

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 HIV, 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	2022-04-20
Valid until	2025-05-26
Registration no.	D1381600026
Report no.	P22-00038-225403
Stuttgart	2022-04-20



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

Attachment of the certificate

No. D1381600026

Date 2022-04-20

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Product category	Product	Class
enzyme-linked immunosorbent assay (ELISA) for detection of disease marker HIV	abia HIV AgAb	List A, Annex II
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



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