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June 22, 2010
BID

Certificate of Conformity

Product:	Nunc CryoTube, 4.5 ml, External thread, round, PP/HDPE, Sterile
Catalogue No.:	337516
Lot No.:	115847
Manufactured:	June, 2010

We hereby confirm that the product indicated above is manufactured from selected materials, which have passed the following tests:

Non-toxic:	Based on Elution Test of raw material according to USP.
Cytotoxicity:	The material has successfully passed the USP biological reactivity class VI test – 50°C (7 days implant).
Non-mutagenic:	Non-mutagenic per Ames Salmonella, microsome assay
Non-pyrogenic:	The product has been tested according to the principles of the LAL-test described in the FDA guidelines. The product is certified non-pyrogenic, as stated in the USP, as to the following points: ♦ For medical devices the requirement is that the documented endotoxin level must be less than 20 Endotoxin Units/device (0.5 Endotoxin Units/ml) ♦ For "water for pharmaceutical purpose" the requirement is that the documented endotoxin level must be less than than 10 Endotoxin Units/device (0.25 Endotoxin Units/ml)
Leak-test:	The product has been tested according to the Title 49 Code of Federal Regulations (CFR); Parts 100-199 (10/1/2002); 173.196 Infectious Substances Paragraph (a)(6-7), at an internal pressure producing a pressure differential of not less than 95 kPa (0,95 bar, 14psi), conditioning –40°C to +55°C and according to IATA International Air Transport Association; Dangerous Goods regulations, 44th Edition, 2003, packing instruction 602 and 650.
Sterility:	Sterility is obtained through irradiation according to ISO 11137 (sterilization of health care products – requirements for validation and routine control - radiation sterilization) with SAL 10^{-6}. Closed systems are based on fluid path method.
Expiry:	Expiry is manufacturing plus 5 (five) years.

The product is CE Marked according to EU directive, 98/79/EC for IVD, Medical device.
Quality assurance of the product indicated above is performed in accordance with the requirements of the Quality Management System ISO 9001:2000, Quality systems - Model for quality assurance in design, development, production, installation, and servicing; and ISO 13485:2003, "Medical devices – Quality management systems – System requirements for regulatory purposes".

Roskilde Site

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