

# 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 Kits for the qualitative and quantitative detection of  
hepatitis C virus RNA and CMV DNA  
(see attachment)**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

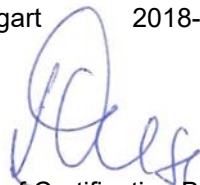
The mdc audit has proven that this quality system  
meets all requirements according to

**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	2018-12-06
Valid until	2021-11-10
Registration no.	D1267700015
Report no.	P18-00795-122706
Stuttgart	2018-12-06



Head of Certification Body



**Attachment of the certificate**

**No. D1267700015**

Date 2018-12-06

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Product category	Product	Class
Real-Time PCR Kit for the qualitative and quantitative detection of HCV RNA	AltoStar <sup>®</sup> HCV RT-PCR Kit 1.5 (REF AS0211513)	List A, Annex II
Real-Time PCR Kit for the qualitative and quantitative detection of CMV DNA	RealStar <sup>®</sup> CMV PCR Kit 1.0 (REF 021013) RealStar <sup>®</sup> CMV PCR Kit 1.2 (REF 021212) kPCR PLX <sup>®</sup> Cytomegalovirus (CMV) DNA Assay (REF BS021013) AltoStar <sup>®</sup> CMV PCR Kit 1.5 (REF AS0021513)	List B, Annex II



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