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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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BIC / SWIFT: RLNWATWWGTD
IBAN €: AT97 3225 0000 0070 6739
IBAN USD: AT52 3225 0301 0070 6739

Certificate

mdc medical device certification GmbH
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

production and distribution of reagents and reagent products for in-vitro diagnosis as well as distribution of instruments for in-vitro diagnosis including accessories

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2016-04-13
Valid until	2019-04-12
Registration no.	D1419000001
Report no.	P16-00378-68897
Stuttgart	2016-04-13

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6 . 70191 Stuttgart

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-16002-06-00

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

EVPÚ®

NOTIFIED BODY No. 1293

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices of the European Parliament and of the Council (IVDD), **Annex IV excluding (4, 6)** *(Module H)* transposed into "Slovak government decree No. 569/2001 Collection of Laws" as amended

No. 40009/101/1/2017/CE

EVPÚ a.s., Notified Body No. 1293, has audited the quality system in accordance with IVDD Annex IV and found that quality system meets the requirements of IVDD Annex IV.

Manufacturer and Facility	**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**
Device(s)	**HBsAg Sensitive ELISA**
Type(s)	**Z12360 (1x96 wells)** **Z12354 (5x96 wells)**
Trade mark:	DIALAB
Device(s)	**in List A**
Relevant report(s)	**40060/2012/C, 4-0009/17/C**
Audit report(s)	**M003/14-3**

EVPÚ, a.s. NOVÁ DUBNICA Notified Body No. 1293

REPUBLICA MOLDOVA mun. CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNIPAMED-PLUS" IDNO 1003600077677

Marek H u d á k

Issued on October 13th, 2017 **Valid until** May 22nd, 2022

Manufacturer can affix the CE mark with number of Notified Body only in case devices are in comply with all relevant and effective Directives of European Parliament and of the Council. For placing on the market of List A devices covered by this certificate an EC Design-Examination Certificate according to IVDD Annex IV (4) is required. Surveillance audits according to IVDD, Annex IV (5) will be held to verify the validity of this Certificate.

The manufacturer must inform EVPÚ a.s. of any plan for substantial changes in the design of the device(s), in construction of the device(s) or in the quality system of production in order to examine whether this Certificate remains valid.

This Certificate is valid until the date specified. Any significant changes in the design of the device(s), in construction of the device(s), in the quality system or amendments to the Directive 98/79/EC may render this Certificate invalid at an earlier date.

The product liability rests with the manufacturer or his representative in accordance with the Directive 85/374/EEC.