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 644631**

Issued To: **Mast Diagnostica GmbH**
Feldstrasse 20
23858 Reinfeld
Germany

In respect of:

Design and manufacture of direct immunoassay kits for Chlamydia, and immunofluorescence antibody test kits and agglutination test kits for Toxoplasmosis.

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: **22 December 2015** Date: **16 February 2016** Expiry Date: **22 March 2021**

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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 Certificate History

Certificate No: **CE 644631**

Date: **16 February 2016**

Issued To: **Mast Diagnostica GmbH**
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Date	Reference Number	Action
22 December 2015	8431571	First issue, transferred from another notified body.
16 February 2016	8482350	Certificate Renewal.

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