

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 في المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الأوروبي المدرجة في ن شركة داياموند دايانغوستكس تصرح و تؤكد أن التعليمات

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

Part Number	Device Name:	Basic UDI-DI	Intended Use
0-DD-CARELYTEPLUS	CareLyte Plus Electrolyte Analyzer	0811403010DDCAREL YTEPLKS	Utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium
0-DD-SMARTLYTEPLUS	SmartLyte Plus Electrolyte Analyzer	0811403010DDSMART LYTEPLGT	Utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium

Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
AV-BP5186D	Fluid Pack	081140301AVBP5186D63	Provides calibration points for electrodes.
AV-BP0380D	Electrode Conditioning Solution	081140301AVBP0380D48	Conditions the Na electrode
AV-BP0521D	Deproteinizer	081140301AVBP0521D3T	Cleans the reference electrode housing
AV-BP0344D	Urine Diluent	081140301AVBP0344D3Y	Dilutes urine samples
AV-BP1025D	ISE Cleaning Solution	081140301AVBP1025D3F	Cleans the sample path

Electrodes & Accessories

Part Number	Device Name	Basic UDI-DI	Intended Use
AV-BP0413D	Na+ Electrode	081140301AVBP0413D3M	Measures Na+ ions present in samples.
AV-BP0359D	K+ Electrode	081140301AVBP0359D4L	Measures K+ ions present in samples.
AV-BP0570D	Cl- Electrode	081140301AVBP0570D4H	Measures Cl- ions present in samples.
AV-BP0360D	Ca++ Electrode	081140301AVBP0360D3W	Measures Ca++ ions present in samples.
AV-BP0962D	Li+ Electrode	081140301AVBP0962D5E	Measures Li+ ions present in samples.
AV-BP5026D	Reference Electrode	081140301AVBP5026D4W	Completes the electrical circuit between the reference electrolyte and electrical ground.
AV-BP5027D	Peristaltic Pump Tubing	081140301AVBP5027D4Z	Aids in fluid flow
AV-BP5006D	Sample Probe	081140301AVBP5006D4L	Aspirate sample
AV-BP5036D	Sample Sensor	081140301AVBP5036D53	Detects sample and measure temperature
AV-BP5019D	Reference Electrode Housing	081140301AVBP5019D52	Maintains proper flow of reference fluid and calibration standards to the reference electrode.
AV-BP5025D	Printer Paper	081140301AVBP5025D4T	Print results
AV-BP5193D	Pinch Valve Tubing Kit	081140301AVBP5193D5X	Use with Electrolyte Analyzer.
AV-BP5014D	Shutdown Kit	081140301AVBP5014D4K	Use with Electrolyte Analyzer.
AV-BP5194D	Startup Kit	081140301AVBP5194D62	Use with Electrolyte Analyzer.
AV-BP9043D	Fillport Assembly	081140301AVBP9043D6B	Connects the pinch valve tubing to the probe

Manufacturer's Name:

Diamond Diagnostics Inc.

Manufacturer's Address:

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

Diamond Diagnostics Inc. Hungary Branch Office
6 Oradna Street
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 Assessment Procedure:

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: 28 May, 2024

