Baxter
Healthcare Corporation

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 - 1000 ML

Lot #:	**G101584**	**Manufactured Date:**	**04/19/2012**
Code:	**2F7114**	**Sterilization Date:**	**04/19/2012**
Expiry:	**APR/2015**		

TEST	LIMIT	RESULT
Conductivity Determination of Water (USP/EP)	NMT 5 uS/cm	1 uS/cm
Oxidizable Substances	Pass	Pass
pH at 25 deg. C	5.0 - 7.0	5.6
Particle Analysis	NMT 25 particles/mL >= 10 microns	0
Particle Analysis	NMT 3 particles/mL >= 25 microns	0
Bacterial Endotoxin	< 0.25 Eu/mL = Pass	Pass
Sterility	Pass Parametric Release	Pass

PARAMETRIC RELEASE IN ACCORDANCE WITH US. 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 4-20-12
Prepared By/Date

ELLEN SOLIZ

J Proctor 4-23-12
Quality Management Approval /Date

Tuila Proctor

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Certificate of Analysis

Product: STERILE WATER FOR IRRIGATION, USP - 1000 ML

Lot #:	**G101840**
Code:	**2F7114**
Expiry:	**MAY/2015**
Manufactured Date:	**05/04/2012**
Sterilization Date:	**05/04/2012**

TEST	LIMIT	RESULT
Conductivity Determination of Water (USP/EP)	NMT 5 uS/cm	2 uS/cm
Oxidizable Substances	Pass	Pass
pH at 25 deg. C	5.0 - 7.0	5.4
Particle Analysis	NMT 25 particles/mL >= 10 microns	1
Particle Analysis	NMT 3 particles/mL >= 25 microns	0
Bacterial Endotoxin	< 0.25 Eu/mL = Pass	Pass
Sterility	Pass Parametric Release	Pass

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