

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Antitoxin GmbH  
Industriestraße 88  
69245 Bammental  
Germany**

for the scope

**Blood grouping testsera:  
AB0-system, rhesus-system (C, c, D, E, e), kell-system,  
duffy-system, kidd-system as well as  
bedside test cards:  
AB0-system and rhesus  
(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	2022-04-11
Valid until	2025-05-26
Registration no.	D1052200083
Report no.	P21-01402-235073
Stuttgart	2022-04-11

  
Head of Certification Body



**Attachment of the certificate**

**No. D1052200083**

Date 2022-04-11

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Product category	Class
Blood grouping testsera: AB0-system, rhesus-system (C, c, D, E, e), kell-system as well as bedside test cards: AB0-system and rhesus	List A, Annex II
Blood grouping testsera: duffy-system, kidd-system	List B, Annex II



  
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Head of Certification Body