


## EC DECLARATION OF CONFORMITY

Product Name: Nunc CryoTube, Internal Thread and Caps

This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer Nunc A/S.

We, the legal manufacturer hereby declare that the mentioned products comply with the Essential Requirements Annex I of the EU Directive 98/79/EC amended by 2011/100/EU

Legal Manufacturer:	Nunc A/S Kamstrupvej 90 4000 Roskilde Denmark
Authorized Representative:	Not applicable
Basic Unique Device Identifier- Device Identifier (UDI-DI)	Not applicable
Single Registration Number (SRN)	Awaits the implementation of EUDAMED
Product Name	Nunc CryoTube, Internal Thread and Caps
Photograph	
GMDN Code + Title:	35347 Container, specimen
CE Marked	December 2003
Catalogue Number:	336078 336081 336088 336092 336094 339349 347023 351934 363401 363436 363452 363515 366524 366656 367997 368632

	373420 377077 377224 377267 379146 379189
Intended purpose	Transportation and storage of biological material
Risk Classification:	Self-Declared as per article 9 of EU Directive 98/79/EC
Conformity Assessment route	Annex III of EU Directive 98/79/EU
Common Specification (CS)	No relevant CS has been released for these IVD
Identification of Notified Body:	Presafe Denmark A/S Identification Number (0543) Tuborg Parkvej 8 DK-2900 Hellerup Denmark
Identification of the Certificate(s):	EC Quality System ISO 13485:2016 Certificate No. DGM-770

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 in Appendix 1 complies with the relevant parts of the DS/EN ISO 13485:2016.

Notified body **Presafe Denmark A/S, Notified Body number: 0543** has confirmed compliance of the company activities and issued the Quality System Certificate – DGM 770 initial date of issue 2011-12-12

Presafe Denmark A/S NB no. 0543 is the sole Notified Body used by Nunc A/S

Roskilde on behalf of Nunc A/S 2020-02-19  
YYYY-MM-DD

Name and function: Karen Bryde Frisk, Regulatory Affairs Manager

Signature:  \_\_\_\_\_

**Appendix 1:****Product Range Table:**

<b>Catalogue no.</b>	<b>Product name and description</b>
<b>336078</b>	Nunc CryoTube, Colored Caps, Clear
<b>336081</b>	Nunc CryoTubes, Colored Caps, Red
<b>336088</b>	Nunc CryoTubes, Colored Caps, Blue
<b>336092</b>	Nunc CryoTubes, Colored Caps, Yellow
<b>336094</b>	Nunc CryoTubes, Colored Caps, Assorted Color
<b>339349</b>	Nunc CryoTube, 1.8 ml, Sterile, internal thread, barcoded
<b>347023</b>	Nunc CryoTube, 1.8 ml, Sterile, internal thread, barcoded
<b>351934</b>	Nunc CryoTube, 1.8 ml, internal thread, round, without cap
<b>363401</b>	Nunc CryoTube, 1.8 ml, sterile, internal thread, round
<b>363436</b>	Nunc CryoTube Cap, clear
<b>363452</b>	Nunc CryoTube, 4.5 ml, sterile, internal thread, round
<b>363515</b>	Nunc CryoTube, 4.5 ml, sterile, internal thread, yellow
<b>366524</b>	Nunc CryoTube, 3.6 ml, sterile, internal thread, round
<b>366656</b>	Nunc CryoTube, 1.0 ml, sterile, internal thread, foot, conical
<b>367997</b>	Nunc CryoTube, 3.6 ml, internal thread, round, without cap
<b>368632</b>	Nunc CryoTube, 1.8 ml, Sterile, internal thread, round
<b>373420</b>	Nunc CryoTube, 1.8 ml, Sterile, starfoot, ink jetted
<b>377077</b>	Nunc CryoTube, 1.8 ml, barcode, starfoot, sterile, internal thread
<b>377224</b>	Nunc CryoTube, 1.0 ml, sterile, internal thread, starfoot, conical
<b>377267</b>	Nunc CryoTube, 1.8 ml, Sterile, internal thread, starfoot, round
<b>379146</b>	Nunc CryoTube, 4.5 ml, sterile, internal thread, starfoot, round
<b>379189</b>	Nunc CryoTube, 3.6 ml, sterile, internal thread, starfoot, round