

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.

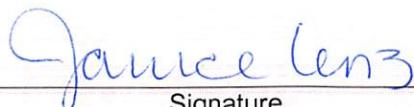
BIOCOMPATIBILITY

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



January 31, 2019

Name

Signature

Date

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