bsi.

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 603095**

Issued To: **Shanghai Promega Biological Products Ltd.**
Building 12B
No. 88 Xinjun Ring Road
Caohejing HiTech Park of Pujiang
Minhang
Shanghai
201114
China

In respect of:

The design & manufacture of CT/NG/UU DNA qPCR Detection Kit & CT DNA qPCR Detection Kit

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **19 March 2014** Date: **15 January 2016** Expiry Date: **18 March 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 603095**
Date:	**15 January 2016**
Issued To:	**Shanghai Promega Biological Products Ltd. Building 12B No. 88 Xinjun Ring Road Caohejing HiTech Park of Pujiang Minhang Shanghai 201114 China**

Subcontractor:	**Service(s) supplied**
Emergo Europe Molenstraat 15 2513 BH, The Hague Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 603095**

Date: **15 January 2016**

Issued To: **Shanghai Promega Biological Products Ltd.**
Building 12B
No. 88 Xinjun Ring Road
Caohejing HiTech Park of Pujiang
Minhang
Shanghai
201114
China

Date	Reference Number	Action
19 March 2014	8032299	First Issue
15 January 2016	8427372	Addition of Emergo Europe as a significant subcontractor

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
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