

Thermo Fisher Scientific
Nunc A/S
Nunc

Page:

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## **Certificate of Conformity**

**Product:** Nunc SlideFlask Chamber, 9 cm<sup>2</sup>

Cell Culture Treated

Item number:170920Lot number:157913Date of manufacture:June 2018Date of expiry:June 2023

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
Cloning efficiency with V-79 cell line	According to specification	Complies*
USP <85> Bacterial endotoxins test	<0.5 endotoxins unit/ml	Complies*
USP <88> "Biological Reactivity test In Vivo, USP Class VI Test"	USP current edition	Complies**
Cell Culture Test L 929 Human Lung Primary chicken embryo	According to specification	Complies*

<sup>\*</sup>Performed as monitoring test

Sterility is obtained through irradiation according to ISO 11137 "Sterilization of health care products - Radiation", with SAL 10E-6.

Quality assurance of the product is performed in accordance with the requirements of the Quality Management System ISO 9001:2008 "Quality management system - Requirements" and ISO 13485:2003 "Medical devices - Quality management systems - System requirements for regulatory purposes".

Roskilde Site

Emil O'Hanlon Cohrt, PhD

Quality Systems, Support and Monitoring, Team Leader

<sup>\*\*</sup>Only performed once