



DECLARATION OF CONFORMITY

23.05.2022 with attachments

3. FEBRUAR 2025

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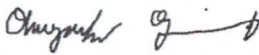
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1. Declaration of Conformity Revision 23.05.2022

Declaration of Conformity	
Manufacturer: CE-IMMUNDIAGNOSTIKA GmbH Karl-Landsteiner-Str. 6, 69151 Neckargemünd, Deutschland 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_QMS 13485 D1415300022_CE Rhesus Anhang IV.4 D1415300023_CE Kell Anhang IV.4 D1415300024_CE ABO Anhang IV.4 D1415300021_CE Anhang IV ohne Abschnitt 4 und 6
place, date of issue:	Neckargemünd, den 23.05.2022
SIGN QMB: (Angela Grajek)	
	<small> CE-IMMUNDIAGNOSTIKA GmbH Karl-Landsteiner-Str. 6 69151 Neckargemünd Tel. +49 (0)6223 - 80094 00 Fax +49 (0)6223 - 80094 99 www.ce-immundiagnostika.com </small>

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Produces: List A+B

REF / Articlenumber	Product designation	Clone	Classification 98/79/EC
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 ^a coombsreactive	-	Liste B
13302, 13305	Anti-Fy ^b coombsreactive	-	Liste B
14302, 14305	Anti-Jk ^a coombsreactive	-	Liste B
15302, 15305	Anti-Jk ^b coombsreactive	-	Liste B
14102, 14105	Anti-Jk ^a	MS-15	Liste B
15102, 15105	Anti-Jk ^b	MS-8	Liste B
34310	AHG polyspez.-rabbit	-	Liste B

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Other Products, self-declaration

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


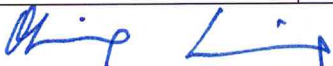

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REF / Articlenumber	Product designation	Clone	Classification 98/79/EC
41160	Alsever's solution	-	Other Products
36110	Albu-LISS reagent	-	Other Products
36210, 36250	LISS reagent	-	Other Products
37110	Bromelin solution	-	Other Products
38110	Bromelin-control reagent	-	Other Products
39110	Bovine albumin 22%	-	Other Products
40110	Bovine albumin 30%	-	Other Products

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2. attachments

The previously integrated declaration of conformity remains valid for Legacy Devices.

date	subject	description
24.05.2024	certificate numbers	Update of certificate number from D1415300015_QMS 13485 In D1415300028_QMS 13485 Expiry 2027-05-09
The conformity of legacy devices according to Regulation (EU) 2017/746 can be extended until May 9, 2027.		
Neckargemünd, 2024-05-24 Sign PRRC (Angela Grajek)  A. Grajek PRRC		
15.08.2024	Notified Body	Clarification regarding the non-involvement of the notified body for the products affected during the transition period to the IVDR: For the products referred to in lists A and B of Annex II , the manufacturer has applied the EC declaration of conformity procedure provided for in Annex IV (full quality assurance system) with the involvement of the notified body ; for all other products, the procedure provided for in Annex III to Directive 98/79/EC has been applied without the involvement of the notified body . The products belong to classes D, C and B according to Regulation (EU) 2017/746.
The transition period for legacy devices has been extended for Class D (with an application for IVDR) products until December 31, 2027.		
	Class A products according to Regulation (EU) 2017/746	Annex to the Declaration of Conformity for Class A Products
Neckargemünd, 2024-05-24 Sign PRRC (Angela Grajek)  A. Grajek PRRC		
03.02.2025	Alsever's solution	Deleted as IVDD product
	Note Validity DoC IVDD	DoC 2022 is still valid. see above
Neckargemünd, 2024-05-24 Sign PRRC (Angela Grajek)  A. Grajek PRRC		

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3. List of Declarations of Conformity for Class A Products

Art.No.	Product	Classification	DNo.	Erstellt am	Version	Valid until
41160	Alsever's solution	Klasse A	0816	2022.10	001	26.05.2026
43110	PEG 4000	Klasse A	0857	2022.10	001	26.05.2026

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3. Declaration of conformity ^{REF} 41160 Alsever's solution 31.10.2022

CE-IMMUNDIAGNOSTIKA GmbH Karl-Landsteiner-Str.6 D-69151 Neckargemuend	
SRN	DE-MF-000030423
<h1 style="margin: 0;">EC declaration of conformity</h1>	

Product name: **Alsever's solution** Trade name: **Alsever's solution**

Product-Code:	41160	EDMS	13.03-90-90-00
Clone/Clones:	N/A	CND	W01030399
EC-Classification: Regulation (EU) 2017/746	Regel 5 a) Klasse A	Basis UDI-DI (GMN):	4049863Alsever_411U5

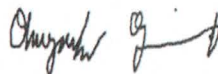
We, CE-Immundiagnostika GmbH, as sole responsible party, confirm the issuance of an EC declaration of conformity for the above-mentioned product, which complies with the general safety and performance requirements of Regulation (EU) 2017/746.

User: medical laboratory professionals

intended purpose: Alsever's solution is used to preserve erythrocytes in suspension.

place, date: Neckargemünd, 2022-10-31

sign PRRC:



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i.A. Angela Grajek

Document valid until: 2026-05-26

DNr.: 0816 Vers. 001 2022-10

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4. Declaration of conformity **REF** 43110 PEG 4000 31.10.2022

CE-IMMUNDIAGNOSTIKA GmbH Karl-Landsteiner-Str.6 D-69151 Neckargemuend	
SRN	DE-MF-000030423
<h1>EC declaration of conformity</h1>	

Product name: **PEG 4000** Trade name: **PEG 4000**

Product-Code:	43110	EDMS	13-03-04-06-00
Clone/Clones:	N/A	CND	WO103030306
EC-Classification: Regulation (EU) 2017/746	Regel 5 a) Klasse A	Basis UDI-DI (GMN):	4049863PEG_433X6

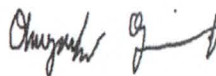
We, CE-Immundiagnostika GmbH, as sole responsible party, confirm the issuance of an EC declaration of conformity for the above-mentioned product, which complies with the general safety and performance requirements of Regulation (EU) 2017/746..

User: medical laboratory professionals

intended purpose: PEG 4000 is used as a chemical additive in the indirect Coombs test.

place, date: Neckargemünd, 2022-10-31

sign PRRC:



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Document valid until: 2026-05-26

DNr.: 0857 Vers. 001 2022-10