

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith grants

**CE-Immundiagnostika GmbH  
Karl-Landsteiner-Str. 6  
69151 Neckargemuend  
Germany**

for the scope

**Reagents for blood typing:  
ABO system, Rhesus, Kell  
(see attachment)**

the

## EC Design Examination Certificate

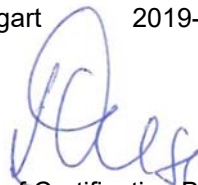
The examination of the design of the product by mdc has proven  
that the design meets the requirements according to

### Annex IV – Section 4 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.

This certificate is only valid in connection with a valid mdc certificate  
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2019-07-22
Valid until	2021-06-30
Registration no.	D1415300011
Report no.	P19-00685-147026
Stuttgart	2019-07-22



Head of Certification Body



**Attachment of the certificate**

**No. D1415300011**

Date 2019-07-22

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Product category	Product	Class
Monoclonal and polyclonal antisera: ABO-System	Anti-A, A-11H5; A-mono-11H5-10 Anti-A, BIRMA-1; A-mono-BIRMA-10 Anti-B, B-6F9; B-mono-6F9-10 Anti-B, LB-2; B-mono-LB2-10 Anti-AB, A-5E10-B-2D7; AB-mono-5E10-10	List A, Annex II
Monoclonal and polyclonal antisera: Rhesus-System	Anti-C, MS24; C-mono-MS24-05, C-mono-MS24-10 Anti-C, MS273; C-mono-MS273-05, C-mono-MS273-10 Anti-c, MS33; c-mono-MS33-05, c-mono-MS33-10 Anti-c, MS35; c-mono-MS35-05, c-mono-MS35-10 Anti-c, incomplete; c-inco-05 Anti-E, MS80/MS258; E-mono-MS80-05, E-mono-MS80-10 Anti-E, MS12/MS260; E-mono-MS12-05, E-mono-MS12-10 Anti-E, incomplete; E-inco-05 Anti-e, MS16/MS21/MS63; e-mono-MS16-05, e-mono-MS16-10 Anti-e, MS62/MS69; e-mono-MS62-05, e-mono-MS62-10 Anti-e, incomplete; e-inco-05 Anti-D, RUM-1; D-mono-RUM-10 Anti-D, MS-201; D-mono-MS201-10 Anti-D blend, TH-28/MS-26; D-mono-blend-TH-10 Anti-D blend 175 2-415 1E4; D-mono-blend-175-10 Anti-D, incomplete; D-inco-10	List A, Annex II
Monoclonal and polyclonal antisera: Kell-System	Anti-Kell, MS56, Kell-mono-MS56-05, Kell-mono-MS56-10 Anti-Kell coombsreactive, Kell-coom-05, Kell-coom-10 Anti-Kell, AEK4, Kell-mono-AEK4-05, Kell-mono-AEK4-10	List A, Annex II



Head of Certification Body

