

# 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	2021-01-01
Valid until	2024-05-26
Registration no.	D1441400005
Report no.	P20-01660-187558
Stuttgart	2020-12-18



Head of Certification Body



**Attachment of the certificate**

**No. D1441400005**

Date 2020-12-18

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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) 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)	List B, Annex II



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