Tiêu chuẩn chủ sở hữu công bố áp dụng

Tài liệu được xác nhận bằng chữ ký số và có hiệu lực kể từ ngày ký.

Hà Nội, ngày 11 tháng 6 năm 2019

Người đại diện hợp pháp của cơ sở

Digitally signed by CÔNG TY
TNHH KỸ THUẬT NAM PHƯƠNG

Giám đốc
Trịnh Diệu Hương

Trinity Biotech

YOUR DIAGNOSTICS PARTNER

EC Declaration of Conformity

(English Only)

The products listed below conform to the:

In Vitro Diagnostic Medical Devices Directive 98/79/EC according to Annex III of the IVDD

Trinity Biotech declares that the diagnostic instruments, reagents, and control materials listed in the schedule below are classified as "General IVD Products" according to annex rules and conforms to the relevant provisions of the EC Council Directive 98/79/EC and Annex III, except Section 6, of the IVDD as implemented by the European Union's Medical Devices Regulations. GMDN Code: 43198. EDMA (GIVD) Code: 12 06 01 06.

Schedule of Products Covered by this Declaration:

Description: **Ultra2 Affinity HbA1c System**
- Analytical Column, Reagents, Calibrator and Controls

Column:	Affinity Analytical Column	REF: 03-02-0079
Reagents:	Ultra2 Buffer 2A Reagent (3.8 L)	REF: 01-03-0054
	Ultra2 Buffer 2A Reagent (940 mL)	REF: 01-03-0053
	Ultra2 Buffer B Reagent (3.8 L)	REF: 01-03-0012
	Ultra2 Buffer B Reagent (940 mL)	REF: 01-03-0011
	2 Diluent Reagent (3.8 L)	REF: 01-03-0056
	2 Diluent Reagent (940 mL)	REF: 01-03-0059
	System Wash Reagent (940 mL)	REF: 01-03-0035
Calibrators	HbA1c (GHb) Calibrator Kit, 500µL (Levels 1 & 2)	REF: 01-04-0022
	HbA1c (GHb) Calibrator Kit, 400µL (Levels 1 & 2)	REF: 01-04-0018
Controls:	HbA1c (GHb) Control Kit, 500µL (Levels 1 & 2)	REF: 01-04-0020
	HbA1c (GHb) Control Kit, 400µL (Levels 1 & 2)	REF: 01-04-0015
Misc:	Enzyme Cleaner Tube	REF: 01-12-0001
Reagent Kit:	Ultra2 Affinity A1c 3000	REF: 01-04-0080

Manufacturer
Name: Trinity Biotech
(Primus Corporation dba Trinity Biotech)
Address: 4231 E. 75th Terrace
Kansas City, Missouri 64132
Country: USA

Authorized Representative
Name: Trinity Biotech, Plc.
Address: IDA Business Park
Bray, Co. Wicklow
Country: Ireland
T+ 353 1 276 9800

Trinity Biotech agrees to develop, implement, and maintain a documented post-production monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

The Trinity Biotech-Kansas City Quality Management System is ISO certified under ISO13485:2003 certificate number MED-0141.

No medicinal products or drugs are incorporated into any of the devices listed.

Designated representative:

Britt Einspahr	Manager of QA & Compliance	22 July 2016
	Title/Position	Date