

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

**HBV Real-Time PCR Kit, Real-Time PCR test for the quantitative detection of
Hepatitis B Virus DNA in human serum or plasma, Ref. 87120**

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	2015-10-19
Valid until	2020-10-18
Registration no.	D1030000041
Report no.	P15-01631-59051
Stuttgart	2015-10-19



Head of Certification Body

