

September.02th, 2022**Certificate of Conformity**

Product: Nunc CryoBank Vial, 1.0 ml
Catalogue No.: 374081
Lot No.: 60590104
Date of manufacture: August 11,2022
Date of expiry: August 28,2027

Thermo Fisher Scientific confirms that the product supplied has been inspected and tested in accordance to relevant specifications

| Test Description | Requirements | Result |
|---|----------------------------|-------------|
| Visual | According to specification | Complies |
| Test of function | According to specification | Complies |
| USP <85> Bacterial endotoxins test | <0.25 endotoxins unit/ml | Complies |
| USP <87> "Biological Reactivity test, In Vitro | USP current edition | Complies** |
| USP <88> "Biological Reactivity test In Vivo, USP Class VI Test" | USP current edition | Complies** |
| Leak Test | IATA current edition | Complies*** |
| DNase/RNase test | Negative | Complies |


**Only performed once

***Performed at certain frequency

Sterility is obtained through irradiation according to ISO 11137 "sterilization of health care products –Radiation" with SAL 10⁻⁶.

Quality assurance of the product is performed in accordance with the requirements of the Quality Management System ISO 13485:2016, "Medical devices – Quality management systems – System requirements for regulatory purposes".

Suzhou Site



Alice Chen
Inspector Leader