

DECLARATION OF CONFORMITY

Diamond Diagnostics, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of In Vitro Diagnostics Medical Devices Regulation EU 2017/746 and Directive 2011/65/EU.

Diamond Diagnostics Inc. ezúton biztosítja és kijelenti, hogy az alább felsorolt termék(ek) megfelelnek az In Vitro Diagnostics Medical Devices EU 2017/46 rendelet és a 2011/65/EU irányelv követelményeinek.

Diamond Diagnostics Inc. versichert und erklärt hiermit, dass das/die unten aufgeführte(n) Produkt(e) den Anforderungen der In-vitro-Diagnostik-Medizinprodukte-Verordnung EU 2017/46 und der Richtlinie 2011/65/EU entsprechen.

Diamond Diagnostics Inc. garantit et déclare par la présente que le ou les produits répertoriés ci-dessous sont conformes aux exigences du règlement sur les dispositifs médicaux de diagnostic in vitro UE 2017/46 et de la directive 2011/65/EU.

Diamond Diagnostics Inc. por la presente garantiza y declara que los productos enumerados a continuación cumplen con los requisitos del Reglamento de dispositivos médicos de diagnóstico in vitro EU 2017/46 y la Directiva 2011/65/EU.

Diamond Diagnostics Inc. 特此确保并声明下列产品符合体外诊断医疗器械法规 EU 2017/46 和指令 2011/65/EU 的要求。

Diamond Diagnostics Inc. garante e declara que o(s) produto(s) listado(s) abaixo cumpre(m) o requisito do Regulamento de Dispositivos Médicos de Diagnóstico In Vitro EU 2017/46 e Diretiva 2011/65/EU.

Diamond Diagnostics Inc. гарантирует и заявляет, что продукты, перечисленные ниже, соответствуют требованиям Регламента ЕС 2017/46 о медицинских устройствах для диагностики in vitro и Директивы 2011/65/EU.

Vitro Diagnostica Medical Regulation 2017/746 and Directive 2011/65/EU المتطلبات الاتحاد الأوروبي المدرجة في التعليمات
ن شركة دايمنونداياغوستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. garantisce e dichiara che i prodotti elencati di seguito sono conformi ai requisiti del Regolamento UE 2017/46 sui dispositivi medici per la diagnostica in vitro e della Direttiva 2011/65/EU.

Diamond Diagnostics, Inc. işbu belge ile aşağıda listelenen ürün(ler)in In Vitro Diagnostics Tıbbi Cihazlar Yönetmeliği EU 2017/746 ve Direktif 2011/65/EU gerekliliklerine uygun olduğunu garanti ve beyan eder.

Product(s) / Produkt(e) / Produit(s) / Producto(s) / 产品 (S) / Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) / Ürün :

Model: Radiometer ISE & pH Blood Gas

Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
RD-943837D	Calibrator 1 Solution	081140301RD943837DQF	Provides calibration point for the pH electrode.
RD-943839D	Calibrator 2 Solution	081140301RD943839DQM	Provides calibration point for the pH electrode.
RD-944071D	Rinse Solution	081140301RD944071DP4	Rinses sample flow path
RD-943795D	Cleaning Solution	081140301RD943795DQY	Cleans sample path.
RD-943794D	Salt Bridge Solution	081140301RD943794DQV	Provides liquid junction for the reference electrode
RD-943791D	7.4 Buffer	081140301RD943791DQL	Provides a calibration point for the pH electrodes.
RD-943792D	6.8 Buffer	081140301RD943792DQP	Provides a calibration point for the pH electrodes.
DD-92123	Mission Control Level 1-2-3	081140301DD921239K	Monitors the measurements of Na ⁺ , K ⁺ , Cl ⁻ , Li ⁺ , Ca ⁺⁺ and CO ₂ in analyzers
RD-943793D	Rinse Solution	081140301RD943793DQS	Rinses the sample flow path.
DD-97123	Trinity R Combination Control Tri Level	081140301DD97123AN	Contains 10 vials of each level at 1.8mL. Assayed for a multitude different analytes.

RD-943906D	Protein Remover	081140301RD943906DQ4	Removes protein from sample path
RD-943770D	tHb Calibration Solution	081140301RD943770DQ7	For tHb Calibration every 3 months
RD-943827D	Deproteinizer Solution	081140301RD943827DQA	Removes protein from the sample path.
DD-92900	Mission Complete CVM BG/ISE Linearity Control	081140301DD92900AF	Monitors performance of analyzers.

Electrodes & Accessories

Part Number:	Device Name:	Basic UDI-DI	Intended Use
RD-945376D	pO2 Electrode	081140301RD945376DQK	Measures the CO2 concentration in a sample
RD-945375D	pCO2 Electrode	081140301RD945375DQG	Measures the O2 concentration in a sample
RD-945383D	pH Electrode	081140301RD945383DQF	Measures the levels of pH in the sample.
RD-945633D	Reference Electrode	081140301RD945633DQB	Completes the electrical circuit between the reference electrolyte and electrical ground.
RD-842194D	Pump Tubing	081140301RD842194DNP	Aide in fluid flow
RD-984057D	Printer Paper	081140301RD984057DQY	Print results

Manufacturer's Name:

Diamond Diagnostics Inc.

Manufacturer's Address:

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Holliston, MA 01746
Tel: +1 (508) 429-0450

Diamond Diagnostics Inc. Hungary Branch Office
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1044 Budapest, Hungary
Tel: + 3617872222

(AR) Authorized Representative:

Diamond Diagnostics Inc., Hungary Branch Office

(SRN) Single Registration Number:

US-MF-000035435

Risk Class:

Class A, Rule 5

Conformity Route:

Annex IV, Self-Declared

Notified Body:

N/A

Quality Systems Registration:

ISO 9001:2015
ISO 13485:2016
EN ISO 9001:2015
EN ISO 13485:2016

Authorized
Officer:

Kathy Fisher
Kathy Fisher
Director, Quality Assurance

Date: 6 May, 2024

