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 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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 644631

Issued To:

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Number	Device Name	Intended use per IFU
Annex II List 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	MASTAFLUOR™ Toxoplasma Screen (10 x 5 Tests) Ref 631181 MASTAFLUOR™ Toxoplasma Screen(10 x 10 Tests) Ref 631182 MASTAFLUOR™ Toxoplasma IgG (10 x 5 Tests) Ref 631183 MASTAFLUOR™ Toxoplasma IgG (10 x 10 Tests) Ref 631184	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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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 644631**
Date: **2021-01-15**
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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.
09 January 2019	8607473	Traceable to NB 0086.
Current	3174471	Renewal

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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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