

DECLARATION OF CONFORMITY

Diamond Diagnostics, Inc. hereby ensures and declares that the product(s) listed below comply with the requirements 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 المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الأوروبي المدرجة في
ن شركة داياموند دايانغونستكس تصرح و تؤكد أن التعليلة

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: IL Flame Photometer, IL ACL Coagulation, IL ACL Elite/Elite Pro

Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
IL-09756904D	Reference Emulsion	081140301IL09756904D7D	Used as a rinse solution and as the optical reference to compare with samples.
IL-20002400D	Reference Emulsion Wash Solution	081140301IL20002400DSS	Used as a rinse solution and as the optical reference to compare with samples.

Electrodes & Accessories

Part Number:	Device Name:	Basic UDI-DI	Intended Use
IL-06799200D	Sample Cups	081140301IL06799200D6C	Used to hold sample for testing
IL-18102002/1	Syringe Seal, Dilutor Block	081140301IL18102002/15G	Prevent leaks and ensure a secure, airtight connection within the syringe
IL-08007504D	Printer Paper	081140301IL08007504DYE	Print Results
IL-06800000D	Rotor	081140301IL06800000DXL	Controls the positioning of cuvettes in the instruments.

Manufacturer's Name: Diamond Diagnostics Inc.

Manufacturer's Address: 333 Fiske Street
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Tel: +1 (508) 429-0450

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(AR) Authorized Representative: Diamond Diagnostics Inc., Hungary Branch Office

(SRN) Single Registration Number: US-MF-000035435

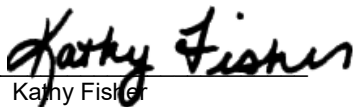
Risk Class: Class A, Rule 5

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
Director, Quality Assurance

Date: 6 May, 2024

