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):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2015-12-22** Date: **2022-03-31** Expiry Date: **2025-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance

Supplementary Information to CE 644631

Issued To:

Mast Diagnostica GmbH
Feldstrasse 20
23858 Reinfeld
Germany

Number	Device Name	Intended use per IFU
Annex II List B		
IVD0303	Toxoreagent Ref: RST7001	Semi-quantitative (titratable) agglutination assay for the detection of antibodies directed against Toxoplasma gondii in human serum as an aid to diagnosis of immunity against toxoplasmosis (presence of specific antibodies).
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	Semi-quantitative (titratable) immunofluorescence assay for the detection of IgG antibodies (and additionally IgM antibodies using the Screen assay) directed against Toxoplasma gondii tachyzoites in human serum as an aid to diagnosis of immunity against toxoplasmosis (presence of specific antibodies).

First Issued: **2015-12-22** Date: **2022-03-31** Expiry Date: **2025-05-26**

EC Certificate - Full Quality Assurance

Supplementary Information to CE 644631

Issued To:

Mast Diagnostica GmbH
Feldstrasse 20
23858 Reinfeld
Germany

Number	Device Name	Intended use per IFU
Annex II List B		
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.

First Issued: **2015-12-22** Date: **2022-03-31** Expiry Date: **2025-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 644631**
Date: **2022-03-31**
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	Renewal.
09 January 2019	8607473	Traceable to NB 0086.
15 January 2021	3174471	Renewal.
05 November 2021	3539344	Amended - Toxoreagent & MASTAFLUOR™ Toxoplasma Screen & MASTAFLUOR Toxoplasma IgG Intended Purpose Updated. Performance data updates in the IFU.
Current	3654653	Change of IVDD expiry date according to Regulation (EU) 2022/112