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

2022-05-22 2025-05-26

Valid until Registration no.

D1030000086

Report no.

P22-00588-233497

Stuttgart

2022-05-22



Head of Certification Body

