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Product statement

Products: Nunc CryoTubes, External thread, neck design

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

The tube is made of Polypropylene (69529)

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, 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.*

Inspection point of the products:

Visual inspection according to specification

Test of function according to specification

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":
Non-pyrogenic test is preformed according the principles of the LAL-test as stated in the USP <85> "Bacterial Endotoxins Test" and is certified non-pyrogenic. Documented endotoxin level is less than 0.25 Endotoxin Units/ml (10 Endotoxin Units/device).

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

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

The products are CE Marked according to EU directive, 98/79/EC for IVD, Medical device.
The products are in compliance with 21 CFR, current Good Manufacturing Practice, Quality System Regulation, part 820, according to product code 88 KJF and regulation No. 864.2240.

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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(YYYY-MM-DD)