

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

Genome Identification Diagnostics GmbH
Ebinger Straße 4
72479 Straßberg
Germany

for the scope

**NAT Tests and Lymphocyte Stimulation Tests for the diagnosis of
Chlamydia and Cytomegalovirus infections
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex IV – excluding Section 4 and 6
of the Council Directive 98/79/EC**

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2022-04-11
Valid until	2025-05-26
Registration no.	D1441400006
Report no.	P21-01485-234784
Stuttgart	2022-04-11



Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

Attachment of the certificate

No. D1441400006

Date 2022-04-11

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Product category	Product	Class
NAT Tests and Lymphocyte Stimulation Tests for the diagnosis of Chlamydia and Cytomegalovirus infections	STD Reverse Hybridization kit (RDB2110, RDB2110X)	List B, Annex II
	STD Amplification mix (RDB2111, RDB2111X)	
	Chlamydia trachomatis Reverse Hybridization kit (RDB2117, RDB2117X)	
	Chlamydia trachomatis Amplification mix (RDB2118, RDB2118X)	
	CAP Bac Reverse Hybridization kit (RDB2135, RDB2135X)	
	CAP Bac Amplification mix (RDB2136, RDB2136X)	
	CMVSpot Interferon- γ (ELSP5530)	
	TransSpot Interferon- γ (ELSP5560)	
	Chlamydia pneumoniae Lysate (EliSpot) (ELSP5923, ELSP5923X)	
	Chlamydia trachomatis Lysate (EliSpot) (ELSP5922)	
	CMV Lysate (EliSpot) (ELSP5910)	
	CMV IE1 (EliSpot) (ELSP5943)	
	CMV Peptide-Mix (EliSpot) (ELSP5944)	
	CMV pp65 (EliSpot) (ELSP5940)	
	STI Reverse Hybridization kit (RDB2335, RDB2335X)	
	STI Amplification mix (RDB2336, RDB2336X)	



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