

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: Shanghai Promega Biological
Products Ltd.
Building 12B
No. 88 Xinjun Ring Road
Minhang
Shanghai
201114, China

上海普洛麦格生物产品有限公司
91310000607216836N
中国
上海
闵行区
新骏环路88号
12B幢
邮编: 201114

Holds Certificate No: **MD 603096**
持有证书

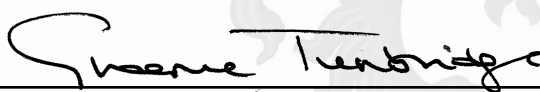
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

并运行符合 ISO 13485:2016 要求的质量管理体系, 认证范围如下:

Design, Development, and Manufacture of in vitro diagnostic reagents for nucleic acid testing of infectious diseases and tumors.

用于传染病和肿瘤核酸检测的体外诊断试剂的设计与制造。

For and on behalf of BSI:
BSI代表:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期: 2013-11-25

Effective Date 生效日期: 2025-11-25

Latest Revision Date 最新发证日期: 2025-09-24

Expiry Date 有效期至: 2028-11-24



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The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn)

本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

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Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部(北京): 北京

市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No. **MD 603096**
持有证书:

Location 地点	Registered Activities 认证活动
Shanghai Promega Biological Products Ltd. Building 12B No. 88 Xinjun Ring Road Minhang Shanghai 201114, China 上海普洛麦格生物产品有限公司 91310000607216836N 中国 上海 闵行区 新骏环路88号 12B幢 邮编: 201114	Manufacture of in vitro diagnostic reagents for nucleic acid testing of infectious diseases and tumors. 传染病、肿瘤核酸检测用体外诊断试剂的生产。
Shanghai Promega Biological Products Ltd. Room 101, Building 3, No.138 Xinjun Ring Road Minhang Shanghai 201114, China 上海普洛麦格生物产品有限公司 91310000607216836N 中国 上海 闵行区 新骏环路138号 3幢101室 邮编: 201114	Design and development, Inspection of in vitro diagnostic reagents for nucleic acid testing of infectious diseases and tumors. 传染病、肿瘤核酸检测用体外诊断试剂的设计、开发、检验。

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