

CE DECLARATION OF CONFORMITY GEM®Premier™ 4000 System

Manufacturer: <i>Hersteller</i> <i>Fabricante</i> <i>Fabricant</i> <i>Produttore</i>		Instrumentation Laboratory Co 180 Hartwell Road Bedford, MA 01730-2443 U.S.A
<i>Fabricante</i> <i>Producent</i> <i>Tillverkare</i> <i>Κατασκευαστής</i>		
EU Authorized Representative: <i>EU-Bevollmächtigte</i> <i>Representante Autorizado por la UE</i> <i>Mandataire</i> <i>Rappresentante Autorizzato in Eu</i>		Instrumentation Laboratory SpA Viale Monza, 338 20128 – Milano, Italy
<i>Representante Autorizado na UE</i> <i>EU-autoriseret repræsentant</i> <i>EU Auktoriserad representant</i> <i>Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ</i>		

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Instrumentation Laboratory déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed att produkt(er) listade nedan, vara förenlig(a) med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Instrumentation Laboratory με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive: *EU-Richtlinie* *Directiva UE* *Directive Européenne* *Direttiva Europea* *Directiva UE* *EU-direktiv* *EU Direktiv* *Οδηγία ΕΕ*
IVD – 98/79/EC (27/10/1998) – Annex I and III

RoHS2 Directive 2011/65/EU (Starting with sn# 1606XXXX)

Standard(s): *Normen und Richtlinien* *Estándar(es)* *Norme(s)* *Norma(e)* *Padrão/Padrões* *Standard(er)* *Standard(er)* *Πρότυπα*

- ISO 9001: 2008 , Quality Management System
- ISO 13485:2003, Medical Devices – Quality Systems
- ISO 14971:2007, Medical Devices – Application of risk management to medical devices
- IEC 61010-1:2001 Second Edition, A1:2003: Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 61010-2-101:2002(ed.1): Particular Requirements for in-vitro diagnostic (IVD) medical equipment.
- IEC 61010-2-081:2001(ed.1) Particular Requirements for automatic and semi-automatic laboratory equipment used for analysis and other purposes.
- IEC 61326-1 Ed. 2 2012-07 Electrical equipment for measurement, control and laboratory use – EMC requirements
- EN 980 (2008) Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices.
- EN ISO 15223-1:2012, Medical Devices – Symbols to be used with medical devices, labelling and information.
- EN ISO 18113-3:2011 In Vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 3- In Vitro diagnostic instruments for professional use.
- EN ISO 18113-2:2011 In vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 2- In vitro diagnostic instruments reagents for professional use.
- ISTA 2a, Shipping Shock and Vibration, Domestic & International Tests.
- ETSI EN 301 489-1 V1.9.2 (2011-09)
- ETSI EN 301 489-17 V2.1.1 (2009-05)


Carol Marble
Director of Regulatory Affairs

Date *21-July-2016*

Product(s) Produkt(e) Producto(s) Produit(s) Prodotto(i)	Producto(s) Produkt(er) Produkt(er) Προϊόντα	Beginning zu beginnen von A partir de Première id. A partire da	Oct 2009 Inicio Gældende fra Fr o m Εναρξη
P/N	Product	GMDN Term	EDMA Code
00025000000	GEM Premier 4000 Instrument	56663	21 07 11 03
00025000115	GEM CVP (Calibration Valuation Product) 1 with CO-OX	52860	11 70 31 50
00025000125	GEM CVP (Calibration Valuation Product) 2 with CO-OX	52860	11 70 31 50
00025000130	GEM CVP (Calibration Valuation Product) 3 Hematocrit	52860	11 70 31 50
00025000140	GEM CVP (Calibration Valuation Product) 4 Hematocrit	52860	11 70 31 50
00025000145	GEM CVP (Calibration Valuation Product) 5 tBili	52860	11 70 31 50
00025000101	GEM System Evaluator 1	30218	11 70 31 50
00025000102	GEM System Evaluator 2	30218	11 70 31 50
00025000103	GEM System Evaluator 3	30218	11 70 31 50
00025000104	GEM Hematocrit Evaluator 1	55868	11 70 31 50
00025000105	GEM Hematocrit Evaluator 2	55868	11 70 31 50
00025000106	GEM Hematocrit Evaluator 3	55868	11 70 31 50
	pH, pCO ₂ , pO ₂ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 21 Days		
00027360004	600 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 21 Days		
00027360008	600 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glu, Lac, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 21 Days		
00027360010	600 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 30 Days		
00027407504	75 sample size	52858	11 70 31 05
00027415004	150 sample size	52858	11 70 31 05
00027430004	300 sample size	52858	11 70 31 05
00027445004	450 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Hct, tBili, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 30 Days		
00027407505	75 sample size	52858	11 70 31 05
00027415005	150 sample size	52858	11 70 31 05
00027430005	300 sample size	52858	11 70 31 05
00027445005	450 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 30 Days		
00027407508	75 sample size	52858	11 70 31 05
00027415008	150 sample size	52858	11 70 31 05
00027430008	300 sample size	52858	11 70 31 05
00027445008	450 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tBili, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 30 Days		
00027407509	75 sample size	52858	11 70 31 05
00027415009	150 sample size	52858	11 70 31 05
00027430009	300 sample size	52858	11 70 31 05
00027445009	450 sample size	52858	11 70 31 05

Product(s) <i>Produkt(e) Producto(s) Produit(s) Prodotto(i)</i>	<i>Produto(s) Produkt(er) Produkt(er) Προϊόντα</i>	Beginning zu beginnen von A partir de Première id. A partire da	Oct 2009 Inicio Gældende fra Fr o m Εναρξη
P/N	Product	GMDN Term	EDMA Code
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glu, Lac, Hct, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 30 Days		
00027407510	75 sample size	52858	11 70 31 05
00027415010	150 sample size	52858	11 70 31 05
00027430010	300 sample size	52858	11 70 31 05
00027445010	450 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glu, Lac, Hct, tBili, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 30 Days		
00027407511	75 sample size	52858	11 70 31 05
00027415011	150 sample size	52858	11 70 31 05
00027430011	300 sample size	52858	11 70 31 05
00027445011	450 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Hct, tBili, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 21 Days		
00027360005	600 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Hct, tBili, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 21 Days		
00027360009	600 sample size	52858	11 70 31 05
	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glu, Lac, Hct, tBili, tHb, O ₂ Hb, COHb, HHb, MetHb, sO ₂ Cartridge - 21 Days		
00027360011	600 sample size	52858	11 70 31 05