

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Shanghai Promega Biological Products Ltd.
Building 12B
No. 88 Xinjun Ring Road
Caohejing HiTech Park of Pujiang
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
漕河泾开发区浦江高科技园
新骏环路88号
12B
邮编: 201114

Holds Certificate No: **MD 603096**

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

The design & manufacture of CT/ NG/ UU DNA qPCR Detection Kit, CT DNA qPCR Detection Kit, HR-HPV (14 types) DNA qPCR detection Kit, HSV 1 and 2 DNA qPCR Detection Kit.
沙眼衣原体/淋球菌/解脲脲原体核酸检测试剂盒、沙眼衣原体核酸检测试剂盒、高危型人乳头瘤病毒（14个型）核酸检测试剂盒、单纯疱疹病毒I和II型核酸分型检测试剂盒的研发和生产。

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-11-25

Effective Date: 2016-11-25

Latest Revision Date: 2018-01-18

Expiry Date: 2019-11-24



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](http://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.