

## DECLARATION OF CONFORMITY

### Manufacturer:

Nalge Nunc International Corporation  
A part of Thermo Fisher Scientific, Inc.  
75 Panorama Creek Drive  
Rochester, NY 14625-2385 USA  
Phone: +1-585-586-8800

### Authorized European Representative:

Nunc A/S  
Thermo Fisher Scientific  
Kamstrupvej 90  
DK-4000 Roskilde, Denmark  
Phone: +45 4631 2000

### Products:

Name: Nalgene™ Cryogenic Tube, 1.2 mL externally-threaded  
Catalog Number: 5000-0012  
GTIN: 10840016058209

Name: Nalgene™ Cryogenic Tube, 2 mL externally-threaded  
Catalog Number: 5000-0020  
GTIN: 10840016058216

Name: Nalgene™ Cryogenic Tube, 5 mL externally-threaded  
Catalog Number: 5000-0050  
GTIN: 10840016058223

Name: Nalgene™ System 100™ Cryogenic Tube, 1 mL externally-threaded  
Catalog Number: 5000-1012  
GTIN: 10840016058230

Name: Nalgene™ System 100™ Cryogenic Tube, 1.5 mL externally-threaded  
Catalog Number: 5000-1020  
GTIN: 10840016058247

Name: Nalgene™ Cryogenic Tube, 1.2 mL externally-threaded, Barcoded  
Catalog Number: 5001-0012  
GTIN: 10840016058254

Name: Nalgene™ Cryogenic Tube, 2 mL externally-threaded, Barcoded  
Catalog Number: 5001-0020  
GTIN: 10840016058261

Name: Nalgene™ Cryogenic Tube, 5 mL externally-threaded, Barcoded  
Catalog Number: 5001-0050  
GTIN: 10840016058278

**Products continued:**

Name: Nalgene™ System 100™ Cryogenic Tube, 1.5 mL externally-threaded, Barcoded  
Catalog Number: 5001-1020  
GTIN: 10840016058285

Name: Nalgene™ Cryogenic Tube, 1.2 mL externally-threaded  
Catalog Number: 5012-0012  
GTIN: 10840016058308

Name: Nalgene™ Cryogenic Tube, 2 mL externally-threaded  
Catalog Number: 5012-0020  
GTIN: 10840016058315

Name: Nalgene™ Specimen Cryogenic Vial, 15 mL externally-threaded  
Catalog Number: 5005-0015  
GTIN: 10840016058292

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded, Racked  
Catalog Number: 374220  
GTIN: 10840016058018

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded, Coded-rack  
Catalog Number: 374220-BR  
GTIN: 10840016058025

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded, Lock-rack  
Catalog Number: 374220LOCK  
GTIN: 10840016058032

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Racked  
Catalog Number: 374221  
GTIN: 10840016058049

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Coded-rack  
Catalog Number: 374221-BR  
GTIN: 10840016058056

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Lock-rack  
Catalog Number: 374221LOCK  
GTIN: 10840016058063

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded, Non-2D, Racked  
Catalog Number: 374222  
GTIN: 10840016058070

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded, Non-2D, Coded-rack  
Catalog Number: 374222-BR  
GTIN: 10840016058087

**Products continued:**

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Non-2D, Racked  
Catalog Number: 374223  
GTIN: 10840016058094

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Non-2D, Coded-rack  
Catalog Number: 374223-BR  
GTIN: 10840016058100

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Non-2D, Lock-rack  
Catalog Number: 374223LOCK  
GTIN: 10840016058322

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded  
Catalog Number: 374258  
GTIN: 10840016058117

Name: Nunc™ Cryobank™ Vial, 2 mL internally-threaded, Non-2D  
Catalog Number: 374259  
GTIN: 10840016058124

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded, Non-2D  
Catalog Number: 374260  
GTIN: 10840016058131

Name: Nunc™ Cryobank™ Vial, 5 mL internally-threaded  
Catalog Number: 374261  
GTIN: 10840016058148

**Medical Device Classification and Rule:**

IVD General (Self-Certified)

**Conformity Assessment Route:**

The above mentioned devices were assessed in conformance with the requirements of the European Directive 98/79/EC for self-certification, not intended for any List A or List B applications.

**Applicable Standards:**

EN 1041:2008+A1:2013 Information Supplied by Manufacturer of Medical Devices

ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

EN ISO 14971:2012 Medical Devices -- Application of Risk Management to Medical Devices

EN 556-1:2001/AC: 2006 Sterilization of Medical Devices – Requirements for Medical Devices to be Designated “Sterile” – Part 1: Requirements for Terminally Sterilized Medical Devices

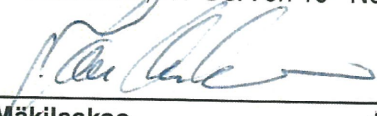


**Applicable Standards continued:**

- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- EN ISO 10993-6:2016 Biological Evaluation of Medical Devices – Part 6: Test for local effects after Implantation
- EN ISO 10993-10:2013 Biological Evaluation of Medical Devices – Part 10: Test for irritation and skin sensitization
- EN ISO 10993-11:2018 Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity
- EN ISO 11137-1:2015 Sterilization of Healthcare Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- EN ISO 11137-2:2015 Sterilization of Healthcare Products – Radiation – Part 2: Establishing the Sterilization Dose
- EN ISO 11737-1:2018 Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products
- EN ISO 11737-2:2019 Sterilization of Medical Devices – Microbiological Methods – Part 2: Test of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
- EN ISO 11137-1:2015 Sterilization of Healthcare Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

**Place and Date of Issue:**

Rochester, NY USA on 16<sup>th</sup> November 2020

  
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2020-11-18

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Date

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Company Stamp

