Instrumentation Laboratory
A Werfen Company

CE DECLARATION OF CONFORMITY

ILab Aries Systems

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**Instrumentation Laboratory SpA** **Viale Monza, 338** **20128 – Milano, Italy**
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*	**N/A**

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

Standard(s):

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

EN 61010-1:2001 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-101:2002 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-81:2002+A1:2003 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-81: Automatic and semi-automatic laboratory equipment for analysis and other purposes.
EN 61326-2-6:2006 - Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
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 reagents for professional use
EN 980:2008 - "Symbols for use in the labelling of medical devices"
ISO 15223-1:2012 - "Medical Devices – symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements"
EN 13640:2002 - "Stability testing of in vitro diagnostic reagents"
EN ISO 13485:20012- "Medical devices - Quality management systems - Requirements for regulatory purposes"

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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*	*Inicio* *Gældende fra* *Fr o m* *Εναρξη*
P/N		**GMDN Term**	**EDMA Code**	**LOT / SN**	
000160258301	ILab Aries w/o ISE with Reag Barcode	56678	21 01 10 01	1608XXX	
000160258302	ILab Aries w/o ISE with Reag and Sample BC	56678	21 01 10 01	1608XXX	
000160258303	ILab Aries with ISE with Reag BC	56678	21 01 10 01	1608XXX	
000160258304	ILab Aries with ISE with Reag and Sample BC	56678	21 01 10 01	1608XXX	
ME005412	Urine Diluent	58208	11 90 01 01	04302	
ME005201	Sodium Electrode	52896	11 04 01 07	04286	
ME005202	Potassium Electrode	52892	11 04 01 06	04260	
ME005207	Chloride Electrode	52876	11 04 01 03	10027	
ME005204	Reference Electrode	52866	11 04 04 01	04292	
0018468000	Acid Cuvette Cleaner	58207	11 90 01 01	I0309081	
0018469500	Probe Rinse	58207	11 90 01 01	I0304058	
0018469600	Cuvette Cleaning	58207	11 90 01 01	I1203284	
0018469700	ISE Calibrator A	52867	11 50 03 03	I1104241	
0018469800	ISE Calibrator B	52867	11 50 03 03	I1104242	
0018482900	ISE Cleaning	52869	11 90 01 01	I1107318	
0018257800	ISE Compensator	52867	11 50 03 01	052006	
00014557200	Adapter bottles 10 mL	-	21 01 10 01	-	
W23010262400	Adapter reagent containers 10/20 mL	-	21 01 10 01	-	
W23935001600	Halogen Lamp	-	21 01 10 01	-	
W23050251400	Reagent Racks	-	21 01 10 01	-	
W23050230800	Sample Racks	62011	21 01 10 01	-	
00018262910	Sample Cups (3 ml)	46237	21 01 10 01	-	
W23C1010207700	Reaction Cuvette	61032	21 01 10 01	-	
W23100252401	Sampling Probe Assay	-	21 01 10 01	-	
W23050252201	Probe (internal cannula)	-	21 01 10 01	-	
W23010192000	Drying Pad	-	21 01 10 01	-	
00018262904	Reagent bottle 10 mL	-	21 01 10 01	-	
00018262902	Reagent bottle 20 mL	-	21 01 10 01	-	
00018475800	Reagent bottle 25 mL	-	21 01 10 01	-	
00018475900	Reagent bottle 50 mL	-	21 01 10 01	-	

Massimiliano Giovannini
Quality Assurance Manager

Milan, July, 2016