

Certificate of Conformity

Product: Nunc CryoTube, 1,8 ml, Internal thread

Date: 2019-05-09

Page: 1

Item number: 363401

Lot number: 161312

Date of manufacture: April 2019

Date of expiry: April 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 In Vivo, USP Class VI Test"	USP current edition	Complies**
Ames test	OECD Guideline for testing no. 471	Complies**
Leak Test	IATA current edition	Complies***
DNase/RNase test	Negative	Complies*

*Performed as monitoring test

**Only performed once

***Performed at certain frequency

Sterility is obtained through irradiation according to ISO 11137 "Sterilization of health care products - Radiation", with SAL 10E-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 9001:2015 "Quality management system - Requirements" and ISO 13485:2016 "medical devices - Quality management systems - System requirements for regulatory purposes".

Roskilde Site



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