

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 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: Beckman CX, CX Delta, CX Pro Series

Reagent & Controls:

BK-A17652D Electrolyte Buffer	BK-450224D Total Protein Reagent	BK-465910D Calibrator 3
BK-A17657D Electrolyte Reference Solution	BK-476015D Probe Rinse Solution	BK-443355D Glucose Reagent
BK-A17647D CO2 Acid Reagent	BK-445865D Wash Concentrate II	BK-671640D Glucose Reagent
BK-443320D CO2 Alkaline Buffer	BK-443365D Calibration Standard 2	BK-664180D Creatinine Reagent Kit
BK-443335D Wash Concentrate	BK-667670D BUN Reagent	BK-443355D Glucose Reagent
BK-443340D Creatinine Reagent	BK-443360D Calibration Standard 1	BK-443340D Creatinine Reagent
BK-443350D BUN Reagent	BK-465908D Calibrator 1	
BK-450890D Calcium Reagent	BK-465909D Calibrator 2	

Electrodes & Accessories:

BK-668295D Na+ Electrode	BK-659895D CO2 Membrane Retainer	BK-447973D Preventive Maintenance Kit
BK-467769D Ca++ Electrode	BK-661750D CO2 Membrane	BK-450661D Lamp Source Ca/Creatinine/TP
BK-441930D Cl- Electrode	BK-670597D Glucose Electrode Membrane	BK-758383D Mixing Paddle
BK-660318D CO2 Electrode	BK-442906D Green Pump Tubing	BK-464786D Reagent Probe (N)
BK-469499D Glucose Electrode, Accusense	BK-669147D Grey Pump Tubing	BK-464791D Sample Probe (N)
BK-651940D BUN Electrode	BK-651870D Red Pump Tubing	BK-652730D Sample Cups
BK-669114D K+ Electrode	BK-949946D Compressor Rebuild Kit	BK-448974D Syringe Plunger 500 uL
BK-669115D K+ Body Electrode	BK-447972D Preventive Maintenance Kit	BK-448945D Syringe Plunger 50 uL
BK-669117D K+ Tip Electrode	BK-447970D Preventive Maintenance Kit	BK-A44148D Compressor Service Kit

(AR) Authorized Representative

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

Authorized Officer:

Kathy Fisher

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

