

Aug. 14, 2019

**Certificate of Conformity**

**Product:** Nunc CryoTube 1.8ML Sterile, Starfoot, External Thread  
Writing area

**Catalogue No.:** 375418

**Lot No.:** 60153652

**Date of manufacture:** July 2019

**Date of expiry:** July 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<sup>-6</sup>.

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



Jing Zhou

Regulatory Affair Engineer