Baxter

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

Certificate of Analysis

Product: **0.9% SODIUM CHLORIDE IRRIGATING SOLUTION**

Lot #: G126169
Code: 2F7124
Expiry: DEC 2019

Manufactured Date: 12/03/2016
Sterilization Date: 12/03/2016
Mixing Specification: 03-15-19-156
Issue Date: 07/02/2002

TEST NUMBER	TEST NAME	LIMIT	RESULT
11-07-19-001	NaCl (g/L)	8.55 - 9.45 g/L	8.99 g/L
11-20-19-006	Sodium ID- USP	Positive	Positive
11-20-19-007	Sodium ID- Flame	Positive	Positive
11-21-16-003	pH at 25 deg. C	4.5 - 7.0	5.7
20-03-07-006	Particle Analysis - Large Volume (Instrumental) Particles >= 10 micron Particles >= 25 micron	 NMT 25 particles/mL >=10 microns NMT 3 particles/mL >=25 microns	 2 ct/mL 0 ct/mL
13-01-10-313	Bacterial Endotoxin	0.5 EU/mL	< 0.01 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 12-7-16
Prepared By/Date

12-13-16
Quality Management Approval /Date

Ellen Soliz