

AUTHORIZATION LETTER

Wr. Neudorf, 09.02.2021

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 Moldavia:

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

This certificate remains in force from 01.01.2021 until 31.01.2022 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



DIALAB
Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A-2351 Wr. Neudorf, Hondastrasse Obj. M55
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Christina ERNST
Export Manager



TUV SUD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

Certificate

No. Q5 026709 0009 Rev. 00

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

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

Certification Mark:



Scope of Certificate: Design and development, production and distribution of reagents and reagent products for in-vitro diagnostics as well as distribution of instruments for in-vitro diagnostics including accessories

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

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). See also notes overleaf.

Report No.: 713146001

Valid from: 2019-03-29

Valid until: 2022-03-28

Date, 2019-03-28

S. Preis

Stefan Preis



ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ СЕРТИФИКАТ ◆ 認證書 ◆



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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

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:	Model No:
	Anti-A, monoclonal	B05405
	Anti-B, monoclonal	B05406
	Anti-AB, monoclonal	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](http://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

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
AUSTRIA

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



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, AUSTRIA

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

