

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Gesellschaft zur Forschung,  
Entwicklung und Distribution von  
Diagnostika im Blutspendewesen mbH  
Altenhöferallee 3  
60438 Frankfurt am Main  
Germany**

for the scope

**screening and confirmatory test kits for detection of  
HCV, HBV, HIV-1/2 and controls**

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	2022-01-14
Valid until	2024-05-26
Registration no.	D1187700084
Report no.	P21-01368-213442
Stuttgart	2022-01-14

  
Head of Certification Body



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für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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