

# EC Certificate - Full Quality Assurance

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

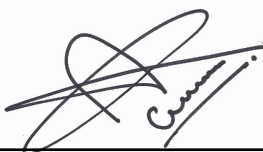
**No.** **CE 644631**  
**Issued To:** **Mast Diagnostica GmbH**  
**Feldstrasse 20**  
**23858 Reinfeld**  
**Germany**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2015-12-22**

Date: **2019-01-09**

Expiry Date: **2021-03-22**

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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.

# EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 644631**  
 Date: **2019-01-09**  
 Issued To: **Mast Diagnostica GmbH**  
**Feldstrasse 20**  
**23858 Reinfeld**  
**Germany**

| Date             | Reference Number | Action   |
|------------------|------------------|--|
| 22 December 2015 | 8431571          | First issue, transferred from another notified body. |
| 16 February 2016 | 8482350          | Certificate Renewal.                                 |
| Current          | 8607473          | Traceable to NB 0086.                                |

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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