

To whom it may concern

Manufacturer's Authorization

Date: 2/21/2020

We *Diamond Diagnostics, Inc* who are official manufacturers of *Radiometer ABL5 consumables* and, having factories at *333 Fiske Street, Holliston, MA 01746 USA*, do hereby declare that

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

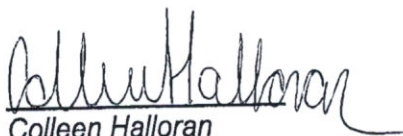
is our official distributor and local representative for *Radiometer ABL5 consumables* of *Diamond Diagnostics Inc*, in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service *Radiometer ABL5 consumables*, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2020.

Diamond Diagnostics, Inc


Colleen Halloran
Customer Service Specialist





global assurance

This is to certify that the Quality Management System of:

Diamond Diagnostics Inc.

333 Fiske Street
Holliston MA 01746
United States of America

(See appendix for additional locations)

applicable to:

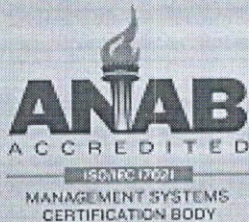
The design, manufacture and warehousing of blood electrolyte systems, consumables and the re-manufacture of clinical diagnostic equipment

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

K M Beaud

For and on behalf of NQA, USA



Certificate Number: 16590

EAC Code: 34

Certified Since: November 10, 2005

Valid Until: November 6, 2020

Reissued: November 7, 2017

Cycle Issued: November 7, 2017



Certificate of Registration

nqa

global assurance

This is to certify that the Quality Management System of:

Diamond Diagnostics Inc.

333 Fiske Street
Holliston MA 01746
United States of America

Central function listed above. See appendix for additional locations

applicable to:

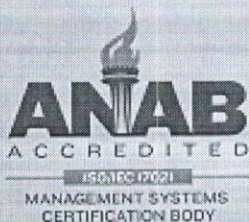
**The design, manufacture and warehousing of blood electrolyte systems, consumables
and the re-manufacture of clinical diagnostic equipment**

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

K M Bland

For and on behalf of NQA, USA



Certificate Number: 17163

EAC Code: 34

Certified Since: February 7, 2006

Valid Until: November 6, 2020

Reissued: November 7, 2017

Cycle Issued: November 7, 2017



DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechikai eszközökről szóló Európai Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Europeia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمات 98/79/EC Vitro Diagnostica Medical Device
ان شركة دايموند دايانوستيكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispositivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 產品(s) / Produto(s) / Продукт(ы) / المنتج(ن) / Prodott(i) :

Model: Radiometer ISE & pH Blood Gas

Reagent & Controls:

RD-943837D Calibrator 1 Solution	RD-944030D Calibrator 1 Solution	RD-943905D Electrode Cleaning Solution
RD-943839D Calibrator 2 Solution	RD-944031D Calibration Solution 2	RD-943906D Protein Remover
RD-944071D Rinse Solution	RD-944032D Rinse Solution	RD-943770D tHb Calibration Solution
RD-943795D Cleaning Solution	RD-943953D Salt Bridge Solution	RD-943959D Cal 1 Solution
RD-943794D Salt Bridge Solution	RD-943955D Cleaning Solution	RD-943960D Cal 2 Solution
RD-943791D 7.4 Buffer	RD-943793D Rinse Solution	RD-943993D Rinse Solution
RD-943792D 6.8 Buffer	RD-944028D Cleaning Solution	RD-944015D Cal 1 Solution
RD-92123 Mission Control Level 1-2-3	RD-944029D Salt Bridge Solution	RD-943827D Deproteinizer Solution
	DD-97123 Trinity R Combination Control Tri Level	DD-92900 Mission Complete CVM BG/ISE Linearity Control

Electrodes & Accessories:

RD-945376D pO2 Electrode	RD-848017D Membrane Pump	RD-905504D Yearly Maintenance Kit
RD-945375D pCO2 Electrode	RD-842194D Pump Tubing	RD-LG500D Calibration Gas 100% CO2
RD-945383D pH Electrode	RD-984058D Thermal Paper	RD-LG505D-4 Calibration Gas 1 ABL5
RD-945633D Reference Electrode	RD-984056D Printer Paper	RD-LG506D-4 Calibration Gas 2 ABL5
RD-945389D Reference Electrode	RD-984057D Printer Paper	

(AR) Authorized Representative

Diamond Diagnostics Kft.
6 Óradsa Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Authorized
Officer:

Kathy Fisher

Date: 28 December, 2017

Kathy Fisher
Global Quality Manager

Quality Systems Registration

ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure

Annex III, Self-Declared

Manufacturer's name: Diamond Diagnostics Inc. (USA)
Manufacturer's address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

CE

The names of various manufacturers and their instruments referred to herein may be protected by trademark or other law, and are used herein solely for purpose of reference. Diamond Diagnostics Inc. expressly disclaims any affiliation with them or sponsorship by them.

