



# DECLARATIONS OF CONFORMITY CLASS A

17.03.2025

<small>REF</small> All products page <b>1</b> to <b>4</b>	DECLARATIONS OF CONFORMITY CLASS A	
---	------------------------------------	---

## Content

1.	list of declarations of conformity class A products .....	2
2.	declaration of conformity .....	3
<small>REF</small>	41160 Alsever's solution 31.10.2022 .....	3
3.	declaration of conformity <small>REF</small> 43110 PEG 4000 31.10.2022 .....	3

<b>REF</b>	<b>DECLARATIONS OF CONFORMITY CLASS A</b>	
All products page 2 to 4		


## 1. list of declarations of conformity class A products

Art.No.	Product	Classification	DNr.	Created on	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

REF All products page 3 to 4	DECLARATIONS OF CONFORMITY CLASS A	

## 2. declaration of conformity

REF 41160 Alsever's solution 31.10.2022

<b>CE-IMMUNDIAGNOSTIKA GmbH</b> Karl-Landsteiner-Str.6      D-69151 Neckargemuend	
SRN	
<h1>EC Declaration of Conformity</h1>	

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

Product-Code:	<b>41160</b>	EDMS	<b>13.03-90-90-00</b>
Clone/Clones:	<b>N/A</b>	CND	<b>W01030399</b>
EC classification: Regulation (EU) 2017/746	<b>Rule 5 a) Class A</b>	Basis UDI-DI (GMN):	<b>4049863Alsever_411U5</b>


**We, CE-Immundiagnostika GmbH, as the sole responsible party, confirm that an EC Declaration of Conformity has been issued for the above-mentioned product, which complies with the General Safety and Performance Requirements of Regulation (EU) 2017/746.**

Users: Professionals in the medical laboratory

Intended use: Alsever's solution is used for the preservation of erythrocytes in suspension.

Place, date: Neckargemünd, 2022-10-31

sign PRRC:



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](http://www.ce-immundiagnostika.com)


i.A. Angela Grajek

Document valid until: 2026-05-26

DNr.: 0816 Vers. 001 2022-10

## 3. declaration of conformity REF 43110 PEG 4000 31.10.2022

REF All products page 4 to 4	DECLARATIONS OF CONFORMITY CLASS A	 IMMUNDIAGNOSTIKA
------------------------------------	------------------------------------	---

CE-IMMUNDIAGNOSTIKA GmbH Karl-Landsteiner-Str.6 D-69151 Neckargemuend	
SRN	DE-MF-000030423
<b>EC Declaration of Conformity</b>	

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	rule 5 a) class A	Basis UDI-DI (GMN):	4049863PEG_433X6

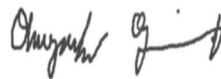
**We, CE-Immundiagnostika GmbH, as the sole responsible party, confirm that an EC Declaration of Conformity has been issued for the above-mentioned product, which complies with the General Safety and Performance Requirements of Regulation (EU) 2017/746.**

Users: Professionals in the medical laboratory

Intended use: PEG 4000 is used as a chemical additive in the indirect Coombs test.

Place, date: Neckargemünd, 2022-10-31

sign PRRC:



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](http://www.ce-immundiagnostika.com)

i.A. Angela Grajek

Document valid until: 2026-05-26

DNr.: 0857 Vers. 001 2022-10