

Certificate of Conformity

Lot Number: 23140469

Part Number: 3581

Item Description: HLT 1000 SOFTFIT RACKED ST100TIPS 8TRAYS 4PACKS 1CASE

Manufacturing Date: 04/14/2023

Irradiation Date: 04/18/2023

Sterility Assurance Level (SAL): 10^{-6}

Sterility Assurance Level for sterilized products is ensured by irradiating the product according to ANSI/AAMI/ISO 11137- 2015 guidelines.

Molecular BioProducts Inc., a part of Thermo Fisher Scientific Inc., hereby certifies that these products are manufactured in a controlled environment in accordance with established manufacturing guidelines, quality requirements and product specifications. They are certified, by validation of the manufacturing processes, to be free of the following contaminants:

- Human and mouse DNA (Deoxyribonucleic Acid) : < 30 pg
- Ribonuclease (RNase): < 10^{-9} Kunitz Units/ μ l
- Deoxyribonuclease (DNase): < 10^{-7} Kunitz Units/ μ l
- PCR Inhibitors: not present
- Endotoxin (Pyrogen) < 0.06 EU/ml
- Adenosine-5'-triphosphate (ATP) < 10^{-13} mg/ μ l

Certified by: _____



08/24/2023

Ana Ibarria
Interim Quality Manager