



DECLARATION OF CONFORMITY

We,

NUNC A/S
Kamstrupvej 90,
DK-4000 Roskilde
Denmark

part of Thermo Fisher Scientific,

hereby declare that the Nunc™ IVD CryoTubes products listed in Appendix 1, fulfills the Essential Requirements in Annex I of the EU Directive 98/79/EC.

This declaration is based on the manufacturer's self-declaration rights for a device for in vitro-diagnostic purpose, not intended for self-evaluation or any List A or List B applications.

Furthermore, the design and production of the listed products complies with the relevant parts of the DS/EN ISO 13485:2016.

The notified body no. 0543, Presafe Denmark A/S, located in Denmark, Tuborg Parkvej 8, 2900 Hellerup, has performed inspection and approved the quality system of NUNC A/S in conformity with the requirements outlined in the Annex V, section 3.2 – Production quality assurance, of the Medical Device Directive 93/42/EEC as transposed into the Danish Law.

The notified body has confirmed compliance of the company activities and the CE-marked medical devices with the regulatory requirements, and issued the Quality System Certificate – DGM 770, date of issue 2019-01-18.

Signed for and on behalf of Nunc A/S:



Karen Bryde Frisk,
Regulatory Affairs Manager

Date: 2019-06-06

(YYYY-MM-DD)

Appendix 1:

Item no.	Product name and description
336078	Nunc CryoTube, Colored Caps, Clear,
336081	Nunc CryoTube, Colored Caps, Red
336088	Nunc CryoTube, Colored Caps, Blue
336092	Nunc CryoTube, Colored Caps, Yellow
336094	Nunc CryoTube, Colored Caps, Assorted Color
337516	Nunc™ CryoTube, 4.5mL, sterile, external thread, starfoot, round
339357	Nunc™ CryoTube, 1.8 mL, external thread, without cap, without print
339349	Nunc™ CryoTube, 1.8 mL, sterile, internal thread, barcoded
340711	Nunc™ CryoTube, 1.8 mL, sterile, external thread, neck design, round
347023	Nunc™ CryoTube, 1.8 mL, sterile, internal thread, barcoded
347597	Nunc™ CryoTube, 1.0mL, sterile, external thread, without print
347627	Nunc™ CryoTube, 1.8mL, sterile, external thread, without print
347643	Nunc™ CryoTube, 4.5mL, sterile, external thread, without print
347783	Nunc™ Stor-It, 1.8 mL, external thread
347791	Nunc™ Stor-It, 4.5 mL, external thread
351934	Nunc™ CryoTube, 1.8mL, internal thread, round, without cap
363401	Nunc™ CryoTube, 1.8mL, sterile, internal thread, round
363436	Nunc™ CryoTube Cap, clear
363452	Nunc™ CryoTube, 4.5mL, sterile, internal thread, round
363515	Nunc™ CryoTube, 4.5mL, sterile, internal thread, yellow
366524	Nunc™ CryoTube, 3,6mL, sterile, internal thread, round
366656	Nunc™ CryoTube, 1,0mL, sterile, internal thread, foot, conical
367997	Nunc™ CryoTube, 3.6 mL, internal thread, round, without cap
368632	Nunc™ CryoTube, 1,8mL, sterile, internal thread, round
373420	Nunc™ CryoTube, 1,8mL, sterile, starfoot, ink jetted
373530	Nunc™ Store-It, 1.8mL, starfoot, ink jetted
373353	Nunc™ CryoTube, 1.0mL, sterile, external thread, starfoot, conical
375353	Nunc™ CryoTube, 1.0mL, sterile, external thread, starfoot, conical
375418	Nunc™ CryoTube, 1,8mL, sterile, external thread, starfoot, round
375420	Nunc™ CryoTube, 1,8mL, external thread, triple bag
377077	Nunc™ CryoTube, 1.8mL, barcode, starfoot, sterile, internal thread
377224	Nunc™ CryoTube, 1,0mL, sterile, internal thread, starfoot, conical
377267	Nunc™ CryoTube, 1,8mL, sterile, internal thread, starfoot, round
379146	Nunc™ CryoTube, 4,5mL, sterile, internal thread, starfoot, round
379189	Nunc™ CryoTube, 3,6mL, sterile, internal thread, starfoot, round