

# 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  
HIV RNA, hepatitis virus DNA or 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	2022-05-13
Valid until	2025-05-26
Registration no.	D1267700031
Report no.	P21-01924-221626
Stuttgart	2022-05-13

  
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. D1267700031

Date 2022-05-13

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Product category	Product	Class
Real-Time PCR Kit for the qualitative and quantitative detection of HBV DNA	AltoStar <sup>®</sup> HBV PCR Kit 1.5 (REF AS0201513)	List A, Annex II
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 HIV RNA	AltoStar <sup>®</sup> HIV RT-PCR Kit 1.5 (REF AS0221513)	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, AS0021543)	List B, Annex II



  
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Head of Certification Body