

**DECLARATION OF CONFORMITY****Manufacturer:**

**CE-IMMUNDIAGNOSTIKA GmbH**  
**Karl-Landsteiner-Str. 6, 69151 Neckargemünd, Germany**  
**Tel. +49 6223-80094 00 Fax +49 6223-80094 99**

Revision: **2022-05-23**Valid until: **2025-05-26**

As the sole responsible manufacturer, we hereby declare that the products listed below comply with the provisions of Council Directive Annex I 98/79/EC for in-vitro diagnostic medical devices (IVDD). All supporting documents are kept on the premises of the manufacturer.

**Supervisory authority :**

Regierungspräsidium Karlsruhe

**Notified body:**

Identificationsnumber: 0483

mdc medical device certification GmbH  
Kriegerstraße 6  
70191 Stuttgart  
Germany

**Conformity assessment:**

For the products named in Lists A and B of Appendix II, the manufacturer has to use the EC declaration of conformity procedure in accordance with Appendix IV (full quality assurance system), for all other products the procedure according to Annex III of the Directive 98/79/EC was applied.

**Certificate numbers:**

D1415300015\_QMS13485  
D1415300022\_EC Rhesus annex IV.4  
D1415300023\_EC Kell annex IV.4  
D1415300024\_EC ABO annex IV.4  
D1415300025\_EC annex IV excluding section 4 and 6

**place, date of issue:**

Neckargemünd, 2022-05-23

**Sign QMB:**

(Angela Grajek)

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**Product: List A/List B**

<b>REF / Articlenumber</b>	<b>Product designation</b>	<b>Clone</b>	<b>Classification 98/79/EC</b>
01110	Anti-A	A-11H5	Liste A
01210	Anti-A	BIRMA-1	Liste A
02110	Anti-B	B-6F9	Liste A
0221	Anti-B	LB-2	Liste A
03110	Anti-AB	A-5E10+B-2D7	Liste A
04105, 04110	Anti-C	MS-24	Liste A
04205, 04210	Anti-C	MS-273	Liste A
05105, 05110	Anti-c	MS-33	Liste A
05205, 05210	Anti-c	MS-35	Liste A
06110	Anti-D	MS-201	Liste A
06210	Anti-D	RUM-1	Liste A
07110	Anti-D blend	TH-28/MS-26	Liste A
07210	Anti-D blend	D175-2;D415 1E4	Liste A
06310	Anti-D incomplete	-	Liste A
08105, 08110	Anti-E	MS-80/MS-258	Liste A
08205, 08210	Anti-E	MS-12/MS-260	Liste A
09105, 09110	Anti-e	MS-16/MS-21/MS-63	Liste A
09205, 09210	Anti-e	MS-62/MS-69	Liste A
10105, 10110	Anti-Kell	MS-56	Liste A
10205, 10210	Anti-Kell	AEK4	Liste A
10305, 10310	Anti-Kell coombsreactive	-	Liste A
12302, 12305	Anti-Fy <sup>a</sup> coombsreactive	-	Liste B
13302, 13305	Anti-Fy <sup>b</sup> coombsreactive	-	Liste B
14302, 14305	Anti-Jk <sup>a</sup> coombsreactive	-	Liste B
15302, 15305	Anti-Jk <sup>b</sup> coombsreactive	-	Liste B
14102, 14105	Anti-Jk <sup>a</sup>	MS-15	Liste B
15102, 15105	Anti-Jk <sup>b</sup>	MS-8	Liste B
34310	AHG polyspez.-rabbit	-	Liste B

**Other Products, self-declaration**

<b>REF / Articlenumber</b>	<b>Product designation</b>	<b>Clone</b>	<b>Classification 98/79/EC</b>
30405, 30410	Anti-A1 Lectine	-	Other product
32102, 32105	Anti-C <sup>w</sup>	MS-110	Other product
32302, 32305	Anti-C <sup>w</sup> incomplete	-	Other product
29302	Anti-Di <sup>a</sup> coombsreactive	-	Other product
31105, 31110	Anti-H (A2)	10934C11	Other product
31405, 31410	Anti-H (A2) Lectine	-	Other product
11302, 11305	Anti-k cellano coombsreactive	-	Other product
16302	Anti-Kp <sup>a</sup> coombsreactive	-	Other product
17302	Anti-Kp <sup>b</sup> coombsreactive	-	Other product
33310	Control reagent incomplete	-	Other product
33110	Control reagent monoclonal	-	Other product
18102, 18105	Anti-Le <sup>a</sup>	LEA2	Other product
19102, 19105	Anti-Le <sup>b</sup>	LEB2	Other product
20302	Anti-Lu <sup>a</sup> coombsreactive	-	Other product
21302	Anti-Lu <sup>b</sup> coombsreactive	-	Other product
22102, 22105	Anti-M	11H2	Other product
23102, 23105	Anti-N	1422C7	Other product
26102, 26105	Anti-P1	650	Other product
24102, 24105	Anti-S	MS-94	Other product
24302, 24305	Anti-S coombsreactive	-	Other product
25102, 25105	Anti-s P3BER	P3BER	Other product
25302, 25305	Anti-s coombsreactive	-	Other product
27302	Anti-Wr <sup>a</sup> coombsreactive	-	Other product
28302	Anti-Xg <sup>a</sup> coombsreactive	-	Other product
35310	Anti-IgG monospez. Sheep	-	Other product

41160	Alsever's solution	-	Other product
36110	Albu-LISS reagent	-	Other product
36210, 36250	LISS reagent	-	Other product
37110	Bromelin solution	-	Other product
38110	Bromelin-control reagent	-	Other product
39110	Bovine albumin 22%	-	Other product
40110	Bovine albumin 30%	-	Other product