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: Biotecnica Targa 3000, 3000 Plus, Elan Atac 8000

Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
BT-6620941D	ISE Reference Solution	081140301BT6620941DT3	Fluid used for the calibration of the ISE equipment, specifically the reference electrode.
BT-6620942D	ISE Buffer	081140301BT6620942DT6	Fluid used in the calibration and measurement process of ISE equipment.
BT-6620945D	Enzymatic Wash Kit	081140301BT6620945DTF	Wash kit with enzymes
BT-6620940SD	ISE Wash Solution	081140301BT6620940SD8F	To clean the sample path
BT-6620943D	ISE Calibrator Low	081140301BT6620943DT9	Provides calibration points for electrodes.
BT-6620944D	ISE Calibrator High	081140301BT6620944DTC	Provides calibration points for electrodes.

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