Baxter

MEDICAL PRODUCTS - CLEVELAND FACILITY
911 North Davis Avenue, Cleveland, MS 38732, Phone: 662.843.9421, Fax: 662.846.5987

Certificate of Analysis

Product: **STERILE WATER FOR IRRIGATION, USP - 500 ML**

Lot #:	**G122580**
Code:	**2F7113**
Expiry:	**APR 2019**

Manufactured Date:	**04/03/2016**
Sterilization Date:	**04/03/2016**
Mixing Specification:	**03-15-53-216**
Issue Date:	**02/26/2015**

TEST NUMBER	TEST NAME	LIMIT	RESULT
11-20-15-001	Oxidizable Substances	Pass	Pass
11-21-16-003	pH at 25 deg. C	5.0 - 7.0	5.7
11-22-03-007	Conductivity Determination of Water (USP/EP)	NMT 5 uS/cm	1 uS/cm
20-03-07-006	Particle Analysis - Large Volume (Instrumental)		
	Particles >= 10 micron	NMT 25 particles/mL >=10 microns	3 ct/mL
	Particles >= 25 micron	NMT 3 particles/mL >=25 microns	0 ct/mL
13-01-10-313	Bacterial Endotoxin	< 0.25 EU/mL	< 0.0200 EU/mL
14-04-01-120	Sterility	Pass Parametric Release	Pass
	PARAMETRIC RELEASE IN ACCORDANCE WITH U.S. FDA REQUIREMENTS		

THIS PRODUCT WAS MANUFACTURED ACCORDING TO CURRENT GMP,
FULLFILLS THE REQUIREMENTS OF THE MASTER PRODUCTION DOCUMENT AND TESTED TO USP COMPLIANCE

E. Soliz 4-11-16
Prepared By/Date

Ellen Soliz

Twila Proctor 4-11-16
Quality Management Approval /Date

Twila Proctor