

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

AB Diagnostic Systems GmbH
Sportfliegerstraße 4
12487 Berlin
Germany

for the scope

**enzyme-linked immunosorbent assay (ELISA) for detection of
disease marker HBV, HCV and for determination of tumor marker PSA
(see attachment)**

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	2021-01-21
Valid until	2024-03-31
Registration no.	D1381600021
Report no.	P20-01738-196343
Stuttgart	2021-01-20

Head of Certification Body



Attachment of the certificate

No. D1381600021

Date 2021-01-20

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Product category	Product	Class
enzyme-linked immunosorbent assay (ELISA) for detection of disease marker HBV	abia HBs Ag	List A, Annex II
enzyme-linked immunosorbent assay (ELISA) for detection of disease marker HCV	abia HCV Ab	List A, Annex II
enzyme-linked immunosorbent assay (ELISA) for determination of tumor marker PSA	abia PSA total abia PSA free	List B, Annex II



Head of Certification Body