

January 3, 2014

To Whom It May Concern,

Filter and non-filtered hand held pipette tips (part numbers in appendix C / F- 690) have been CE marked and properly registered as an IVDD in compliance with the requirements of DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

The authorized European Representative is Emergo Europe, Molenstraat 15, 2513 BH, The Hague, Netherlands.

Also, attached find the Declaration of conformity document with the Competent Authority of the Netherlands

Sincerely,



Rafael Flores,
Director of Quality Assurance
Biotix, Inc.

Declaration of Conformity

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

European Representative: *EMERGO EUROPE*
Molenstraat 15, 2513 BH, The Hague
The Netherlands
Tel: +31 (0) 70 345 8570
Fax: +31 (0) 70 346 7299

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

Brand: Biotix and Neptune

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

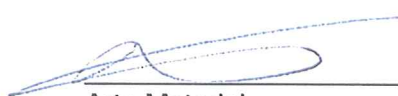
Date of Start of CE Marking: December 17th, 2012

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

Signature:


Arta Motadel
Chief Technical Officer

	Number	Title	Version	Effectivity Date
	F-690	<i>Private Label Part List (Appendix C-Technical File 01)</i>	A	1/2/2014

1. Private Label Part List.

Private Label Brands		Customer
Part Number	Description	
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

2.

HISTORY OF CHANGES

Revision Letter	Issue Date	Description of Changes
A	1/2/2014	New Release