

Certificate of Conformity

Product: Nunc Flasks with Filter Caps

Date: 2025-04-11

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Item number: 178905

Lot number: 185630

Date of manufacture: April 2025

Date of expiry: April 2030

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 units/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* |

*Performed as monitoring test

**Only performed once

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 9001:2015 "Quality Management System - Requirements" and ISO 13485:2016 "Medical Devices - Quality Management Systems - System requirements for regulatory purposes".

Roskilde Site



Per Bernack
Senior Quality Assurance Manager

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