

**Declaration of Conformity**

Manufacturer: Biotix Inc.  
9880 Mesa Rim Rd.  
San Diego, CA 92121  
United States of America

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Product: Laboratory Consumable Products. Pipette tips, PCR Tubes, Microcenterfuge Tubes, Titer Plates and Solution Basins. (Refer to Appendix C)

Brand: Clearline filtered and non-filtered hand held pipette tips.

Part Numbers: Refer to Appendix C Product Cards and Product Numbers

Date of Start of CE Marking: December 17th, 2012

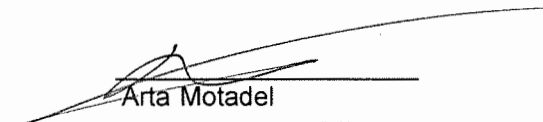
Place of Issue: San Diego, CA, United States of America

We herewith declare that the above mentioned products meet the provisions of the DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.


*Conformity assessment route; Self declaration under Annex III of 98/79/EC*

Product classification: General IVD / Class I.

Signature:


  
Arta Motadel  
Chief Technical Officer

3 - 22 -17  
Date

	<b>Number</b>	<b>Title</b>	<b>Version</b>	<b>Effective Date</b>
	<b>F-957</b>	Private Label Part List - DD (Appendix C-CE Mark Technical File 01)	<b>B</b>	03/07/19

## 1. Private Label Part List.

Private Label Brands		
Part Number	Description	Customer
713110	10µl ClearLine natural reload tips Non-sterile	Dominique Dutscher
713111	200µl ClearLine natural reload tips Non-sterile	Dominique Dutscher
713112	1000µl ClearLine natural reload tips Non-sterile	Dominique Dutscher
713113	1250µl ClearLine natural reload tips Non-sterile	Dominique Dutscher
713114	10µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713115	20µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713116	100µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713117	200µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713118	1000µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713119	1250µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713120	Rack for 10 to 200µl tips	Dominique Dutscher
713121	Rack for 1000/1250µl tips	Dominique Dutscher
713128	10µl ClearLine natural reload short tips Non-sterile	Dominique Dutscher
713129	300µl ClearLine natural reload tip Non-sterile	Dominique Dutscher
713130	10µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713131	300µl ClearLine Filter tips pre-sterile	Dominique Dutscher
713135	10XL RACK DOM DUTCH	Dominique Dutscher
713136	10UL RACK DOM DUTCH	Dominique Dutscher
713137	200UL RACK DOM DUTCH	Dominique Dutscher
713138	300UL RACK DOM DUTCH	Dominique Dutscher
713139	1000UL RACK DOM DUTCH	Dominique Dutscher
713140	1250UL RACK DOM DUTCH	Dominique Dutscher
713141	DUTSCHER 10XL RACK NF LR	Dominique Dutscher
713142	DUTSCHER 10UL RACK NF LR	Dominique Dutscher
713145	DUTSCHER 1000UL RACK NF LR	Dominique Dutscher
713146	DUTSCHER 1250UL RACK NF LR	Dominique Dutscher
713147	DUTSCHER 10XL RELOAD LR	Dominique Dutscher
713149	1000UL RELOAD NS LR DUTR	Dominique Dutscher
713150	1250UL RELOAD NS LR DUTR	Dominique Dutscher
713151	10UL RELOAD NS LR DUTR	Dominique Dutscher
713152	25ML BULK RESERVOIR NS	Dominique Dutscher
713153	50ML BULK RESERVOIR NS	Dominique Dutscher
713154	100ML BULK RESERVOIR NS	Dominique Dutscher
713155	25ML 1/BAG STRL RESERVOIR	Dominique Dutscher
713156	50ML 1/BAG STRL RESERVOIR	Dominique Dutscher
713157	100ML 1/BAG STRL RESERVOIR	Dominique Dutscher

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713158	25ML 5/BAG STRL RESERVOIR	Dominique Dutscher
713159	50ML 5/BAG STRL RESERVOIR	Dominique Dutscher
713160	100ML 5/BAG STRL RESERVOIR	Dominique Dutscher
713165	10ul Dutscher CleanPK NLR	Dominique Dutscher
713166	10xl Dutscher CleanPK NLR	Dominique Dutscher
713167	200ul Dutscher CleanPK NLR	Dominique Dutscher
713169	1000ul Duts CleanPK NLR	Dominique Dutscher
713170	1250ul Duts CleanPK NLR	Dominique Dutscher
713172	10ul Dutscher CleanPK LR	Dominique Dutscher
713173	10xl Dutscher CleanPK LR	Dominique Dutscher
713176	1000ul Duts CleanPK LR	Dominique Dutscher
713177	1250ul Duts CleanPK LR	Dominique Dutscher
713181	20ul RACK xTIP DOM DUTCH	Dominique Dutscher
713183	1000ul RACK xTIP DOM DUTC	Dominique Dutscher
713184	20ul RACK xTIP DOM DUTCH	Dominique Dutscher
713186	1000ul RACK xTIP DOM DUTC	Dominique Dutscher
713187	20ul CLEANPACK xTIP DOM D	Dominique Dutscher
713189	1000ul CLEANPACK xTIP DOM	Dominique Dutscher
713190	20ul CLEANPACK xTIP DOM D	Dominique Dutscher
713192	1000ul CLEANPACK xTIP DOM	Dominique Dutscher

**2.**

**HISTORY OF CHANGES**

Revision Letter	Issue Date	Created by	Description of Changes
<b>A</b>	10/08/18	Jorge L.	Add new part numbers. / New ID form – before was F-690.
<b>B</b>	03/07/19	Jorge L.	Add new part number (713167).