Trinity Biotech

YOUR DIAGNOSTICS PARTNER

EC Declaration of Conformity

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. The GMDN code is 30838.

Schedule of Products Covered by this Declaration:

Description: Premier Hb9210 Hemoglobin A1c HPLC Testing
- Instrument, Analytical Column, Reagents, Calibrator and Controls

Instrument:	Premier Hb9210 HbA1c Analyzer	REF: 09-00-0001
Columns:	Premier HbA1c Analytical Column (1000)	REF: 09-06-0046
	Premier HbA1c Analytical Column (500)	REF: 09-06-0050
Reagents:	Premier Hb9210 Buffer A Reagent (940 mL)	REF: 01-03-0095
	Premier Hb9210 Buffer A Reagent (3.8L L)	REF: 01-03-0080
	Premier Hb9210 Buffer B Reagent (940 mL)	REF: 01-03-0096
	Premier Hb9210 Buffer B Reagent (3.8L L)	REF: 01-03-0081
	Premier Hb9210 Diluent Reagent (3.8 L)	REF: 01-03-0097
	Premier Hb9210 Wash Reagent (940 mL)	REF: 01-03-0098
Calibrators:	HbA1c (GHb) Calibrator Kit, 500uL (Levels 1 & 2)	REF: 01-04-0022
	HbA1c (GHb) Calibrator Kit, 400uL (Levels 1 & 2)	REF: 01-04-0018
Controls:	HbA1c (GHb) Control Kit, 500uL (Levels I & II)	REF: 01-04-0020
	HbA1c (GHb) Control Kit, 400uL (Levels I & II)	REF: 01-04-0015
Reagent Kits:	Premier Affinity A1c 3000	REF: 09-03-0007
	Premier Affinity A1c 1000	REF: 09-03-0010
	Premier Affinity A1c 500	REF: 09-03-0008

Manufacturer		Authorized Representative	
Name:	Trinity Biotech *(Primus Corporation dba Trinity Biotech)*	Name:	Trinity Biotech, Plc.
Address:	4231 E. 75th Terrace Kansas City, Missouri 64132	Address:	IDA Business Park Bray, Co. Wicklow
Country:	USA	Country:	Ireland
		Phone:	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 and ISO9001:2008 with certificate numbers MED-0141 and US-2425g.

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

Designated representative:

Britt Einspahr	Manager of QA & Compliance	27 JAN 14
	Title/Position	Date

Digitally signed by Chirița Alexandru
Date: 2021.03.03 09:06:42 EET
Reason: MoldSign Signature
Location: Moldova