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Jan 2024

Product statement

Products: Nunc CryoTubes, External thread

We hereby confirm that the products above are manufactured from selected materials:

The tube is made of Polypropylene (69436)

The cap is made of High-Density Polyethylene (43847)

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 (edition USP 31)*
- *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.

Leak-test:

The products are tested according to the Title 49 Code of Federal Regulations (CFR); Parts 100-185; 173.196(a)(6-7), at an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 131°F), and according to IATA International Air Transport Association; Dangerous Goods regulations, packing instructions 620 and 650.

USP <85> "Bacterial Endotoxins Test":

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“Bacterial Endotoxins Test” and is certified non-pyrogenic. Documented endotoxin level is less than 0.25 Endotoxin Units/ml (10 Endotoxin Units/device).

DNase/RNase:

The products are certified free of DNase and RNase contamination in accordance to DNaseAlert™ QC System and RNaseAlert™ QC system.

Sterility and bioburden:

Sterility is obtained through beta irradiation according to ISO 11137 (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. Sterility audit is performed on fluid pathway.

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

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

Quality assurance of the product is performed in accordance with the requirements of the Quality Management System ISO 13485:2016 "Medical devices – Quality management systems - System requirements for regulatory purposes".

Suzhou Site

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