

## 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 المنجاة المذكورة أدناه تتوافق مع متطلبات الاتحاد الأوروبي المدرجة في في ن شركة دايموند دايانغونستكس تصرح و تؤكد أن التعلية

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) / Product(s) / 产品 (S) / Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) / Ürün :**

**Model: Alfa Wassermann Starlyte III, Starlyte V**

### Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
AV-BP5016D	Fluid Pack	081140301AVBP5016D4R	Provides calibration points for electrodes.
AV-BP5186D	Fluid Pack	081140301AVBP5186D63	Provides calibration points for electrodes.
AV-BP0380D	Electrode Conditioning Solution	081140301AVBP0380D48	Conditions the Na <sup>+</sup> electrode.
AV-BP1025D	ISE Cleaning Solution	081140301AVBP1025D3F	Cleans the sample path.
AV-BP0521D	Deproteinizer Solution	081140301AVBP0521D3T	Removes protein from the sample flow path.
DD-92123	Blood Gas & Electrolyte Control Tri Level	081140301DD921239K	For quality control of Electrolyte Analyzers.
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
AV-BP0413D	Na <sup>+</sup> Electrode	081140301AVBP0413D3M	Measures Na <sup>+</sup> ions present in samples.
AV-BP0359D	K <sup>+</sup> Electrode	081140301AVBP0359D4L	Measures K <sup>+</sup> 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-BP5012D	Pinch Valve Tubing Kit	081140301AVBP5012D4D	Use with Electrolyte Analyzer.
AV-BP5006D	Sample Probe	081140301AVBP5006D4L	Aspirate sample.
AV-BP5025D	Printer Paper	081140301AVBP5025D4T	Print results.
AV-BP5019D	Reference Electrode Housing	081140301AVBP5019D52	Maintains proper flow of reference fluid and calibration standards to the reference electrode.
AV-BP5027D	Peristaltic Pump Tubing	081140301AVBP5027D4Z	Aids in fluid flow.
AV-BP5036D	Sample Sensor	081140301AVBP5036D53	Use with Electrolyte Analyzer.

**Manufacturer's Name:** Diamond Diagnostics Inc.

**Manufacturer's Address:** 333 Fiske Street  
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**(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* **Date:** 6 May, 2024  
Kathy Fisher  
Director, Quality Assurance

