

Certificate of Conformity

Product: Nunc Cell Factory, 13 trays, PS, Sterile**Date:** 2021-07-09**Page:** 1**Item number:** 169118**Lot number:** 170066**Date of manufacture:** May 2021**Date of expiry:** May 2026

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
Light obscuration particle count test using the guidelines for counting (particles/mL) provided in USP <788>	<25 particles/mL of particles sized >10µm <3 particles/mL of particles sized >25µm	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**
Cloning efficiency with V79 cell line	According to specification	Complies
Cell culture test L929 Human Lung Primary chicken embryo	According to specification	Complies

**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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Operations Quality Manager

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