

Certificate of Analysis

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Product: Sterile Water for Irrig, USP 1000 mL Uromatic Container
Lot #: Y438223 **Sublot:** N/A **Code:** 2B7114X
Manufactured Date: 01-Dec-2023 **Sterilization Date:** 01-Dec-2023 **Expiry Date:** 11/2024
Parametric Release Status: Pass **Released Date:** 07-Dec-2023 **Quantity Released:** NA
Chemical Spec: 03-15-53-216 **Chemical Spec Effective Date:** 03-May-2021 **Bacterial Endotoxin Spec:** Per Product Control Specification

Test	Limits	Result
pH	5.0 - 7.0	5.7
Particles >= 10 um	NMT 25 Particles/mL	7 Particles/mL
Particles >= 25 um	NMT 3 Particles/mL	0 Particles/mL
Conductivity	NMT 5 us/cm	2 µS/cm
Total Organic Carbon (TOC)	NMT 8.00 mg/L	3.81 mg/L
Bacterial Endotoxin Disposition	Less than 0.25 EU/mL	Pass

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

Product sterility is verified using parametric release.

Stedman 12.8.23

Prepared By / Date

 08 Dec 2023
Quality Manager or Designee Approved by /
Date

N/A= Not Available

Report: DR_GLBL_COA_USC-NC_NEW
CUSTOMER COA_V2
Baxter Confidential

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