ThermoFisher SCIENTIFIC

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Product Statement

Product: Nunc IVF 4-Well Dish, Nunclon

Item number: 144444

Raw material: Polystyrene (61662)

Thermo Fisher Scientific hereby confirms that the product above was produced, inspected and found to be in compliance with the following product and quality specifications.

The products and the materials have successfully passed the following tests:

- *Biological evaluation of medical devices – ISO 10993-12, Sample preparation and reference materials, 2008.*
- *Biological evaluation of medical devices – ISO 10993-18, Chemical characterization of materials, 2005.*
- *USP <661> Physicochemical Tests – Plastics.*
- *SOP PM 061, version # 03, „Recording of GC/MS fingerprints of medical devices and packaging materials“* and have passed the tests according to the product intended use.
- *Biological evaluation of medical devices – ISO 10993-5, tests for in vitro cytotoxicity.* The cell line used is L-929 (mouse connective tissue).
- *USP <87> “Biological Reactivity Tests, In Vitro, Elution test”.*
- *USP <88> “Biological Reactivity tests, In Vivo”, Class VI.*
- *Biological evaluation of medical devices – ISO 10993-3, “test for genotoxicity, carcinogenicity and reproductive toxicity”.*
- *Ames Salmonella, microsome assay, referring to OECD Guideline for testing of chemicals No. 471.*

Inspection point of the products:

Visual control according to our quality inspection procedures and specifications.

Test of function according to our quality inspection procedures and specifications.

Mouse Embryo Assay one Cell, MEA:
Blastocyst formation rate larger that 80% for fully expanded blastocysts both in test and control after 96 hours. The embryo toxicity test is a release test.

USP <85> Bacterial endotoxin test:
The products are tested according to the principles of the Limulus Amoebocyte Lysate (LAL) test and certified non-pyrogenic with a documented endotoxin level of less than 20 endotoxin units/device (0.5 endotoxin units/ml), as stated in the United States Pharmacopoeia, Bacterial Endotoxin Test Criteria.

Sterility and Bioburden:
Sterility is obtained through gamma irradiation according to ISO 11137-2 (sterilization of health care products – requirements for validation and routine control – radiation sterilization), with SAL 10^{-6}, and with consecutive audit of sterility every 3 months. Sequential inspection of the particle level is made in the production environment.

Nunc A/S
Kamstrupvej 90
P. O. Box 280
DK-4000 Roskilde
Denmark
AS 24482 VAT/SE NO. DK 39582910

+45 4631 2000 phone
+45 4631 2042 fax
Info.nunc@thermofisher.com

www.thermofisher.com
www.nuncbrand.com

The expiry date is manufacturing date plus 5 (five) years.

The products are CE Marked and classified as class IIa, according to EU directive 2007/47/EC amending 93/42/EC for IVF, Medical device.
The product is in compliance with 21 CFR, current Good Manufacturing Practice, Quality System Regulation, part 820, according to product code 85 MQK and regulation No. 864.6160 and registered with 510(K) number K070047.

Quality assurance of the products are performed in accordance with the requirements of the Quality Management System ISO 9001:2008 “Quality management system – Requirements” and ISO 13485:2003, “Medical devices – Quality management systems – System requirements for regulatory purposes”.

Roskilde Site,

Signature: 
Louise Wohlfahrt, QA Engineer

Date: 2015-01-09
(YYYY-MM-DD)