

Certificate of Analysis

Product: Nunc IVF Petri Dishes, Non Treated

Date: 2025-06-27

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Item number: 150270

Lot number: 185813

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 |
| USP <85> Bacterial endotoxins test | <0.5 endotoxins units/mL | Complies |
| Human Sperm Survival Assay, HSSA | >70 % | Complies |
| Mouse Embryo Assay one cell, MEA | Blastocyst development > 80 % | 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** |
| Ames test | OECD Guideline for testing no. 471 | Complies** |

**Only performed once

***Performed at certain frequency

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

The product is CE marked according to Regulation (EU) 2017/745, Article 120, Regulation on Medical Devices. 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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