

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	2019-04-01
Valid until	2024-03-31
Registration no.	D1187700049
Report no.	P18-01043-126248
Stuttgart	2019-01-16



Head of Certification Body

