

**EC DECLARATION OF CONFORMITY**  
**EG-KONFORMITÄTSERKLÄRUNG**



Dialab Produktion und Vertrieb von  
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.  
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

<b>REF</b>	<b>Product Name / Produktname</b>	<b>Content / Inhalt</b>
	See addendum to the declaration of Conformity	

We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

**Devices other than those covered by Annex II**

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on the Conformity Assessment Procedure according to Annex III of the aforesaid Directive .

Hiermit erklären wir, auf eigene Verantwortung, dass unser oben genanntes Produkt, gemäß der Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert als:

**Andere als die in Anhang II genannten Produkte**

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Diese Erklärung basiert auf dem Konformitätsbewertungsverfahren nach Anhang III der oben angeführten Richtlinie

Wiener Neudorf, 2023-10-04

  
Almira Dugic  
Qualitätsmanagementbeauftragte  
Quality Management Representative

**Addendum to the Declaration of Conformity of Devices  
other than those covered by Annex II**

**CLINICAL CHEMISTRY**

Reagents REF	Product	Content
913816	Adenosine Deaminase (ADA), Enzymatic	6 x 25 mL
913813	Adenosine Deaminase (ADA), Enzymatic	3 x 25 mL
917810	Adenosine Deaminase (ADA), Enzymatic	3 x 10 mL
D97202B	Albumin, BCG	1 x 1 L
D09550	Albumin, BCG	4 x 250 mL
D97203	Albumin, BCG	5 x 100 mL
D00204	Albumin, BCG	5 x 50 mL
D00205	Albumin, BCG	5 x 25 mL
D00206	Albumin, BCG	5 x 10 mL
D51911	Albumin, BCG	10 x 50 mL
D0401917	Albumin, BCG	9 x 65 mL
DK0701	Albumin, BCG	5 x 50 mL
DA0801	Albumin, BCG	5 x 50 mL
DT1001	Albumin, BCG	4 x 50 mL
DE1801	Albumin, BCG	10 x 50 mL
DB20301	Albumin, BCG	10 x 50 mL
D03101B	Alkaline Phosphatase, IFCC	1 x 1.25 L (1 x 1 L R1 + 1 x 0.25 L R2)
D95564	Alkaline Phosphatase, IFCC	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D95565	Alkaline Phosphatase, IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00523	Alkaline Phosphatase, IFCC	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D00524	Alkaline Phosphatase, IFCC	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D52911	Alkaline Phosphatase, IFCC	10 x 50 mL (10 x 40 mL R1 + 4 x 25 mL R2)
D0402917	Alkaline Phosphatase, IFCC	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DA0803	Alkaline Phosphatase, IFCC	5 x 50 mL (5 x 40 mL R1 + 5 x 10 mL R2)
DT1003	Alkaline Phosphatase, IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
DK0703	Alkaline Phosphatase, IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DE1803	Alkaline Phosphatase, IFCC	2 x 62.5 mL (2 x 50 mL R1 + 2 x 12.5 mL R2)
DB20302	Alkaline Phosphatase, IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
D03103B	Alpha-Amylase, mod. IFCC	1 x 1.25 L (1 x 1 L R1 + 1 x 250 mL R2)
D94570	Alpha-Amylase, mod. IFCC	5 x 100 mL (4 x 100 mL R1 + 1 x 100 mL R2)
D94571	Alpha-Amylase, mod. IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
D00578	Alpha-Amylase, mod. IFCC	5 x 25 mL (4 x 25 mL R1 + 1 x 25 mL R2)
D96569	Alpha-Amylase, mod. IFCC	5 x 10 mL (4 x 10 mL R1 + 1 x 10 mL R2)
D54911	Alpha-Amylase, mod. IFCC	5 x 50 mL (4 x 50 mL R1 + 2 x 25 mL R2)
D0406917	Alpha-Amylase, mod. IFCC	5 x 62.5 mL (4 x 62.5 mL R1 + 1 x 62.5 mL R2)
DK0705	Alpha-Amylase, mod. IFCC	5 x 50 mL (4 x 50 mL R1 + 1 x 50 mL R2)
DA0806	Alpha-Amylase, mod. IFCC	5 x 20 mL (4 x 20 mL R1 + 1 x 20 mL R2)
DT1006	Alpha-Amylase, mod. IFCC	5 x 20 mL (4 x 20 mL R1 + 1 x 20 mL R2)
DE1806	Alpha-Amylase, mod. IFCC	2 x 62.5 mL (2 x 50 mL R1 + 2 x 12.5 mL R2)
DB20304	Alpha-Amylase, mod. IFCC	4 x 62.5 mL (4 x 50 mL R1 + 4 x 12.5 mL R2)
397756B	alpha-Amylase, CNP-G3	1 x 1 L
397758	alpha-Amylase, CNP-G3	5 x 100 mL
397759	alpha-Amylase, CNP-G3	5 x 50 mL
300760	alpha-Amylase, CNP-G3	5 x 25 mL
396754	alpha-Amylase, CNP-G3	5 x 10 mL
355911	alpha-Amylase, CNP-G3	10 x 50 mL

5E1848 | Zinc, 5-Br-PAPS | 5 x 20 mL

#### Auxiliary Reagents, Supplements and Additives

REF	Product	Content
D96361	Pyridoxal-5'-Phosphate	1 x 4 mL
D96122B	Cholesterol HDL Precipitant	1 x 1 L
D14125	Cholesterol HDL Precipitant	5 x 100 mL
D00127	Cholesterol HDL Precipitant	5 x 50 mL
D00142	Cholesterol HDL Precipitant	5 x 25 mL
D00129	Cholesterol HDL Precipitant	5 x 10 mL
D13136	Cholesterol LDL Precipitant	5 x 100 mL
D13137	Cholesterol LDL Precipitant	5 x 50 mL
D13138	Cholesterol LDL Precipitant	5 x 25 mL
D13139	Cholesterol LDL Precipitant	5 x 10 mL

#### Calibrators

REF	Product	Content
D98485	Diacal Auto	5 x 3 mL
D98485SV	Diacal Auto	1 x 3 mL
D13585SV	Diacal Lipids	1 x 2 mL
D13595	Diacal CK-MB	5 x 1 mL
D13595SV	Diacal CK-MB	1 x 1 mL
913870SV	ADA Calibrator	1 x 1 mL
Y17565SV	G6PDH Calibrator	1 x 0,5 mL
908550	Homocysteine Calibrator Set (5 levels)	5 x 1 mL
Z05880	Ethanol Calibrator/Control Set	4 x 1 mL
F03710SV	HDL-Cholesterol Calibrator	1 x 3 mL
F03711SV	LDL-Cholesterol Calibrator	1 x 1 mL
Y04705SV	Hemoglobin Total Calibrator	1 x 2 mL

#### Standards

REF	Product	Content
D95555	Albumin Standard	1 x 3 mL
Y08310SV	Ammonia Standard	1 x 5 mL
903210	Bile Acids Standard	1 x 3 mL
D95094	Calcium Standard	1 x 3 mL
D95108	Chloride Standard	1 x 3 mL
D95114	Cholesterol Standard	1 x 3 mL
D06520SV	CO <sub>2</sub> Standard	1 x 3 mL
507163SV	Copper Standard	1 x 3 mL
D94592	Creatinine Standard	1 x 3 mL
D95223	Glucose Standard	1 x 3 mL
D10090SV	beta-Hydroxybutyrate Standard	1 x 3 mL
D95305	Iron Standard	1 x 3 mL
910280	Lithium Standard Set (3 levels)	3 x 3 mL
D95339	Magnesium Standard	1 x 3 mL
D07963SV	NEFA Standard	1 x 3 mL
D95362	Phosphorus Standard	1 x 3 mL
910180	Potassium Standard Set (2 levels)	2 x 3 mL
D94683	Protein Total Standard	1 x 3 mL
D03600	Protein Total in Urine/CSF Standard	1 x 3 mL
909680	Sodium Standard Set (2 levels)	2 x 3 mL
D95380	Triglycerides Standard	1 x 3 mL
D95706	Urea Standard	1 x 3 mL
D94708	Uric Acid Standard	1 x 3 mL
507263SV	Zinc Standard	1 x 3 mL

<b>Controls REF</b>	<b>Product</b>	<b>Content</b>
D98481	Diacon N	12 x 5 mL
D14481	Diacon N	5 x 5 mL
D98481SV	Diacon N	1 x 5 mL
D98482	Diacon P	12 x 5 mL
D14482	Diacon P	5 x 5 mL
D98482SV	Diacon P	1 x 5 mL
D99486	Diacon Lipids	3 x 3 mL
D99486SV	Diacon Lipids	1 x 3 mL
D11487	Diacon Lipids High	3 x 3 mL
D11487SV	Diacon Lipids High	1 x 3 mL
D08581	Diacon Urine Level 1	12 x 5 mL
D08581SV	Diacon Urine Level 1	1 x 5 mL
D08582	Diacon Urine Level 2	12 x 5 mL
D08582SV	Diacon Urine Level 2	1 x 5 mL
913880	ADA Control Set (2 levels)	2 x 1 mL
Y08330	Ammonia Control Set (2 levels)	2 x 5 mL
D16525	CO2 Control	3 x 3 mL
D16525SV	CO2 Control	1 x 3 mL
Y17560	G6PDH Control Set (3 levels)	6 x 0,5 mL
Y04706	Hemoglobin Total Control Set (3 levels)	6 x 2 mL
905620	Homocysteine Control Set (4 levels)	4 x 1 mL
910290	Lithium Control Set (2 levels)	2 x 3 mL
910190	Potassium Control Set (2 levels)	2 x 3 mL



Product Service

# Certificate

No. Q5 026709 0009 Rev. 01

**Holder of Certificate:** DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.  
 IZ-NOE Sued  
 Hondastrasse, Objekt M55  
 2351 Wr. Neudorf  
 AUSTRIA

**Certification Mark:**



**Scope of Certificate:** Design, development, production and distribution of in-vitro diagnostic reagents and testkits in the areas of immunological detection of infectious diseases, immunochemistry/immunology/clinical chemistry biomarkers (analytes: enzymes, substrates, electrolytes reagents; controls/standards/calibrators), urinalysis, haematology, haemostasis and immuno haematology (blood grouping). Distribution of in-vitro diagnostic instruments including accessories for immunology, clinical chemistry, haematology, haemostasis and urinalysis.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 026709 0009 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 026709 0009 Rev. 01)

**Report No.:** 713237224

**Valid from:** 2022-03-29  
**Valid until:** 2025-03-28

**Date,** 2022-03-17

*C. Dicks*

Christoph Dicks  
 Head of Certification/Notified Body





# Certificate

No. Q5 026709 0009 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):** DIALAB Produktion und Vertrieb von chemisch-technischen  
 Produkten und Laborinstrumenten Gesellschaft m.b.H.  
 IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf,  
 AUSTRIA

See Scope of Certificate

**Parameters: ./.**

