

Certificate of Conformity

Product: Nunc 12 well Multidishes, UpCell

Date: 2025-04-09

Page: 1

Item number: 174900

Lot number: NU12W2444

Date of manufacture: November 2024

Date of expiry: November 2027

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	<0.5 endotoxins units/mL	Complies*
ISO 10993-5 "tests for in vitro cytotoxicity"	ISO 10993-5	Complies***
USP <88> "Biological Reactivity test In Vivo, USP Class VI Test"	USP current edition	Complies**
Cell growth with 3T3-swiss Albino cell line	Minimum of 80 % confluence	Complies**
Cell detachment with 3T3-swiss Albino cell line	Not less than 50% cell detachment at temperature below 32°C	Complies**

*Performed as monitoring test

**Only performed once

***Performed at certain frequency

Sterility is obtained by ethylene oxide gas according to ISO 11135-1 "Sterilization of health care products - Ethylene oxide", 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".

Roskilde Site



Per Bernack
Senior Quality Assurance Manager

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