

AUTHORIZATION LETTER

Wr. Neudorf, 10.01.2022

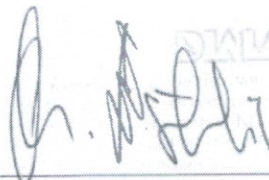
TO WHOM IT MAY CONCERN

We, **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**, headquarter in Austria, IZ-NÖ Süd, Hondastrasse Obj. M55, A-2351 Wr. Neudorf hereby declares that the below mentioned company is our official **representative** and is authorized to register, sell and distributor our products in the territory of Moldova:

ECHIPAMED PLUS SRL
Valea Trandafirilor str., 24B, of.80,
MD-2001 Chisinau, Moldova

This certificate remains in force from 01.02.2022 until 31.01.2023 or is terminated during that period on the expiry of not less than 30 days' notice in writing given by either party to the other.

Signed for and on behalf of
DIALAB GmbH



Murat ESTELIK
Managing Director



DIALAB Produktion und Vertrieb
von chemisch-technischen
Produkten und Laborinstrumenten
Gesellschaft m.b.H.

IZ-NÖE Süd
Hondastrasse, Objekt M55
2351 WR. NEUDORF
AUSTRIA

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www.dialab.at

Managing Director: Murat Estelik
Murat Estelik, Dipl. Ing. Marlene Ramsey
FN 108 078p | Landesgericht Wr. Neustadt
UID/VAT: ATU 150 134 04 | DVR: 0130885

Reiffeisen Regionalbank Muebling
BIC / SWIFT: RLHWAT33XXX
IBAN #: AT97 3225 0000 0070 6739
IBAN USD: AT52 3225 0301 0070 6739



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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0008 Rev. 01

Manufacturer:

**DIALAB Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.**

IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product:

**Reagents and reagent products for blood typing
AB0-system**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7_026709_0008_Rev._01

Report No.:

713205841

Valid from:

2021-04-23

Valid until:

2023-05-23

Date,

2021-04-20

C. Dicks

Christoph Dicks

Head of Certification/Notified Body





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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0008 Rev. 01

Model(s):

Anti-A, monoclonal
Anti-B, monoclonal
Anti-AB, monoclonal

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,
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Parameters:

Model Name:
Anti-A, monoclonal
Anti-B, monoclonal
Anti-AB, monoclonal

Model No:
B05405
B05406
B05407





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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0007 Rev. 01

Manufacturer:

**DIALAB Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.**

IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product:

**Reagents and reagent products for blood typing
Rhesus (C,c,D,E,e)**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7_026709_0007_Rev_01

Report No.:

713205840

Valid from:

2021-04-23

Valid until:

2023-05-23

Date,

2021-04-21

C.D.M.

Christoph Dicks

Head of Certification/Notified Body





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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0007 Rev. 01

Model(s):

Anti-D (IgM/IgG), monoclonal
Anti-C, monoclonal
Anti-c, monoclonal
Anti-E, monoclonal
Anti-e, monoclonal

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,
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Parameters:

Model Name:	Model No:
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-c, monoclonal	B06413
Anti-E, monoclonal	B06412
Anti-e, monoclonal	B06414





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Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Manufacturer:

**DIALAB Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.**

IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
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**Product Category(ies): Products according to Directive 98/79/EC
Annex II**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1_026709_0004_Rev_02

Report no.: 713205839

Valid from: 2021-04-23

Valid until: 2024-05-26

Date, 2021-04-22



C.D.M.

Christoph Dicks
Head of Certification/Notified Body



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Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Model(s):

The products detailed below are covered under the scope of this certificate

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,
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Products according to Annex II List A Devices:

Product

REF

Anti-A, monoclonal	B05405
Anti-B, monoclonal	B05406
Anti-AB, monoclonal	B05407
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-E, monoclonal	B06412
Anti-c, monoclonal	B06413
Anti-e, monoclonal	B06414
Anti-D Negative Control	B09936
DIAQUICK HIV Plus	H18100
DIAQUICK HIV Plus WB	H18101
DIAQUICK HCV Plus	H18200
DIAQUICK HCV Plus WB	H18201



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Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Products according to Annex II List B Devices:

Product	REF
Anti-HG, polyspecific/monoclonal	B05181
Rubella IgG	V00045
Rubella IgM	V05061
DIAQUICK Rubella IgM Cassette	J15020
Toxoplasma IgG	V00064
Toxoplasma IgM	V05079
DIAQUICK Toxoplasma IgM Cassette	J15011
CMV IgG	V00004
CMV IgM	V00012
DIAQUICK CMV IgM Cassette	J15030
DIAQUICK Chlamydia Cassette	Z98226CE
PSA	Z00338
DIAQUICK PSA Cassette	Z08010
DiaCheck® Pro Blood Glucose Monitoring System	P13110
DiaCheck® Pro Blood Glucose Test Strips	P13125
DiaCheck® Pro Glucose Control Solution	P13134





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
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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 immunohaematology (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 requirements 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

Report No.: 713237224

Valid from: 2022-03-29

Valid until: 2025-03-28

Date, 2022-03-17

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,
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See Scope of Certificate

Parameters: ./.



BLOOD GROUPING & RHESUS TYPING

ABO & Rhesus Typing



CE

Anti-A, monoclonal	✓
Anti-B, monoclonal	✓
Anti-AB, monoclonal	✓
Anti-D (IgM/IgG), monoclonal	✓
Anti-A1 Lectin	
Anti-C, monoclonal	✓
Anti-E, monoclonal	✓
Anti-c, monoclonal	✓
Anti-e, monoclonal	✓
Anti-Cw, monoclonal	✓

Rare Blood Grouping Reagents

CE

Anti-H Lectin	✓
Anti-k, monoclonal	✓
Anti-K, monoclonal	

Auxiliary Reagents

CE

Anti-HG, polyspecific / monoclonal	✓
BSA 22%	✓
BSA 30%	✓
LISS Solution	✓
Papain	✓
Anti-D Negative Control	✓

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