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Part Number: XXXXXXXX
Lot Number: xxxxx
Date of Manufacture: 8/31/18
Expiration Date: 8/31/23

The above part number and lot number have passed our quality control standards and undergone the elaborate testing outlined below to certify them Bioready® for use with life science applications. This product is free of any detected defects and Biotix® will replace any product that fails to perform as promised.

All Biotix products are manufactured and assembled in a FDA registered ISO 9001:2015 compliant manufacturing facility. All products are shipped from Sorrento Valley in San Diego, California.

Traceability
Biotix tips are manufactured with the lot number printed on each of the racks for superior traceability. The lot begins with four digits that represent the date of manufacture. The remaining number/letter sequence is the lot number which is traceable to the precise hour of the day it was manufactured. We took traceability a step further and can track each tip to the individual core it was produced from to help improve our responsiveness to any issues a customer may face and to isolate any issues to the most basic level.

Functional Testing
Each lot is tested to our internal specifications by our Quality Control team to ensure the proper form, fit, and function. Functional testing includes a test for leaking using distilled water, and an accuracy test using the maximum volume of the tip. CV values are generated and compared to internal standards for the respective tip. They are then printed directly on the pack/case boxes as a proud mark of our tips accuracy and precision. A comprehensive fit test is performed by the QC team to ensure that the automation and Manual tips fit, draw and eject on the liquid handlers or manual pipettes they are intended for. Each lot is tested in this way to ensure that only the best product reach our customers.

Bio Contamination Testing
Tips considered Pre-Sterile undergo electron-beam irradiation under ISO 11137-2 guidelines. All Biotix tips are certified Bioready with tests performed at the following sensitivity levels.

Contaminate Tested for	Test Sensitivity
RNase/DNase	10^{-7} Kunitz units/µL
Nucleic Acid	10 ng
Endotoxin/Pyrogen	.06 EU/mL
PCR Inhibitors	The above lot was tested with a PCR amplification and gel electrophoresis analysis

Material BSE/TSE
Biotix products are manufactured with virgin polypropylene, meeting FDA requirements contained in the Code of Federal Regulations 21 CFR 177.1520(a)(1)(i) and (c)1.1a. The resin may be safely used in polymers for the manufacture of articles that come into direct contact with chemicals and biologics. The material supplier confirms that the raw materials used are free of animal sources or are treated through hydrogenation, alkaline hydrolysis and distillation ensuring the elimination of BSE (bovine spongiform encephalopathy) and TSE (transmissible spongiform encephalopathy). Exposure during the resin manufacturing process to temperatures of 260 degrees C and pressures up to 4800 KPa destroys any virus, bacteria, or substance causing immunological diseases fulfilling requirements in regulations: 1069/2009/EC, and 142/2011/EC and the "Note for Guidance EMEA/410/01, rev. 3". No plasticizers, latex, GMO's or mold release agents are used in the manufacturing process or by our material supplier.

Certificates are uploaded on the week the product is manufactured and can be found at http://biotix.com/resources/certificates-of-analysis/

Arta Motadel

Chief Technology Officer