



MEDICAL PRODUCTS - CLEVELAND FACILITY  
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## Certificate of Analysis

**Product:** STERILE WATER FOR IRRIGATION, USP - 1000 ML

**Lot #:** G133579  
**Code:** 2F7114  
**Expiry:** APR 2021

**Manufactured Date:** 04/08/2018  
**Sterilization Date:** 04/08/2018  
**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                        | 5.5          |
| 11-22-03-007                                                | Conductivity Determination of Water (USP/EP)    | NMT 5 uS/cm                      | 2 uS/cm      |
| 20-03-07-006                                                | Particle Analysis - Large Volume (Instrumental) |                                  |              |
|                                                             | Particles >= 10 micron                          | NMT 25 particles/mL >=10 microns | 1 ct/mL      |
|                                                             | Particles >= 25 micron                          | NMT 3 particles/mL >=25 microns  | 0 ct/mL      |
| 13-01-10-313                                                | Bacterial Endotoxin                             | < 0.25 EU/mL                     | < 0.02 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 4-11-18  
Prepared By/Date

Ellen Soliz

[Signature] 4-12-18  
Quality Management Approval /Date