



## Technical Data Sheet

### Product specification

<b>1. Product Name</b>	USP Sterile Water	
<b>2. Description</b>	Sterile Water for Irrigation USP (100 mL, 250 mL, 500 mL, 1000 mL bottle)	
<b>3. Characteristics</b>	Sterile water for wound cleansing, wound dressing and device irrigation.	
<b>4. Intended use</b>	This device is intended for moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts abrasions and minor skin irritations and for device irrigation.	
<b>5. Instructions for use</b>	See Directions for Use on label.	
<b>6. Sizes and REF numbers</b>	Part Number	Size/Volume
	6250	100 mL, Bottle
	6260	250 mL, Bottle
	6290	500 mL, Bottle
	6291	1000 mL, Bottle
	6390	500 mL, Bottle
	6391	1000 mL, Bottle

### Technical information

	Component name	Material
<b>1. List of materials</b>	Bottle	HDPE
	Water	USP sterile water for irrigation
<b>2. Latex free</b>	Not made with natural latex rubber	
<b>3. PHT / DEHP / BPA free</b>	Yes	
<b>4. Shelf life</b>	2 years	



<b>5. Sterilization method</b>		Gamma irradiation	
<b>6. Packaging specification</b>	Sales Unit	Part Number	Units per Case
		6250	48
		6260	24
		6290	18
		6291	6
		6390	18
		6391	6

## Quality and Regulatory Information

<b>1. Quality certificate</b>	COA	
<b>2. Product classification</b>	FDA: Unclassified; Health Canada: Class 2	
<b>3. List of standards</b>	<b>The product is compliant with the following standards and regulations:</b>	
	<b>Document reference</b>	<b>Title</b>
	USP <85>	Bacterial Endotoxins Test
	USP Monograph	Sterile Water for Irrigation USP
	ANSI/AAMI/ISO 11737-2	Sterilization of Medical Devices-Microbiological Methods-Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
	ANSI/AAMI/ISO 11737-1	Sterilization of Health care products-Microbiological methods-Part 1: Determination of a Population of Microorganisms on Products
	ANSI/AAMI/ISO 11137-2	Sterilization of Health care products-Radiation-Part 2: Establishing the Sterilization Dose
	ANSI/AAMI/ISO 11137-1	Sterilization of Health care products-Radiation-Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices