

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

altona Diagnostics GmbH
Mörkenstraße 12
22767 Hamburg
Germany

for the scope

AltoStar® HBV PCR Kit 1.5
(REF: AS0201513)

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	2022-05-13
Valid until	2025-05-26
Registration no.	D1267700033
Report no.	P21-02058-223538
Stuttgart	2022-05-13


Head of Certification Body



Benannt durch/Designated by
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