

DECLARATION OF CONFORMITY

Diamond Diagnostics, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of In Vitro Diagnostics Medical Devices Regulation EU 2017/746 and Directive 2011/65/EU.

Diamond Diagnostics Inc. ezúton biztosítja és kijelenti, hogy az alább felsorolt termék(ek) megfelelnek az In Vitro Diagnostics Medical Devices EU 2017/46 rendelet és a 2011/65/EU irányelv követelményeinek.

Diamond Diagnostics Inc. versichert und erklärt hiermit, dass das/die unten aufgeführte(n) Produkt(e) den Anforderungen der In-vitro-Diagnostik-Medizinprodukte-Verordnung EU 2017/46 und der Richtlinie 2011/65/EU entsprechen.

Diamond Diagnostics Inc. garantit et déclare par la présente que le ou les produits répertoriés ci-dessous sont conformes aux exigences du règlement sur les dispositifs médicaux de diagnostic in vitro UE 2017/46 et de la directive 2011/65/EU.

Diamond Diagnostics Inc. por la presente garantiza y declara que los productos enumerados a continuación cumplen con los requisitos del Reglamento de dispositivos médicos de diagnóstico in vitro EU 2017/46 y la Directiva 2011/65/EU.

Diamond Diagnostics Inc. 特此确保并声明下列产品符合体外诊断医疗器械法规 EU 2017/46 和指令 2011/65/EU 的要求。

Diamond Diagnostics Inc. garante e declara que o(s) produto(s) listado(s) abaixo cumpre(m) o requisito do Regulamento de Dispositivos Médicos de Diagnóstico In Vitro EU 2017/46 e Diretiva 2011/65/EU.

Diamond Diagnostics Inc. гарантирует и заявляет, что продукты, перечисленные ниже, соответствуют требованиям Регламента ЕС 2017/46 о медицинских устройствах для диагностики in vitro и Директивы 2011/65/EU.

Vitro Diagnostica Medical Regulation 2017/746 and Directive 2011/65/EU المنجاة المذكورة أدناه تتوافق مع متطلبات الاتحاد الأوروبي المدرجة في
ن شركة داياموند دايانغونستكس تصرح و تؤكد أن التعليم

Diamond Diagnostics Inc. garantisce e dichiara che i prodotti elencati di seguito sono conformi ai requisiti del Regolamento UE 2017/46 sui dispositivi medici per la diagnostica in vitro e della Direttiva 2011/65/EU.

Diamond Diagnostics, Inc. işbu belge ile aşağıda listelenen ürün(ler)in In Vitro Diagnostics Tıbbi Cihazlar Yönetmeliği EU 2017/746 ve Direktif 2011/65/EU gerekliliklerine uygun olduğunu garanti ve beyan eder.

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

Model: Mission Controls

Quality Controls

Device Name:	Part Number:	Basic UDI-DI	Intended Use
DD-92001	Mission Control Level 1	081140301DD9200194	For the quality control of pH/Blood gas and Electrolyte Analyzers
DD-92002	Mission Control Level 2	081140301DD9200296	For the quality control of pH/Blood gas and Electrolyte Analyzers
DD-92003	Mission Control Level 3	081140301DD9200398	For the quality control of pH/Blood gas and Electrolyte Analyzers
DD-92004	Mission Control Level 4	081140301DD920049A	For the quality control of pH/Blood gas and Electrolyte Analyzers
DD-92123	Mission Control Level 1-2-3	081140301DD921239K	For the quality control of pH/Blood gas and Electrolyte Analyzers
DD-92900	Mission Complete Linearity Control	081140301DD92900AF	For monitoring performance of blood gas, electrolyte and matabolyte analyzers.
DD-96001	Mission Trinity B Level 1	081140301DD960019Y	For quality control of pH, Blood Gas and Electrolyte Analyzers

DD-96002	Mission Trinity B Level 2	081140301DD96002A2	For quality control of pH, Blood Gas and Electrolyte Analyzers
DD-96003	Mission Trinity B Level 3	081140301DD96003A4	For quality control of pH, Blood Gas and Electrolyte Analyzers
DD-96123	Mission Trinity B Level 1-2-3	081140301DD96123AF	For quality control of pH, Blood Gas and Electrolyte Analyzers
DD-97001	Mission Trinity R Level 1	081140301DD97001A7	For quality control of pH, Blood Gas and Electrolyte Analyzers
DD-97002	Mission Trinity R Level 2	081140301DD97002A9	For quality control of pH, Blood Gas and Electrolyte Analyzers
DD-97003	Mission Trinity R Level 3	081140301DD97003AB	For quality control of pH, Blood Gas and Electrolyte Analyzers
DD-97123	Mission Trinity R Level 1-2-3	081140301DD97123AN	For quality control of pH, Blood Gas and Electrolyte Analyzers

Manufacturer's Name: Diamond Diagnostics Inc.

Manufacturer's Address: 333 Fiske Street
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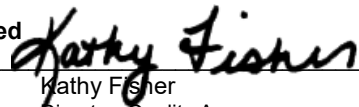
(SRN) Single Registration Number: US-MF-000035435

Risk Class: Class A, Rule 5

Conformity Assessment Procedure: Annex IV, Self-Declared

Notified Body: N/A

Quality Systems Registration: ISO 9001:2015
ISO 13485:2016
EN ISO 9001:2015
EN ISO 13485:2016

Authorized Officer: 
Kathy Fisher
Director, Quality Assurance

Date: 6 May 2024

