IMMUNDIAGNOSTIKA

# DECLARATION OF CONFORMITY

23.05.2022 with attachments

3. FEBRUAR 2025

# Content

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:**<br><br>Identificationsnumber: 0483 | mdc medical device certification GmbH<br>Kriegerstraße 6<br>70191 Stuttgart<br>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<br>D1415300022_CE Rhesus Anhang IV.4<br>D1415300023_CE Kell Anhang IV.4<br>D1415300024_CE ABO Anhang IV.4<br>D1415300021_CE Anhang IV ohne Abschnitt 4 und 6 |
| **place, date of issue:** | Neckargemünd, den 23.05.2022 |

**SIGN QMB:** (Angela Grajek)

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## Productes: 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 |

## 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 |

| 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 |

## 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 |
| | | |
| | | |

## 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 |

3. Declaration of conformity REF 41160 Alsever´s solution 31.10.2022

| CE-IMMUNDIAGNOSTIKA GmbH<br>Karl-Landsteiner-Str.6 D-69151 Neckargemuend | CE-ID |
|---|---|
| SRN | DE-MF-000030423 |

# EC declaration of conformity

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

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

# EC declaration of conformity

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