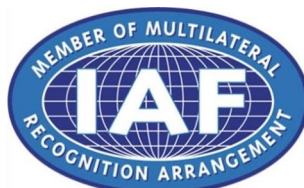
Room PA2-01, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City,
Jiangsu Province, P.R. China

Manufacture of injection parts used for in vitro diagnostic medical devices

Nanjing Vazyme Biotech Co., Ltd.

Room 207, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City,
Jiangsu Province, P.R. China

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



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