

## Certificate of Conformity

**Product:** Nunc Cell Factory Systems, 10 Trays

Date: 2025-05-14  
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**Item number:** 170009

**Lot number:** 185041

**Date of manufacture:** March 2025

**Date of expiry:** March 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<br>In Vivo, USP Class VI Test" | USP current edition        | Complies** |
| Cell Culture Test<br>L 929<br>Human Lung<br>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



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Senior Quality Assurance Manager  
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