

# 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):

Gary E Slack, Senior Vice President Medical Devices

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

Date: **2021-01-15**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 644631

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Number	Device Name	Intended use per IFU
<b>Annex II List B</b>		
IVD0303	Toxoreagent Ref: RST7001	A latex reagent agglutination test for the semi-quantitative determination of anti-Toxoplasma gondii antibodies in human serum samples.
IVD0303	<p>MASTAFLUOR™ Toxoplasma Screen (10 x 5 Tests) Ref 631181</p> <p>MASTAFLUOR™ Toxoplasma Screen(10 x 10 Tests) Ref 631182</p> <p>MASTAFLUOR™ Toxoplasma IgG (10 x 5 Tests) Ref 631183</p> <p>MASTAFLUOR™ Toxoplasma IgG (10 x 10 Tests) Ref 631184</p>	MASTAFLUOR™ Toxoplasma is an indirect immunofluorescence test system for the qualitative and quantitative detection of specific antibodies to Toxoplasma gondii in human serum.
IVD0305	MASTAZYME™ Chlamydia Elisa Kit Ref 695010	MASTAZYME™ CHLAMYDIA is a qualitative, sensitive enzyme immunoassay for detection of Chlamydia antigen in endocervical and urethral specimens as an aid to diagnosis of chlamydiosis.

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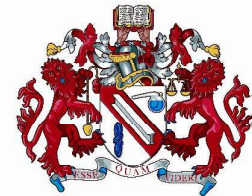
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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 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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# EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 644631**  
 Date: **2021-01-15**  
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<b>Date</b>	<b>Reference Number</b>	<b>Action</b>
22 December 2015	8431571	First issue, transferred from another notified body.
16 February 2016	8482350	Certificate Renewal.
09 January 2019	8607473	Traceable to NB 0086.
Current	3174471	Renewal