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24<sup>th</sup> February 2020

CERTIFICATE OF FREE SALE

To Whom It May Concern

The Health Products Regulatory Authority hereby certifies that:

- 1) Trinity Biotech plc, IDA Business Park, Southern Cross Road, Bray, Co Wicklow, Ireland is the authorised representative for the in-vitro diagnostic medical devices specified in the attached schedule. These devices are manufactured by Trinity Biotech (Primus Corporation dba Trinity Biotech), 4231 E., 75<sup>th</sup> Terrace, Kansas City, MO USA 64132.
2) The in-vitro diagnostic medical devices specified in the attached schedule are CE marked in accordance with the European Communities (In-vitro Diagnostic Medical Device) Regulations, 2001 (which transposed the In-vitro Diagnostic Medical Devices Directive 98/79/EC into Irish law) and may be marketed and sold in Ireland.
3) Exportation of the in-vitro diagnostic medical devices listed in the attached schedule is not prohibited.
4) The granting of this certificate is based on the information available to the Health Products Regulatory Authority on the date of issue of the certificate.

Issued To: Trinity Biotech plc IDA Business Park Southern Cross Road Bray Co. Wicklow Ireland

Expiry Date: 24<sup>th</sup> February 2025

Patrick Keating Compliance Department Health Products Regulatory Authority


CFS010715

Seen for the authentication of signature/seal of Patrick Keating Health Products Regulatory Authority Signed MSewell Position eo Date 26/03/2020





CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia: **Việt Nam**  
Country
- Giấy tờ, tài liệu này  
*This public document*
2. do Ông (Bà): **Matthew Sewell** ký  
*has been signed by*
3. với chức danh: **Cán bộ lãnh sự**  
*acting in the capacity of*
4. và con dấu của **Bộ Ngoại giao và Thương mại Ai-len**  
*bears the stamp of*
- được chứng nhận / hợp pháp hóa lãnh sự  
*Certified*
5. tại **London** 6. Ngày **20/ 07/ 2020**  
*at the*
7. Cơ quan cấp: Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len  
*by*
8. Số: **2620**  
*Nº*
- Ký tên và đóng dấu  
Signature and seal/stamp  
Tham tán Công sứ  
Minister Counsellor
-   
Nguyễn Thị Lan Anh



## MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
01-03-0019	Genesys Diluent Reagent, 3.8L
01-05-0017	Genesys Analytical Column
01-03-0020	Genesys 1 Reagent, 3.8 L
01-03-0022	Genesys 2 Reagent, 3.8 L
01-03-0056	2 Diluent Reagent, 3.8 L
01-03-0059	2 Diluent Reagent, 940 mL
01-03-0035	System Wash Reagent, 940 mL
01-04-0043	A2+F Control Material Kit
03-06-0010	Tri-stat Reagent Kit
03-06-0011	Tri-stat Liquid Controls Kit
01-03-0054	ultra2 Buffer 2A Reagent, 3.8 L
01-03-0053	ultra2 Buffer 2A Reagent, 940 mL
01-03-0012	ultra2 Buffer B Reagent, 3.8 L
01-03-0011	ultra2 Buffer B Reagent, 940 mL
03-02-0079	Affinity Analytical Column
01-12-0001	Enzyme Cleaner Tube
01-03-0064	PDQ 1 Reagent, 940 mL
01-03-0065	PDQ 2 Reagent, 940 mL
01-03-0066	PDQ Diluent Reagent, 940 mL
01-03-0067	PDQ Wash Reagent, 940 mL
01-03-0040	Mobile Phase 1 Reagent, 3.8 L
01-03-0042	Mobile Phase 1 Reagent, 940 mL
01-03-0041	Mobile Phase 2 Reagent, 3.8 L
01-03-0044	Mobile Phase 2 Reagent, 940 mL
01-04-0042	FASC Position Marker Kit
01-05-0015	Resolution Analytical Column
01-04-0018	HbA1c (GHb) Calibrator Kit, Level 1 & Level 2, 400µL
01-04-0015	HbA1C (GHb) Controls Level I & Level II, 400µL
01-03-0098	Premier Wash Reagent 940ml
01-03-0097	Premier Diluent Reagent, 3.8L
01-03-0096	Premier Buffer B Reagent, 940 mL
01-03-0081	Premier Buffer B Reagent, 3.8 L
01-03-0095	Premier Buffer A Reagent, 940 mL
01-03-0080	Premier Buffer A Reagent, 3.8 L
09-06-0046	Premier Hb9210 HbA1c Analytical Column (1000)
09-06-0050	Premier Hb9210 HbA1c Analytical Column (500)
09-03-0010	Premier Affinity A1c 1000
09-03-0008	Premier Affinity A1c 500
09-00-0001	Premier Hb9210 HbA1c Analyzer
09-03-0007	Premier Affinity A1c 3000
01-04-0022	HbA1C (GHb) Calibrator Kit, 500µL (Levels 1 & 2)
01-04-0020	HbA1c (GHb) Controls Kit, 500µL (Levels I & II)
01-03-0093	Premier Resolution Piston Wash Reagent (940mL)
01-04-0046	Premier Resolution FASC Position Marker Kit
01-04-0045	Premier Resolution A2+F Control Kit
01-04-0044	Premier Resolution A2+F Calibrator Kit

## MEDICAL DEVICE SCHEDULE

<b>Item Number/Product Code</b>	<b>Description of Device</b>
01-03-0085	Premier Resolution Mobile Phase 2 Reagent (3.8L)
01-03-0084	Premier Resolution Mobile Phase 1 Reagent (3.8L)
10-06-0006	Premier Resolution Analytical Column
10-00-0001	Premier Resolution Analyzer
01-03-0088	Premier Resolution Wash Reagent (940mL)
01-03-0087	Premier Resolution Diluent Reagent (3.8L)
11-00-0001	TLA Premier Hb9210 HbA1c Analyzer
09-03-0018	Premier Hb9210 HbA1c Reagent Pack (500)
09-03-0017	Premier Hb9210 HbA1c Reagent Pack (1000)
01-04-0079	PDQ 800 Reagent Pack
B01-04-0081	ultra 2 Genesys 3000 Reagent Kit
B01-04-0078	ultra 2 Variant 1000 Reagent Kit
03-06-0072	Tri-stat Reagent Kit (90)
03-06-0071	Tri-stat Reagent Kit (60)
03-06-0070	Tri-stat Reagent Kit s(30)
01-05-0011	ultra2 Resolution Analytical Column
03-06-0002	Tri-stat 2 Analyzer
10-06-0006	Premier Resolution Analytical Column
01-03-0082	Premier Resolution Mobile Phase 1 Reagent, 940mL
<b>01-03-0083</b>	<b>Premier Resolution Mobile Phase 2 Reagent, 940 mL</b>