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 المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في
ن شركة دايموند دياغنوستكس تصرح و تؤكد أن التعليمة

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: Siemens Rapidlab Blood Gas

Reagent & Controls

Part Number	Device Name:	Basic UDI-DI	Intended Use
CD-473496D	Buffer Pack	081140301CD473496DC7	Provide calibration points for the pH electrode
CD-473497D	Wash Pack	081140301CD473497DCA	Clean the sample path for Blood Gas Analyzer.
CD-104227D	Buffer Pack	081140301CD104227D6N	Provide calibration point(s) for the Na+, K+, Cl-, Ca++, pH, and hematocrit electrodes.
CD-104226D	Wash Pack	081140301CD104226D6K	Clean the sample path for Blood Gas Analyzer.
CD-105610D	Deproteinizer Solution	081140301CD105610D73	Remove protein build-up from sample flow path.
CD-478535D	Na/K/Ca/Cl Filling Solution	081140301CD478535DD4	Refill electrodes used on analyzers.
CD-478533D	pH Filling Solution	081140301CD478533DCW	Refill the pH electrode used on analyzers.
CD-478822D	Reference Fill Solution	081140301CD478822DDB	For use on Chiron Blood Gas/ISE Analyzers.
CD-478701D	Conditioning Solution	081140301CD478701DCP	Clean and Condition the Na+ and/or pH electrodes on the Ciba-Corning Analyzers.
CD-105670D	Hct Slope Solution	081140301CD105670D7Z	Solution standard for calibration of instrumentation.

DD-92001	Mission Control Level 1	081140301DD9200194	Monitors the measurements of pH pCO2, pO2 in blood gas analyzers and Na+, K+, Cl-, Li+, Ca++ and CO2 in ISE electrolyte analyzers.
DD-92002	Mission Control Level 2	081140301DD9200296	Monitors the measurements of pH pCO2, pO2 in blood gas analyzers and Na+, K+, Cl-, Li+, Ca++ and CO2 in ISE electrolyte analyzers.
DD-92003	Mission Control Level 3	081140301DD9200398	Monitors the measurements of pH pCO2, pO2 in blood gas analyzers and Na+, K+, Cl-, Li+, Ca++ and CO2 in ISE electrolyte analyzers.
DD-92004	Mission Control Level 4	081140301DD920049A	Monitors the measurements of pH pCO2, pO2 in blood gas analyzers and Na+, K+, Cl-, Li+, Ca++ and CO2 in ISE electrolyte analyzers.
DD-92123	Mission Control Tri Level	081140301DD921239K	For quality control of Analyzers
DD-96001	Mission Trinity B I Level 1	081140301DD960019Y	For quality control of Analyzers
DD-96002	Mission Trinity B Level 2	081140301DD96002A2	For quality control of Analyzers
DD-96003	Mission Trinity B Level 2	081140301DD96003A4	For quality control of Analyzers
DD-96123	Mission Trinity B Level 1-2-3	081140301DD96123AF	For quality control of Analyzers
DD-92900	Mission Complete Linearity Control	081140301DD92900AF	Confirms the calibration and linearity of Analyzers.

Electrodes & Accessories

Part Number	Device Name:	Basic UDI-DI	Intended Use
CD-476247	pCO2 Electrode	081140301CD4762479H	Measures partial CO2 concentration in a sample
CD-476246	pO2 Electrode	081140301CD4762469F	Measures partial O2 concentration in a sample
CD-476267D	pH Electrode	081140301CD476267DCE	Measures the levels of pH in the sample.
CD-476273D	Reference Electrode	081140301CD476273DC7	Completes the electrical circuit between the reference electrolyte and electrical ground.
CD-105673D	Reagent Pump Tubing	081140301CD105673D8A	Aide in fluid flow
CD-673252D	Printer Paper	081140301CD673252DBT	Print results
DD-0019-4	Slope, 10% CO2 Bal N2	081140301DD001946R	Test gas/Calibration gas
DD-0018-4	Calibration Gas, 5% CO2 12% O2 Bal N2	081140301DD001846N	Test gas/Calibration gas
CD-105070D	Cal/Slope Gas, 348	081140301CD10570D6P	Gas standard for calibration of instrumentation.

DIAMOND
Smart Lab Solutions

Manufacturer's Name:	Diamond Diagnostics Inc.
Manufacturer's Address:	333 Fiske Street Holliston, MA 01746 Tel: +1 (508) 429-0450 Diamond Diagnostics Inc. Hungary Branch Office 6 Oradna Street 1044 Budapest, Hungary Tel: + 3617872222
(AR) Authorized Representative:	Diamond Diagnostics Inc., Hungary Branch Office
(SRN) Single Registration Number:	US-MF-000035435
Risk Class:	Class A, Rule 5
Conformity Route:	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 **Date:** 6 May, 2024

Kathy Fisher
Director, Quality Assurance

CE