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www.dialab.at

AUTHORISATION LETTER

Wr. Neudorf, 06.02.2019

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 01.01.2019 until 31.12.2019 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 Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
Objekt M55
A-2351 Wr. Neudorf
AUSTRIA

Christina Schneider
Export Manager

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Mail: office@dialab.at
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Managing Director | Geschäftsführer
Murat Estelik, Dipl. Ing. Marlene Ramsey
FN 100 078p | Landesgericht Wr. Neustadt
UID/VAT: ATU 150 136 06 | DVR: 0130885
Raiffeisen Regionalbank Moedling
BIC / SWIFT: RLNWATWWGTD
IBAN €: AT97 3225 0000 0070 6739
IBAN USD: AT52 3225 0301 0070 6739

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

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

for the scope

Reagents and reagent products for the determination of the blood groups AB0 system and Rhesus (C, c, D, E, e); reagents for the determination of irregular Anti-Erythrocytic Antibodies (AHG); reagents and reagent products for detection and quantification of the following infectious diseases: Rubella, Toxoplasmosis, Cytomegalovirus and Chlamydia; reagents and reagent products for detection and quantification of tumoral marker PSA; devices for self-diagnosis for the measurement of blood sugar; devices for self-diagnosis for pregnancy and ovulation (hormones) (see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2017-09-29
Valid until	2021-04-22
Registration no.	D4000100005
Report no.	P17-00988-105929
Stuttgart	2017-09-29

Head of Certification Body

ZLG-BS-247.10.05

medical device certification mdc
mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D4000100005 Date 2017-09-29 Page 1 of 1

Product category	Product	Class
Reagents and reagent products for the determination of the blood groups AB0 system	Anti-A monoclonal, Clone 9113D10 Anti-B monoclonal, Clone 9621A8 Anti-AB monoclonal, Clone 152D12+9113D10	List A, Annex II
Reagents and reagent products for the determination of the blood groups Rhesus system (C, c, D, E, e)	Anti-D monoclonal, Clone RUM-1+MS-26 Anti-C monoclonal, Clone MS-24 Anti-c monoclonal, Clone MS-33 Anti-E monoclonal, Clone MS-258 Anti-e monoclonal, Clone MS-16+MS-63 Anti-D negative control	List A, Annex II
Reagents for the determination of irregular Anti-Erythrocytic Antibodies	Anti-HG polyspecific/monoclonal	List B, Annex II
Reagents and reagent products for detection and quantification of the following infectious diseases: Rubella, Toxoplasmosis, Cytomegalovirus and Chlamydia (ELISA, immonchromatographic test)	Toxoplasma IgG, Toxoplasma IgM Rubella IgG, Rubella IgM CMV IgG, CMV IgM DIAQUICK Toxoplasma IgM Cassette DIAQUICK Rubella IgM Cassette DIAQUICK CMV IgM Cassette DIAQUICK Chlamydia Cassette	List B, Annex II
Reagents and reagent products for detection and quantification of tumoral marker PSA (ELISA, immunochromatographic rapid test)	PSA DIAQUICK PSA Cassette	List B, Annex II
Devices for self-diagnosis for the measurement of blood sugar	DiaCheck Pro Blood Glucose Monitoring System DiaCheck Pro Blood Glucose Test Strips DiaCheck Pro Glucose Control Solution	List B, Annex II
Devices for self-diagnosis for pregnancy and ovulation (hormones)	DIALAB Pregnancy Test (hCG) DiaFem Schwangerschaftstest (hCG)	self-testing not Annex II

Head of Certification Body

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REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

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EC DECLARATION OF CONFORMITY

We

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

declare, on our own responsibility, that our products specified in the enclosed addendum
"Devices of List A, Annex II (mdc), Rev.06 (1 page)",
classified as follows according to the directive on in vitro diagnostic medical devices
98/79/EC:

Devices of List A, Annex II

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

This Declaration is based on Conformity Assessment Procedures according to Annex IV, section 3 and 4 of the aforesaid Directive in cooperation with the notified body

mdc medical device certification GmbH, code no. 0483
Kriegerstraße 6 / 70191 Stuttgart / Germany

This Declaration is valid until 2021-04-22.

Wr. Neudorf, 2017-12-21

DI Marlene Ramsey
Managing Director

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Raiffeisen Regionalbank Moedling, BIC / SWIFT: RLNWATWWGTD, IBAN €: AT97 3225 0000 0070 6739, IBAN USD: AT52 3225 0301 0070 6739

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Addendum to the Declaration of Conformity of Devices for List A, Annex II (mdc)

ABO and Rhesus Typing	REF	CONT	LOT
Anti-A, monoclonal	B05405	10 mL	*600129-B2, 600129-B3, 600134-A4, 600135-A3, 600135-C2, 600136-H2, 600139-F4*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-B, monoclonal	B05406	10 mL	*610154-A2, 610156-B3, 610159-A4, 610159-C3, 610160-A2, 610161-G2, 610164-H3*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-AB, monoclonal	B05407	10 mL	*620116-B3, 620119-C2, 620121-C2, 620124-B3, 620125-F3*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-D (IgM/IgG), monoclonal	B05408	10 mL	*740156-B2, 740158-B3, 740162-A2, 740162-B4, 740162-D2, 740163-F3, 740163-H2*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-D Negative Control	B09936	10 mL	*650293-B7*
CE-Certificate No.: D4000100004 and D4000100005			

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EC DECLARATION OF CONFORMITY

We

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

declare, on our own responsibility, that our products specified in the enclosed addendum "Other Products (Blood Grouping), Rev.08 (1 page)", classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Blood Grouping)

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

CE marking has been carried out following the procedure referred to in Annex III of the aforesaid Directive.

This declaration is valid until 2019-04-12.

Wiener Neudorf, 2018-05-02

DI Marlene Ramsey
Managing Director

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Addendum to the Declaration of Conformity for Other Products (Blood Grouping)

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BLOOD GROUPING AND RHESUS TYPING

ABO and Rhesus Typing

	REF	CONT
Anti-C^w, monoclonal	B13001	1x 2 mL

Rare Blood Grouping Reagents

	REF	CONT
Anti-H Lectin	B09934	1x 2 mL
Anti-k, monoclonal	B18908	1x 2 mL

Auxiliary Reagents

	REF	CONT
BSA 22%	B05176	1x 10 mL
BSA 30%	B05175	1x 10 mL
LISS solution	B05178	1x 10 mL
Papain	B08000	1x 10 mL
Papain	B08001B	1x 1 L

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