Baxter
Healthcare

**NORTH COVE FACILITY**
**65 Pitts Station Road**
**Marion N.C. 28752**
**Telephone: (828) 756-4151**
**Fax: (828) 756-4821**

# Certificate of Analysis

**Product:** **0.9% Sodium Chloride Irrigation, USP, 1000 mL Uromatic Cont**

**Lot #:** Y225409

**Code:** 2B7124X

**Manufacture/ Sterilization Date:** 02/13/2017

**Expiry:** 08/2018

Chemical Testing per Specification: **03-15-19-061** Issue Date: **10/30/2015**

| TEST | LIMIT | RESULT |
|---|---|---|
| NaCl (g/L) | 8.55 - 9.45 g/L | 9.10 g/L |
| Sodium ID | Positive | Positive |
| Sodium ID- Flame | Positive | Positive |
| pH at 25 deg. C | 4.5 - 7.0 | 5.6 |
| Particle Analysis | NMT 25 ≥ 10 um/ml | NMT 25 |
| Particle Analysis | NMT 3 ≥ 25 um/ml | NMT 3 |
| Sterility | Pass Parametric Release | Pass |

Endotoxin Testing per Product Control Specification

| RESULT | LIMIT | DISPOSITION | DATE PASSED |
|---|---|---|---|
| < 0.25 EU/ml | < 0.25 EU/ml | Pass | 2/18/2017 |

This is to certify that this product was manufactured according to current GMP and fulfills the requirements of the Master Production Document.

| Date Batch Released | Parametric Release Date | Quantity Released |
|---|---|---|
| 2/18/2017 | 2/18/2017 | NA |

| | Print Name | Signature/Date |
|---|---|---|
| **Prepared by:** | Sherrie Hopson | Sherrie Hopson 5/1/17 |
| **Approved by:** Quality Manager or Designee | Jonathan Moore | JM 5-1-17 |