

## 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) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic 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 المنجاة 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 dispositivi 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 SmartLyte/CareLyte/Gemlyte**

**Reagent & Controls:**

AV-BP5186D Fluid Pack AV-BP0521D Deproteinizer AV-BP1025D ISE Cleaning Solution  
AV-BP0380D Electrode Conditioning Solution AV-BP0344D Urine Diluent

**Electrodes & Accessories:**

AV-BP0413D Na+ Electrode AV-BP5027D Peristaltic Pump Tubing AV-BP5193D Pinch Valve Tubing Kit  
AV-BP0359D K+ Electrode AV-BP5006D Sample Probe AV-BP5014D Shutdown Kit  
AV-BP0570D Cl- Electrode AV-BP5036D Sample Sensor AV-BP5194D Startup Kit  
AV-BP0360D Ca++ Electrode AV-BP5019D Reference Electrode Housing AV-BP9043D Fillport Assembly  
AV-BP0962D Li+ Electrode AV-BP5025D Printer Paper  
AV-BP5026D Reference Electrode

**(AR) Authorized Representative**

Diamond Diagnostics Kft.  
6 Óradna Street  
1044 Budapest Hungary  
Tel: + 3617872222 Fax: + 3617872255

**Authorized  
Officer:**

  
Kathy Fisher  
Global Quality Manager

**Date:** 30 April, 2018

**Manufacturer's name:** Diamond Diagnostics Inc. (USA)

**Manufacturer's address:** 333 Fiske Street  
Holliston, MA 01746 USA  
Tel: +1 (508) 429-0450  
Fax: +1 (508) 429-0452

**Quality Systems Registration**

ISO 13485:2016  
ISO 9001:2015

**Conformity Assessment Procedure**  
Annex III, Self-Declared

