

## 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 Orvostechikai 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 التعليمات ان شركة دايموند دايانوستكس 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 ProLyte, Medica EasyLyte, ILyte, Menarini SpotLyte**

### Reagent & Controls:

IL-2121D Fluid Pack  
IL-2121D+ Fluid Pack  
IL-2123D Fluid Pack Na/K/Ca/pH  
ME-2121D Fluid Pack

MN-2121D Fluid Pack  
ME-2123D Fluid Pack  
ME-2118D Daily Rinse Kit  
ME-2309D Flush Solution

ME-2111D Urine Diluent  
ME-2492D Internal Filling Solution  
ME-2577D Urine Standard  
ME-2578D Red Test Dye

### Electrodes & Accessories:

ME-2102D Na+ Electrode  
ME-2101D K+ Electrode  
ME-2113D Cl- Electrode  
ME-2150D Ca++ Electrode  
ME-2258D Membrane Assembly  
ME-2257D Sample Detector

ME-2104D Pump Tubing  
ME-2108D Solutions Valve  
ME-2100D Calcium Tubing Kit  
ME-2323D Probe Wiper  
ME-2541D Printer Paper

ME-2572D Troubleshooting Service Kit  
ME-2095D Maintenance Kit  
ME-2107D Sample Probe  
ME-2106D Lithium Electrode  
ME-2103D Reference Electrode

Authorized  
Officer: \_\_\_\_\_

*Kathy Fisher*

Kathy Fisher  
Global Quality Manager

Date: 30 April, 2018

### (AR) Authorized Representative

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### Quality Systems Registration

ISO 13485:2016  
ISO 9001:2015

### Conformity Assessment Procedure

Annex III, Self-Declared

