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 2017/746 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 2017/746 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 2017/746 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 2017/746 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 2017/746 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 2017/746 e Diretiva 2011/65/EU.

Diamond Diagnostics Inc. гарантирует и заявляет, что продукты, перечисленные ниже, соответствуют требованиям Регламента ЕС 2017/746 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 2017/746 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: Olympus Chemistry, Beckman AU400, AU480, AU640, AU680, AU2700, AU5200, AU5400, AU5800

Reagent & Controls

Part Number:	Device Name:	Basic UDI-DI	Intended Use
BK-AUH1011D	ISE Buffer	081140301BKAUH1011DGZ	For the quantitative determination of Na+, K+, and Cl- concentrations in human serum and urine.
BK-AUH1012D	ISE Mid-Standard	081140301BKAUH1012DH4	For the quantitative determination of Na+, K+, and Cl- concentrations in human serum and urine.
BK-AUH1013D	ISE Reference Solution	081140301BKAUH1013DH7	For the quantitative determination of Na+, K+, and Cl- concentrations in human serum and urine.
BK-AUH1014D	ISE Low Standard	081140301BKAUH1014DHA	To provide calibration points for the Na+, K+, Cl- electrodes in human serum mode on Beckman Analyzers.
BK-AUH1015D	ISE High Standard	081140301BKAUH1015DHD	To provide calibration points for the Na+, K+, Cl- electrodes in human serum mode on Beckman Analyzers.
BK-AUH1016D	Low/High Urine Standard	081140301BKAUH1016DHG	To provide calibration points for the Na+, K+, Cl- electrodes in human serum mode on Beckman Analyzers.

Part Number:	Device Name:	Basic UDI-DI	Intended Use
BK-AUH1017D	ISE Internal Reference Solution	081140301BKAUH1017DHK	Reference Fill Solution for use on Beckman AU systems.
BK-AUH1018D	ISE Na/K Selectivity Check Solution	081140301BKAUH1018DHN	To provide calibration points for the Na+, K+, Cl- electrodes in human serum mode on Beckman AU Analyzers.
BK-AUH1019D	ISE Cleaning Solution	081140301BKAUH1019DHR	For ISE Cleaning procedure on Beckman Analyzers.
BK-OSR0001D	Wash Solution 2L	081140301BKOSR0001DTT	For ISE Wash on AU Analyzers.
BK-ODR2000D	Wash Solution 5L	081140301BKODR2000DLF	For ISE Wash on AU Analyzers.

Electrodes & Accessories

Part Number:	Device Name:	Basic UDI-DI	Intended Use
BK-B16554/1D	Seal, Wash Syringe Type 2 Assembly	081140301BKB165541DSX	Use with the Beckman AU Analyzer.
BK-B53167D	Liquid Cooler, TE Tech	081140301BKB53167DLP	Use with the Beckman AU Analyzer.
BK-MU6901D	Liquid Cooler, Peltier	081140301BKMU6901D8H	Use with the Beckman AU Analyzer.
BK-MU8267D	Mixer Paddle L R2	081140301BKMU8267D96	Used to mix samples
BK-MU8550D	Lamp, Photometer	081140301BKMU8550D8Z	Functions as a light source
BK-MU8554D	Mixer Paddle, Spiral, 3pk	081140301BKMU8554D9D	Used to mix samples
BK-MU8555D	Mixer Paddle, L-Shaped, 3pk	081140301BKMU8555D9G	Used to mix samples
BK-MU9194D	Na+ Electrode	081140301BKMU9194D9G	Use with the Beckman AU Analyzer.
BK-MU9195D	K+ Electrode	081140301BKMU9195D9K	Use with the Beckman AU Analyzer.
BK-MU9196D	Cl- Electrode	081140301BKMU9196D9N	Use with the Beckman AU Analyzer.
BK-MU9197D	Reference Electrode	081140301BKMU9197D9R	Use with the Beckman AU Analyzer.
BK-MU9599D	Mixing Paddle Spiral	081140301BKMU9599DAT	Used to mix samples
BK-MU9602D	Dry Nozzle	08114030l081140301BK	Use with the Beckman AU Analyzer.
BK-MU9623D	Pump Tubing	081140301BKMU9623D9D	Aide in fluid flow
BK-MU9888D	Photometer Lamp	081140301BKMU9888DB8	Functions as a light source
BK-MU9934D	Sample Probe	081140301BKMU9934DAA	Aspirate sample
BK-MU9958D	Reagent Probe	081140301BKMU9958DAY	Aspirate reagent
BK-ZM0016D	Wash Syringe, E Type, Assembly	081140301BKZM0016D8R	Use with the Beckman AU Analyzer.
BK-ZM0111/1	Sample Syringe Seal	081140301BKZM011117D	Use with Beckman Systems.
BK-ZM0111D	Sample Syringe Beckman	081140301BKZM0111D8H	Use with Beckman Systems.
BK-ZM0112/1	Reagent Syringe Seal	081140301BKZM011217G	Use with Beckman Systems.
BK-ZM0112D	ISE/Reagent Syringe	081140301BKZM0112D8L	Use with Beckman Systems.
BK-ZM0635D	Halogen Lamp	081140301BKZM0635DAA	Functions as a light source
BK-ZM2970D	Tubing, ISE Pinch Valve	081140301BKZM2970DBS	Aide in fluid flow
BK-ZM3079D	DI Water Filter	081140301BKZM3079DAZ	Use with Beckman Systems.
OY-ZM001800D	G Syringe	081140301OYZM001800DRR	Used to draw up sample

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:** 9 July, 2026

Kathy Fisher
Director, Quality Assurance

CE