Instrumentation Laboratory

CE

DECLARATION OF CONFORMITY

Electrodes for IL Blood Gas Instruments

GEM Premier Cartridges

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**Instrumentation Laboratory Co** **113 Hartwell Avenue** **Lexington – MA 02421 U.S.A.**
EU Authorized Representative: *EU-Bevollmächtigte* *Representante Autorizado por la UE* *Mandataire* *Rappresentante Autorizzato in Eu*	*Representante Autorizado na UE* *EU-autoriseret repræsentant* *EU Auktoriserad representant* *Εξουσιοδοτημένος αντιπρόσωπος στην Ε*	**Instrumentation Laboratory SpA** **Viale Monza, 338** **20128 – Milano, Italy**

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 Ενωσης 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

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

- ISO 13485:1996, Quality systems – Medical Devices
- 21CFR Part 809.10, 812.5, 820.130-820.160(a), 820.30, 820.70
- ISO 14971:2000, Medical Devices - Application of risk management to medical devices
- EN 980:1996 + A1:1998, Graphical symbols for use in the labeling of medical devices
- ISO 15223:2000, Medical Devices – Symbols to be used with medical devices, labelling and information to be supplied
- EN 591:2001, Instructions for use for in vitro diagnostic instruments for professional use

William Wood
Quality Assurance Director

Lexington, October, 2003

Instrumentation Laboratory

Product(s) *Produkt(e)* *Produto(s)* *Producto(s)* *Produkt(er)* *Produit(s* *Produkt(er)* *Prodotto(i)* *Προϊόντα*		**Beginning** *zu beginnen von* *Inicio* *A partir de* *Gældende fra* *Première id.* *Fr o m* *A partire da* *Εναρξη*
P/N		**LOT / SN**
005327	GEM Premier PAK 7	First production lots after November 15, 2003
005328	GEM Premier PAK 8	

Instrumentation Laboratory

CE

DECLARATION OF CONFORMITY

GEM®Premier™ 3000 System

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**Instrumentation Laboratory Co** **113 Hartwell Avenue** **Lexington – MA 02421 U.S.A.**
EU Authorized Representative: *EU-Bevollmächtigte* *Representante Autorizado por la UE* *Mandataire* *Rappresentante Autorizzato in Eu*	*Representante Autorizado na UE* *EU-autoriseret repræsentant* *EU Auktoriserad representant* *Εξουσιοδοτημένος αντιπρόσωπος στην Ε*	**Instrumentation Laboratory SpA** **Viale Monza, 338** **20128 – Milano, Italy**

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 Ενωσης 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

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

- ISO 13485:1996, Quality systems – Medical Devices
- 21CFR Part 809.10, 812.5, 820.130-820.160(a), 820.30, 820.70
- EN 1441:1997, Medical Devices - Risk Analysis
- ISO 14971:2000, Medical Devices - Application of risk management to medical devices
- EN 61010-1:1990 + A1:92: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN 61326-1:1998 Class A, Emission Radiated and Line-conducted, Annex B Immunity, Electrical equipment for measurement, control and laboratory use – EMC requirements
- EN 980:1996 + A1:1998, Graphical symbols for use in the labelling of medical devices
- ISO 15223:2000, Medical Devices – Symbols to be used with medical devices, labelling and information to be supplied
- EN 375:2000, Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- EN 591:2001, Instructions for use for in vitro diagnostic instruments for professional use

William Wood
William Wood
Quality Assurance Director

Lexington, September 2003

Claire E. Theobald
A True Copy Attest 8/3/05
CLAIRE E. THEOBALD
NOTARY PUBLIC
My commission expires Aug. 29, 2008

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόντα*	Beginning *zu beginnen von* *A partir de* *Première id.* *A partire da*	*Inicio* *Gældende fra* *Fr o m* *Εναρξη*
P/N		LOT / SN	
0057000100	GEM Premier 3000 with NTSC	First production lots after October 1, 2003	
	GEM Premier 3000 Pak for Blood Gas/Hct		
0024307504	75 sample size		
0024315004	150 sample size		
0024330004	300 sample size		
0024345004	450 sample size		
	GEM Premier 3000 Pak for Blood Gas/Hct/Lytes		
0024307507	75 sample size		
0024315007	150 sample size		
0024330007	300 sample size		
0024345007	450 sample size		
0024360007	600 sample size		
	GEM Premier 3000 Pak for Blood Gas/Hct/Lytes/Glucose/Lactate		
0024315009	150 sample size		
0024330009	300 sample size		
0024345009	450 sample size		
0024360009	600 sample size		
	GEM Premier 3000 iQM Pak for Blood Gas/Hct		
0024307584	75 sample (3 week)		
0024407584	75 sample (4 week)		
0024315084	150 sample size		
0024330084	300 sample size		
0024345084	450 sample size		
	GEM Premier 3000 iQM Pak for Blood Gas/Hct/Lytes		
0024307587	75 sample size		
0024315087	150 sample size		
0024330087	300 sample size		
0024345087	450 sample size		
0024360087	600 sample size		
	GEM Premier 3000 iQM Pak for Blood Gas/Hct/Lytes/Gluc./Lact.		
0024307589	75 sample size		
0024315089	150 sample size		
0024330089	300 sample size		
0024345089	450 sample size		
0024360089	600 sample size		

Claire E Theobald 8/3

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CLAIRE E. THEOBALD
NOTARY PUBLIC
My commission expires Aug. 29, 2008