



DECLARATION OF CONFORMITY

ILab Taurus 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 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

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"



Product(s) <i>Produkt(e) Produto(s) Producto(s) Produkt(er) Produit(s) Produkt(er) Prodotto(i) Προϊόντα</i>				Beginning <i>zu beginnen von Inicio A partir de Gældende fra Première id. Fr o m A partire da Έναρξη</i>	
P/N		GMDN Term	EDMA Code	LOT / SN	
00001070301	ILab Taurus without ISE 230V	56678	21 01 10 01	77xx01xxx	
00001070302	ILab Taurus with ISE 230V	56676	21 01 10 01	77xx01xxx	
00001070303	ILab Taurus without ISE 120V	56678	21 01 10 01	77xx01xxx	
00001070304	ILab Taurus with ISE 120V	56676	21 01 10 01	77xx01xxx	
0001156021	ILab Taurus Twin Option	-	21 01 10 01	79xx01xxx	
0001156008	ILab Taurus Touch Screen Option	-	21 01 10 01	78xx01xxx	
0018262300	Reference Electrode	52866	11 04 04 01	1606A	
0018262400	Sodium Electrode	52896	11 04 01 07	1606A	
0018263500	Potassium Electrode	52892	11 04 01 06	1605A	
0018263600	Chloride Electrode	52876	11 04 01 03	1605A	
0018253400	ISE Diluent	52869	11 04 04 02	I1203253	
0018253500	ISE Reference	52869	11 50 03 03	I1103217	
0018253710	Alkaline Detergent	58207	11 90 01 01	I1003199	
0018253800	Acid Detergent	58207	11 90 01 01	I903158	
0018469000	Alkaline Cuvette Cleaner	58207	11 90 01 01	I1203261	
0018469100	Acid Cuvette Cleaner	58207	11 90 01 01	I1203262	
0018469200	ISE Low Calibrator	52867	11 50 03 03	I1003203	
0018469300	ISE High Calibrator	52867	11 50 03 03	I0903174	
0018469400	Bath Additive	58207	11 90 01 01	I1103224	
0018482900	ISE Cleaning	52869	11 90 01 01	I1107318	
0018257800	ISE Compensator	52867	11 50 03 01	I1207296	
0018461100	Reagent adapter inner ring 20 mL	-	21 01 10 01	-	
0018461200	Reagent adapter outer ring 20 mL	-	21 01 10 01	-	
0018475600	Reagent adapter inner ring 50 mL	-	21 01 10 01	-	
0014557200	Reagent adapter 10 mL	-	21 01 10 01	-	
0018262903	Sample cups (3 ml)	-	21 01 10 01	-	
0018262910	Sample cups (3 mL)	-	21 01 10 01	-	
0018514100	ILab Taurus Racks Kit	15186	21 01 10 01	-	
0018471350	Lamp photometer	-	21 01 10 01	-	
001155923	ILab 600/650/Taurus start up kits ISE	-	21 01 10 01	-	
001156009	ILab Taurus Start up kit	-	21 01 10 01	-	
001156023	Packing List ILab Taurus Systems	-	21 01 10 01	-	
0001156007	Kit labels ILab Taurus Racks	-	21 01 10 01	-	

Massimiliano Giovannini
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Quality Assurance Manager

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