

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**Virotech Diagnostics GmbH
Waldstrasse 23 A2
63128 Dietzenbach
Germany**

for the scope

**ELISA test kits and reagents for the detection of
antibodies against cytomegalo-virus**

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	2022-02-14
Valid until	2025-05-26
Registration no.	D1078600016
Report no.	P21-01533-215797
Stuttgart	2022-02-14



Head of Certification Body



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bei Arzneimitteln und
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