
Certificate of Analysis

Product: Nunc IVF 4-Well Dishes, Non Treated

Date: 2019-03-29

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Item number: 179830**Lot number:** 160015**Date of manufacture:** February 2019**Date of expiry:** February 2021

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 EU directive, 2007/47/EC amending 93/42/EC for IVF, Medical device. 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".

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