

DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) c- dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostici in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics Inc 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعلية
ان شركة دايموند داياغنونستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che I prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispostivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 產品 (S) / Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) ;

Model: Diamond Diagnostics Unity

Reagent & Controls:

DD-61010 Cleaning Solution
DD-61011 Conditioner
DD-61012 Fluid Pack
DD-61013 Standard B

DD-61014 Fluid Pack with Standard B
AV-BP0380D Electrode Conditioning Solution
AV-BP0521D Deproteinizer

AV-BP0344D Urine Diluent
AV-BP1025D ISE Cleaning Solution

Electrodes & Accessories:

DD-61100 Pump
DD-61102 Pinch Valve
DD-61103 CPU Board
DD-61104 Electrode Cable

DD-62003 Na+ Electrode
DD-62004 K+ Electrode
DD-62005 Cl- Electrode
DD-61001 Reference Electrode

DD-61002 Reference Electrode Housing
DD-62006 Sample Sensor
DD-61105 Pump Head

(AR) Authorized Representative

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Authorized Officer: _____

Kathy Fisher
Kathy Fisher
Global Quality Manager

Date: 30 April, 2018

Quality Systems Registration

ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure

Annex III, Self-Declared

Manufacturer's name: Diamond Diagnostics Inc. (USA)
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Fax: +1 (508) 429-0452



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