

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

Human



Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany

for the scope

anti-HCV ELISA test for the detection of antibodies to HCV (REF 51275)

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

Annex IV – Section 4 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.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2017-09-19
Valid until	2022-09-18
Registration no.	D1030000062
Report no.	P15-01627-58960
Stuttgart	2017-09-19

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