Thermo Fisher Scientific
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Product Statement

Products: Nunc EasYFlasks, Nunclon

Raw materials: Polystyrene, PS (65927)
High Density Polyethylene HDPE (43847)
Masterbatch, blue (48452)
Sartorius Filter (35690)[1]

Thermo Fisher Scientific hereby confirms that the above-mentioned products have been designed and are manufactured from selected materials.

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

- *Biological evaluation of medical devices – ISO 10993-12, Sample preparation and reference materials.*
- *Biological evaluation of medical devices – ISO 10993-18, Chemical characterization of materials.*
- *USP <661> Physicochemical Tests – Plastics.*
- *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.*

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.

Cell culture validation tests:
Monolayer formation of two different cell lines and one primary cell culture. The cell lines are L-929 Connective tissue from mouse and Diploid human lung, and the primary cell culture is chicken embryo.

Cloning efficiency:
Specially selected cell line with high sensitivity to toxic components is used: V-79 Chinese hamster lung cell.

Non-pyrogenic:
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.

Integrity testing:
100 % leak testing is performed as in-line test as part of the automatic assembly process.

[1] Only for filter caps

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).

Consecutive audit of sterility is performed every 3 months. Sterility audit is performed on fluid pathway.

Sequential inspection of the particle level is made in the production environment.

Sterility assurance level (SAL): 10^{-6}

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

Quality assurance of the products are 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

Signature: Maria Elisa Rex
Maria Elisa Rex, QA Coordinator

Date: 2021-03-24
(YYYY-MM-DD)