DIAMOND DIAGNOSTICS

SAO Y BẢN CHÍNH

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) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 产品 (S) / Produto(s) / Продукт (ы) / (ق) المنتج / Prodotti(i) ;

Model: Siemens Rapidlab Blood Gas

Reagent & Controls:

CD-473496D Buffer Pack
CD-473497D Wash Pack
CD-104227D Buffer Pack
CD-104226D Wash Pack
CD-473386D 6.8 Buffer
CD-473385D 7.3 Buffer
CD-570096D G/L Calibrator
CD-473387D Wash Zero Solution
CD-473389D Cleaning Solution C1/C2
CD-105610D Deproteinizer Solution
CD-478535D Na/K/Ca/Cl Filling Solution
CD-478533D pH Filling Solution
CD-478822D Reference Filling Solution
CD-478701D Conditioning Solution
CD-105670D Hct Slope Solution
CD-673390D Activated Glutaraldehyde Solution
CD-570405D Hct Level A
CD-570406D Hct Level B
CD-570097D High G/L
DD-92001 Mission Control Level 1
DD-92002 Mission Control Level 2
DD-92003 Mission Control Level 3
DD-92004 Mission Control Level 4
DD-92123 Mission Control Tri Level
DD-96001 Mission Trinity B I Level 1
DD-96002 Mission Trinity B Level 2
DD-96003 Mission Trinity B Level 3
DD-96123 Mission Trinity B Level 1-2-3
DD-92900 Mission Complete Linearity Control

Electrodes & Accessories:

CD-476247 pCO2 Electrode
CD-476246 pO2 Electrode
CD-476267D pH Electrode
CD-476266D Na+ Electrode
CD-476270D K+ Electrode
CD-476268D Ca++ Electrode
CD-476279D Cl- Electrode
CD-476273D Reference Electrode
CD-673705D Pump Tubing
CD-105673D Sample/Reagent Pump Tubing
CD-673358D Pump Tubing
CD-673709D Printer Paper
CD-673252D Printer Paper
DD-0019-4 Slope Gas, 10% CO2 Bal N2
DD-0018-4Calibration Gas, 5% CO2 12% O2 Bal N2
CD-105070D Cal/Slope Gas, 348

(AR) Authorized Representative
Diamond Diagnostics Kft.
6 Óradna Street
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

CE

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

CÔNG TY TRÁCH NHIỆM HỮU HẠN TRANG THIẾT BỊ Y TẾ MAI ĐÔNG Q. TÂN BÌNH - TP. HỒ CHÍ MINH

GIÁM ĐỐC
KS.ĐẶNG NGỌC ĐẠM

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Authorized Officer: Kathy Fisher **Date:** 28 December, 2017
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