

MINNTECH

THERAPEUTIC TECHNOLOGIES GROUP

Product Description: HF1200 China
Part Number: 93024-132
Lot Number: 946389A

Has been manufactured in a controlled environment in accordance with the requirements of the Current Good Manufacturing Practices (21 CFR Part 820) as published in the Federal Register of the United States of America. *MEDIVATORS Inc. is an ISO 13485 certified company.

☒ **BACTERIAL ENDOTOXIN TESTING**

This testing is performed on a routine basis and was evaluated repeatedly during the manufacturing of this lot of product to ensure that it remained under the required limits per AAMI ST72.

☒ **PRODUCT INTEGRITY**

Each unit has been integrity tested.

☒ **DIMENSIONS**

All fiber included herein conforms to established dimensional criteria.

☒ **BIOCOMPATIBILITY**

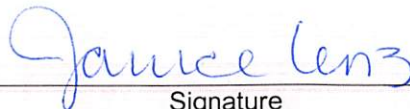
Product meets Biological Evaluation of Medical Devices for ISO 10993-1.

☒ **ETHYLENE OXIDE STERILIZATION**

Each unit has been EtO sterilized and achieved a SAL 10^{-6} . Products were validated to ISO 11135-1. Each sterilization lot has been released based on process cycle parameters and results of biological indicators. EtO and ECH residual levels meet the requirements stated in ISO 10993-7.

Janice Lenz

Name



Signature

January 31, 2019

Date

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