

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 المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعلية ان شركة دايغونستكس 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) / 产品(S) / Produto(s) / Продукт(ы) / المنتج(ق) / Prodott(i) ;

Model: Roche Hitachi, Roche Modular, *Dirui Chemistry ISE Modules

Reagent & Controls:

BM-450043D ISE Diluent	BM-820639D KCL Electrolyte Solution	BM-1224310D CellClean Solution
BM-820637D ISE Diluent	BM-450042D ISE Internal Reference	BM-1489828D ISE Compensator
BM-820638D ISE Diluent	BM-836246D ISE Internal Reference	BM-1131079D System Cleaning Solution
BM-1135329D Hitergent Solution	BM-620427D ISE High Standard	BM-450041D KCL Electrolyte Solution
BM-409149D Hitergent Solution	BM-620428D ISE Low Standard	
BM-1131079D System Cleaning Solution		

Electrodes & Accessories:

BM-371037D Na+ Electrode	BM-7170551D Cuvettes	BM-7140570D Reagent Probe
BM-371038D K+ Electrode	BM-717035D Cuvettes	BM-7140575D Sample Probe
BM-372039D Cl- Electrode	BM-409186D Reaction Cuvette 24 Sections	BM-7671578D Reagent Probe
BM-704589D Reference Electrode	BM-7070212D Mixing Paddle	BM-7672193D Sample Probe
BM-373039D Reference Electrode	BM-7140602D Mixing Paddle	BM-7130202D Reagent Probe
BM-409041D Sample Cups	BM-7131264D Mixing Paddle	BM-7130201D Sample Probe
BM-7130282D Cuvettes	BM-7070926D Reagent Probe	BM-7170189D Reagent Probe
BM-409079D Halogen Lamp	BM-70703101D Sample Probe	BM-7170301D Sample Probe

(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

