



BIOMEDICAL SYSTEMS
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2019, October 17

Certificate of Analysis:


Macroduct® Supply Kit

Catalog Number: SS-032
Lot for SS-032 222661
Expiration Date: 2021, April 30
Description: Pilogel Discs for Macroduct®
Lot for SS-023: 221353
Expiration Date: 2021, April 30


This is to certify that the product noted above is manufactured under ISO 13485:2016, and FDA 21 CFR 820 Standards. Macroduct® Supply Kit and its packaging are inspected for damage or defects in material and workmanship. All tests were performed using samples of the batch product. All test instruments are calibrated annually and verified before use with NIST* traceable standards.

Test Results		
Test Performed	Specification/Reference	Result
Weight to Disc	3.525 to 4.220 (g)	4.111
Corrected Absorbance A ₂₀₆ for Weight	1.255 to 1.449	1.369
Color Verified	Semitransparent in appearance with slight yellow to brown	Pass
Texture Verified	Cracks in or on the surface of pilogel disc unacceptable	Pass
	Perimeter of the disc, smooth	Pass
	Ends of the disc smooth to slightly wavy	Pass
	Debris of any kind is not permitted	Pass

Authorized by:



 Justin Allen
 Quality Control Supervisor



 Date

*NIST refers to United States Department of Commerce National Institute of Standards and Technology, located in Gaithersburg, Maryland, USA.