

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	2021-03-13
Valid until	2024-05-26
Registration no.	D1052200075
Report no.	P20-01745-189026
Stuttgart	2021-03-03




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. D1052200075

Date 2021-03-03

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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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