DIAMOND
DIAGNOSTICS

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 Uniós 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklä 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 exigencies 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 requisites 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 التعليمة
ان شركة دايموند دياغنوستكس تصرح و تؤكد أن

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

Product(s) / Termékek / Produkt(e) / Produit(s) / Producto(s) / 产品 (S) / Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) ;

Model: Ciba Corning 2xx, 6xx

Reagent & Controls:

CD-471818D Ca++ Slope Solution
CD-473510D Fluids Pack
CD-473605D Fluids Pack
CD-473606D Slope Solution Li+
CD-473691D Fluids Pack
CD-473692D Slope Solution
CD-478541D Fluids Pack
CD-478548D Fluids Pack
CD-478855D 7.3 Buffer
CD-478856D 6.8 Buffer
CD-478857D Wash Solution
CD-478858D Wash Solution 2
CD-478859D tHb Solution
CD-478861D Wash Solution 1
CD-478864D Calibrator Solution
CD-478865D Slope Solution
CD-478868D Release Solution

(AR) Authorized Representative
Diamond Diagnostics Kft
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1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Authorized Officer: Kathy Fisher **Date:** 28 December, 2017
Kathy Fisher
Global Quality Manager

Quality Systems Registration
ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure
Annex III, Self-Declared

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