Instrumentation Laboratory
A Werfen Company

CE DECLARATION OF CONFORMITY
GEM®Premier™ 3500 System

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**Instrumentation Laboratory Co** **180 Hartwell Road** **Bedford, MA 01730-2443 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 ΕΕ*	**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
RoHS2 Directive 2011/65/EU (Starting with sn# 16076731)
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, Quality systems – Medical Devices
- ISO 14971:2007, Medical Devices - Application of risk management to medical devices
- IEC 61010-1:2001 (2nd Edition) : 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.
- IEC 61326-1:2012 Class B Electrical equipment for measurement, control and laboratory use – EMC requirements
- IEC 61326-2-6 Class B: 2012 Electrical equipment for measurement, control and laboratory use- EMC requirements –Part 2-6: Particular requirements- In vitro diagnostic (IVD) medical equipment
- ETSI EN301 489-1:V1.9.2 (2011-09), ETSI EN 489-17: V2.2.1 (2012-09) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- EN ISO 15223-1:2012, Medical Devices – Symbols to be used with medical devices, labelling and info. to be supplied
- 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.
- EN 980 (2008 Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices.

Carol Marble
Director of Regulatory Affairs

Date 21-July-2016

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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	March 2007 Inicio Gældende fra Fr o m *Εναρξη*
P/N	Product	GMDN Term	EDMA Code
00026000000	GEM Premier 3500 Analyzer	56663	21 07 11 03
00024001587	GEM CVP Multipak (4 x 5 x 2.5ml)	52860	11 70 31 50
00024001811	GEM CVP 1 (20 x 2.5ml)	52860	11 70 31 50
00024001812	GEM CVP 2 (20 x 2.5ml)	52860	11 70 31 50
00024001813	GEM CVP 3 (20 x 2.5ml)	52860	11 70 31 50
00024001814	GEM CVP 4 (20 x 2.5ml)	52860	11 70 31 50
00024001515	IL PVP (4 x 4 x 2.5ml)	52860	11 70 31 50
00024001516	IL critPVP (4 x 5 x 2.5ml)	52860	11 70 31 50
00024001418	ContrIL 9 Multipak (10 x 3 x 2ml)	52860	11 70 31 50
0002309	Crit Check Multilevel (15 x 2 x 3ml)	55867	11 70 31 50
00024001419	ContrIL 9 Level 1 30 x 2ml	52860	11 70 31 50
00024001420	ContrIL 9 Level 2 30 x 2ml	52860	11 70 31 50
00024001421	ContrIL 9 Level 2 30 x 2ml	52860	11 70 31 50
00026403584	GEM Premier 3500 iQM BG/HCT 35 4 WEEK	52858	11 70 31 05
00026407584	GEM Premier 3500 iQM BG/HCT 75 4 WEEK	52858	11 70 31 05
00026307584	GEM Premier 3500 iQM BG/HCT 75	52858	11 70 31 05
00026407587	GEM Premier 3500 iQM BG/LYTES 75 4 WEEK	52858	11 70 31 05
00026307587	GEM Premier 3500 iQM BG/LYTES 75	52858	11 70 31 05
00026307589	GEM Premier 3500 iQM BG/LYTES/GL 75	52858	11 70 31 05
00026315084	GEM Premier 3500 iQM BG/HCT 150	52858	11 70 31 05
00026315087	GEM Premier 3500 iQM BG/LYTES 150	52858	11 70 31 05
00026315089	GEM Premier 3500 iQM BG/LYTES/GL 150	52858	11 70 31 05
00026330084	GEM Premier 3500 iQM BG/HCT 300	52858	11 70 31 05
00026330087	GEM Premier 3500 iQM BG/LYTES300	52858	11 70 31 05
00026330089	GEM Premier 3500 iQM BG/LYTES/GL 300	52858	11 70 31 05
00026345084	GEM Premier 3500 iQM BG/HCT 450	52858	11 70 31 05
00026345087	GEM Premier 3500 iQM BG/LYTES 450	52858	11 70 31 05
00026345089	GEM Premier 3500 iQM BG/LYTES/GL 450	52858	11 70 31 05
00026360084	GEM Premier 3500 iQM BG/HCT 600	52858	11 70 31 05
00026360087	GEM Premier 3500 iQM BG/LYTES 600	52858	11 70 31 05
00026360089	GEM Premier 3500 iQM BG/LYTES/GL 600	52858	11 70 31 05
00024001170	Kit Safety Draw Plastic Capillary 1000P	35770	21 07 11 03
00024001177	Adaptor, Capillary Tube 100/PER	47832	21 07 11 03