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 المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في
ن شركة دايموند دياغنوستكس تصرح و تؤكد أن التعليمة

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: Siemens Dimension XL, RXL, RXL Max, ARX, Xpand, Xpand Plus, EXL

Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
DA-S620D	Standard A	081140301DAS620DJS	Fluid used in the calibration process of IMT modules.
DA-S625D	Standard B	081140301DAS625DK9	Fluid used in the calibration process of IMT modules.
DA-S630D	Flush Solution	081140301DAS630DJX	Cleans the fluid path.
DA-S635D	Sample Diluent	081140301DAS635DKE	Dilutes samples.
DA-S640D	IMT Diluent Check	081140301DAS640DK4	Dilutes urine in IMT modules.
DA-D105D	Salt Bridge Solution	081140301DAD105DCP	Fluid solution allows for proper reference electrode function in the IMT modules.

DIAMOND
Smart Lab Solutions

Electrodes & Accessories

Part Number:	Device Name:	Basic UDI-DI	Intended Use
DA-D828D	Cuvette Cartridge	081140301DAD828DET	For use in clinical chemistry analyzers for the testing of patient samples, such as blood or urine. It relates to automatic chemical analyzers for directly measuring properties of reacted liquids by photometric systems to determine optical absorbency and or fluorescence of samples, thus producing qualitative and quantitative analyses of tested samples.
DA-D829D	Printer Paper	081140301DAD829DEW	Prints Results.

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 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

CE