

Jun. 18th, 2019**Certificate of Conformity**

Product: Nunc, CryoTube, 4.5ml, Starfoot, External Thread
Writing area

Catalogue No.: 337516

Lot No.: 60141865

Date of manufacture: May 2019

Date of expiry: May 2024

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 | USP current edition | Complies** |
| In Vivo, USP Class VI Test" | | |
| Ames test | OECD Guideline for testing no. 471 | 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.

The product is CE marked according to EU directive, 2007/47/EC amending 93/42/EC and 98/79/EC for IVD, Medical device.

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



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