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PRODUCT SPECIFICATION SHEET – PHARMASSIST SERIES

FDA FACILITY REGISTRATION: MPS Pharma & Medical, Inc. # 3018125942

PRODUCT ID: 1 PHARM-6, 1 PHARM-6FG, 2 PHARM-6

PRODUCT NAME: Pump Transfer Set

PRODUCT DESCRIPTION: Sterile, Non-Pyrogenic, Biocompatible

ORIGIN: All final assembly, packaging, labeling activities, inspections, sterilization, and microbial release testing is performed in the USA.

MATERIAL SPECIFICATIONS: All materials comply with applicable biocompatibility testing.

BSE STATEMENT: No raw materials that contain, or are derived from, animals are specified in the manufacture of this product.

QUALITY CONTROL: Inspections are performed for each manufacturing batch to ensure all product specifications are satisfied.

VALIDATION TESTS PERFORMED: Dimensional testing for all componentry, tensile strength testing for all bonded joints, accuracy testing after repeated use, accuracy testing using multiple viscosities of fluid, connector compatibility, solvent soak to ensure set integrity.

STERILIZATION VALIDATION SPECIFICATIONS: The products are sterilized to an SAL of 10^{-6} using ethylene oxide as the sterility method in compliance with applicable sections from:

- **ISO 11135** – *Sterilization of Healthcare Products – Ethylene Oxide*
- **ISO 10993-7** – *Ethylene Oxide Sterilization Residuals*

Sterility Assurance Level (SAL)	10^{-6} Using Biological Indicator Testing as acceptance Criterion	
Endotoxin Limits per USP 85 Requirements	≤ 0.5 IU/ml or 20 IU/device / Non-Pyrogenic	
EO Residual Limits per ISO 10993-7	EO <4 mg/device	ECH <9 mg/device
Biocompatibility Testing Performed		
Cytotoxicity	Sensitization	Acute System Toxicity
Irritation	Pyrogen	Hemolysis

SHELF LIFE: Sterile barrier testing, along with 5-year shelf life study, has been performed in accordance with ISO 11607-1 and FDA requirements.

This specification shall remain in effect until withdrawn by MPS Pharma & Medical, Inc.