



1220 Graphite Dr Corona, CA 92881 Tel: 800-797-1405

Batch Sterility Report

Date: Mar. 06, 2021

Product:	ISOEVA50	ISOEVA50	ISOEVA50	ISOEVA100	ISOEVA250
Lot:	20211230	20220224	20220226	20220112	20220116
Exp:	2024-12-29	2025-02-23	2025-02-25	2025-01-11	2025-01-15
Qty:	5,700PCS	5,100PCS	5,100PCS	5,700PCS	5,350PCS
	ISOEVA250				
	20220220				
	2025-02-19				
	5,700PCS				

We hereby certify that this lot of infusion set have been sterilized with Ethylene Oxide and found to conform to the sterility requirements of EN550 & ISO 11135:2014.

Intravascular Set construction materials are medical grade , biocompatibility tested and in conformance with 510K 121161 submission

Sterilization was verified by the following:

1. Compliance with Validation parameters
2. Placement of EZTest EO Test Pack in the center of the load and confirming no growth after 48 hours

Disposable Biological EO Test Pack Lot No.:G-223

Exp. Date: Nov. 09, 2022

Quality Control Dept.

ISO-MED, INC.

ITEM CODE: ISOEVA50/ ISOEVA100/ ISOEVA250						PO: 5404-1
LOT: 20211230/20220224/20220226 20220112/ 20220116/20220220						EXP: 2024-12-29/2025-02-23/2025-02-25/ 2025-01-11/ 2025-01-15/2025-02-19
ETO STERILIZATION DATE: 2022-03-06						
Biological Indicators For Ethylene Oxide Sterilization						
Brand: EZTest						
LOT: G-223						
EXPIRATION: 2022-11-09						
INCUBATION DATE INITIATED: 2022-03-06						
INCUBATION DATE COMPLETED: 2022-03-08						
INDICATOR VERIFIED AS: Negative						

