

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that



altona Diagnostics GmbH
Mörkenstraße 12
22767 Hamburg
Germany

for the scope

**Real-Time PCR Kit for
the qualitative detection and quantification of CMV DNA
(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	2018-01-19
Valid until	2021-11-10
Registration no.	D1267700012
Report no.	P17-00680-112585
Stuttgart	2018-01-19

A handwritten signature in blue ink, appearing to read "R. Alts", is written over the signature line.

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. D1267700012

Date 2018-01-19

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Product category	Product	Class
Real-Time PCR Kit for the qualitative detection and quantification of CMV DNA	RealStar [®] CMV PCR Kit 1.0 (REF 021013) RealStar [®] CMV PCR Kit 1.2 (REF 021212) kPCR PLX [®] Cytomegalovirus (CMV) DNA Assay (REF BS021013) AltoStar [®] CMV PCR Kit 1.5 (REF AS0021513)	List B, Annex II



Head of Certification Body

