

# 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	2018-11-08
Valid until	2020-05-05
Registration no.	D1381600012
Report no.	P18-00032-111821
Stuttgart	2018-11-08



Head of Certification Body



**Attachment of the certificate**

**No. D1381600012**

Date 2018-11-08

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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



Head of Certification Body

