

Certificate of Conformity

Lot Number: 20200044

Part Number: 2779-HR

Item Description: ART 1000L, 1000UL SOFTFIT L,CLEAR, PRE-STERILIZED

Manufacturing Date: 06/18/2020

Irradiation Date: 06/22/2020

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

Sterility Assurance Level for sterilized products is ensured by irradiating this product according to ANSI/AAMI/ISO 11137-2006 guidelines.

Thermo Fisher Scientific 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:

- Deoxyribonucleic Acid (DNA): < 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: _____ 9/28/2020



Maria Luisa Quiros
Quality Manager