

**Declaration of
Conformity**

Trinity Biotech
(Primus Corporation dba Trinity Biotech)
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The undersigned hereby declares that the products described below are in conformity with the relevant Community harmonization legislation as follows:

Directive 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical devices, as amended by Directive 2011/100/EU of 20 December 2011 and its transposition into Irish Law under SI Number 304 of 2001 IVD Medical Devices.

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

And that the relevant harmonized standards referenced below have been applied:

ISO 13485:2016	Medical Device Quality Management Systems
ISO 14971:2012	Risk Management for Medical Devices
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
IEC 61010-1:2010	Safety Requirements for Electrical Equipment for Laboratory Use
IEC 61010-2-010:2014	Particular Requirements for Heating of Materials
IEC 61010-2-101:2015	Particular Requirements for In-vitro Diagnostic Medical Equipment
IEC 62304:2006	Medical Device Software Life Cycle Processes
NB-MED/2.2/Rec4	Software and Medical Devices

Product of the Declaration:

Description: Premier Hb9210 HbA1c System – Analyzer, reagents and analytical column.
(Note: Calibrator and controls are listed on a separate declaration.)

Product Codes: A listing of related product codes is provided on the next page.

GMDN Code: 35968 and 53316

GMDN Term: Glycated haemoglobin (HbA1c) analyzer IVD, Glycated haemoglobin (HbA1c) IVD, reagent

Intended Use: For in vitro diagnostic quantitative determination of haemoglobin A1c (HbA1c) in whole blood from venous draw and finger stick. HbA1c is useful to health care providers in the monitoring of long-term glycemic control in individuals with diabetes mellitus. For *in vitro* diagnostic use only.

The conformity assessment procedure follows that described in Annex III (excluding section 6) of Directive 98/79/EC. The Premier Hb9210 HbA1c System and accessories do not appear on the Annex II List A or B and is not for self-test.

Product Codes:

REF	Alternate Branding REF	Description	Unit / Size	UDI-DI (GTIN)
09-00-0001	42790	Premier Hb9210 HbA1c Analyzer	1 Each	05391516744751
11-00-0001	48284	TLA Premier Hb9210 HbA1c Analyzer	1 Each	05391516749466
09-06-0046	45404	Premier Hb9210 HbA1c Analytical Column (1000)	1 Column	05391516748056
09-06-0050	49254	Premier Hb9210 HbA1c Analytical Column (500)	1 Column	05391516748063
01-03-0095	42663	Premier Buffer A Reagent	940 mL	05391516744768
01-03-0080	45065	Premier Buffer A Reagent	3.8L L	05391516748094
01-03-0096	42664	Premier Buffer B Reagent	940 mL	05391516744775
01-03-0081	45066	Premier Buffer B Reagent	3.8 L	05391516748100
01-03-0097	42666	Premier Diluent Reagent	3.8 L	05391516744782
01-03-0098	42665	Premier Wash Reagent	940 mL	05391516744799
<i>Not Used</i>	49255	Premier Hb9210 HbA1c Column Pack (3000)	1 Pack	05391516749596
09-03-0007	<i>Not Used</i>	Premier Affinity A1c 3000 Reagent Pack	1 Pack	05391516748148
09-03-0010	<i>Not Used</i>	Premier Affinity A1c 1000 Reagent Pack	1 Pack	05391516748131
09-03-0008	<i>Not Used</i>	Premier Affinity A1c 500 Reagent Pack	1 Pack	05391516748124
09-03-0017	<i>Not Used</i>	Premier Hb9210 HbA1c Reagent Pack (1000)	1 Pack	05391516749473
09-03-0018	<i>Not Used</i>	Premier Hb9210 HbA1c Reagent Pack (500)	1 Pack	05391516749480

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Trinity Biotech of Kansas City, Missouri USA. Valid date of this certificate: 2019-09-18. For, and on behalf of, Trinity Biotech-Kansas City:

Signature:




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Full Name: Britt Einspahr Position: Manager of Quality Assurance Date: 2019-09-18