

## Instructions for Use

These instructions are valid for:



- Nunc™ Universal Tube, 2 mL internally-threaded
- Nunc™ Universal Tri-coded Tubes, 1.8 mL Ext Sharp V-bottom Bulk
- Nunc™ Universal Tri-coded Tubes, 1.8 mL Ext Sharp V-bottom Bulk (Special)
- Nalgene™ Cryogenic Tube, 2 mL externally-threaded
- Nalgene™ Cryogenic Tube, 5 mL externally-threaded



- 374512
- 374506-WP1D
- SP374506-WP1D
- 5000-0020
- 5000-0050

GTIN

- 10850016058574
- 10850016058062
- 10850016058079
- 10850016058598
- 10850016058604

GMDN

- 47775

### Intended Use

|                                    |  |
|------------------------------------|--|
| <b>Intended Purpose/Use</b>        | These polypropylene tubes are specimen receptacles and are intended for use in cryogenic storage and inter-laboratory ground transportation of human specimens containing biological materials and cells subjected to <i>in vitro</i> diagnostic (IVD) examination. The tubes can be used to store samples down to the vapor phase of liquid nitrogen temperatures. The tubes are disposable and for single use only. Intended for laboratory and healthcare professional use. |
| <b>Indications for Use</b>         | To be used when a healthcare professional has ordered <i>in vitro</i> diagnostic testing to be performed on patient specimens.   |
| <b>Intended User Group</b>         | Healthcare and laboratory professionals.   |
| <b>Use Environment</b>             | Hospitals, clinical collection sites and clinical laboratories.  |
| <b>Intended Patient Population</b> | Patients with a medical or clinical condition requiring <i>in vitro</i> diagnostic investigation, diagnosis, and possible medical treatment.   |
| <b>Contraindications</b>           | No known contraindications have been identified.   |

## Instructions for Use

1. Fill the tubes to no more than 90% total capacity.
2. Ensure that the threads of tube and cap are dry before closing.
3. Tighten the cap.
4. Specific instructions for use of these tubes in cold storage must be defined and implemented by the end user according to the type of sample stored as well as the downstream application.
5. If used with liquid nitrogen (LN<sub>2</sub>), only place these cryogenic tubes in the vapor phase of the LN<sub>2</sub>.

## Conditions of Use (without Specimen)

| Nunc™ Universal™ Tubes and Nalgene™ Cryogenic Tubes |   |
|---|---|
| Transportation Conditions                           | Ambient temperature (-30°C to 60°C or -22°F to 140°F) |
| Suggested Storage Conditions                        | Room temperature (20°C to 25°C or 68°F to 77°F)       |

## Limitation of Use

The Nunc™ Universal Tubes and Nalgene™ Cryogenic Tubes are only intended for use in cryogenic storage and inter-laboratory ground transportation of human specimens containing biological materials and cells subjected to in vitro diagnostic (IVD) examination.

## Technical Information

Disposal of the device must be handled according to local regulations.

This medical device complies with IVDR (EU) 2017/746.

Declaration of Conformity is available from the manufacturer and/or EU Representative.



## Warnings and Precautions

To ensure correct usage, familiarise yourself with the following warnings before using the device.

1. Warning: For use in vapor phase of liquid nitrogen only. Submersion can lead to hazardous situation.
2. Overfilling can lead to caps bursting during sample expansion, which can lead to leakage and contamination.
3. For single use only.
4. Nunc™ Universal Tube, 2 mL internally-threaded have a two year shelf life. Nalgene™ Cryogenic Tube, 2 mL and 5 mL externally-threaded have a five-year shelf life. Do not use after expiry date.
5. This device is supplied sterile via irradiation sterilization method. Do not use the product if the product packaging is unsealed or damaged.
6. Fluid path is sterile and non-pyrogenic while cap is intact. Discard any tube that arrives with cap missing or askew.
7. If samples are being shipped by methods other than ground, shipping on dry ice to prevent leakage is recommended.
8. Dispose of used tubes in appropriate biohazard collection container.
9. Report any serious incident that occurred in relation to these devices to the manufacturer and EU competent authority.
10. Use of Nunc™ CryoFlex Tubing (Catalog # 343958) can offer additional safe handling protection.

Report to the manufacturer and local competent authority if you experience unexpected operation or serious incident with the device during or because of its use. The manufacturer will support and if relevant report it to the competent authorities.

**Quality Assurance Release Specifications**

**5000-0020, 5000-0050**

| TEST   | RELEASE LIMIT(S)                        |
|--|---|
| Pyrogen (endotoxin)                          | < 0.5 EU/mL                             |
| Irradiation Certificate of Processing Review | SAL 10 <sup>-6</sup>                    |
| DNase  | 8 x 10 <sup>-7</sup> Kunitz units/μL    |
| RNase  | 1.9 x 10 <sup>-10</sup> Kunitz units/μL |

**374512**

| TEST   | RELEASE LIMIT(S)                        |
|--|---|
| Pyrogen (endotoxin)                          | < 0.5 EU/mL                             |
| Irradiation Certificate of Processing Review | SAL 10 <sup>-6</sup>                    |
| DNase  | 8 x 10 <sup>-7</sup> Kunitz units/μL    |
| RNase  | 1.9 x 10 <sup>-10</sup> Kunitz units/μL |

**374506-WP1D, SP374506-WP1D**

| TEST   | RELEASE LIMIT(S)                        |
|--|---|
| Pyrogen (endotoxin)                          | < 0.5 EU/mL                             |
| Irradiation Certificate of Processing Review | SAL 10 <sup>-6</sup>                    |
| DNase  | 8 x 10 <sup>-7</sup> Kunitz units/μL    |
| RNase  | 1.9 x 10 <sup>-10</sup> Kunitz units/μL |

**Pack Label**

**thermo**scientific

Nunc™ Universal™ Tube, 2 mL  
internally-threaded

2.0 mL 48 tubes per bag

**REF 374512**

**UDI**  (01) 1 0850016 05857 4  
(11) 240611  
(17) 290610  
(10) 999999999  
**LOT** 999999999 (240) 374512

**LOT** 999999999 2029-06-10

**IVD**  **STERILE R**

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CH REP** Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800


Assembled/Packed in USA  8-1030-201 0324 **00088**  
www.thermofisher.com


**Case Label**

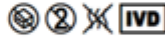
**thermo**scientific **REF 374512**


Nunc™ Universal™ Tube, 2 mL  
internally-threaded


2 mL 480 / C.S 48 tubes per bag

**UDI**  (01) 1 0850016 05857 4  
(11) 210916  
(17) 260915  
(10) 0000000  
**LOT** REF (240) 374512

 2026-09-15 **STERILE R**

**IVD** 

**LOT**  +H2863745120


**LOT**  00000000

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CH REP** Thermo Fisher Scientific Inc. (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland +41 61 716 77 00

**EC REP** Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800

www.thermofisher.com

Case: 00004  01234 8-1030-210


**Made in USA**

**thermo**scientific****

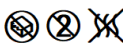
Nalgene™ Cryogenic Tube, 2 mL externally-threaded

2.0 mL 25 tubes per bag

**REF 5000-0020**

**UDI**  **GTIN** (01) 1 0850016 05859 8  
(11) 240611  
(17) 290610  
(10) 999999999  
(240) 5000-0020


**LOT** 999999999 **2029-06-10**

**IVD**  **STERILE R**

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CE** 2797

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


made in USA  8-1030-210 0324 **00088**  
www.thermofisher.com

**thermo**scientific****

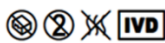
Nalgene™ Cryogenic Tube, 2 mL externally-threaded

2 mL 500 / CS 25 tubes per bag

**REF 5000-0020**

**UDI**  **GTIN** (01) 3 0850016 05859 2  
(11) 210916  
(17) 260915  
(10) 0000000  
(240) 5000-0020

**LOT** 00000000 **2026-09-15** **STERILE R**


**IVD** 

**CH REP** Thermo Fisher Scientific Inc. (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland +41 61 716 77 00

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CE** 2797

Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800 www.thermofisher.com


Case: 00004  01234 8-1030-210 **Made in USA**

**thermo**scientific****

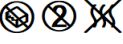
Nalgene™ Cryogenic Tube, 5 mL externally-threaded

5.0 mL 10 tubes per bag

**REF 5000-0050**

**UDI**  **GTIN** (01) 1 0850016 05860 4  
(11) 240514  
(17) 290513  
(10) 999999999  
(240) 5000-0020


**LOT** 999999999 **2029-05-13**

**IVD**  **STERILE R**

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CE** 2797

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


made in USA  8-1030-210 0324 **00088**  
www.thermofisher.com

**thermo**scientific****

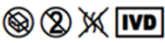
Nalgene™ Cryogenic Tube, 5 mL externally-threaded

5 mL 500 / CS 10 tubes per bag

**REF 5000-0050**

**UDI**  **GTIN** (01) 3 0850016 05860 8  
(11) 210916  
(17) 260915  
(10) 0000000  
(240) 5000-0050

**LOT** 00000000 **2026-09-15** **STERILE R**


**IVD** 

**CH REP** Thermo Fisher Scientific Inc. (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland +41 61 716 77 00

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CE** 2797

Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800 www.thermofisher.com


Case: 00004  01234 8-1030-210 **Made in USA**

**thermo**scientific****


Nunc™ Universal Tri-coded Tubes 1.8mL Ext Sharp V-bottom Bulk

1.8 mL 48 tubes per bag

**REF 374506-WP1D**

**UDI**  **GTIN** (01) 0 0000000 00000 0  
(11) YYMMDD  
(17) YYMMDD  
(10) 123456789  
(240) 374506-WP1D


**LOT** 123456789 **YYYY-MM-DD**

**IVD**  **STERILE R**

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000

**CE** 2797

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


Made in USA  8-1030-210 0324 **01234**  
www.thermofisher.com

**thermo**scientific****

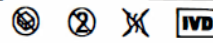
Nunc™ Universal Tri-coded Tubes 1.8mL Ext Sharp V-bottom Bulk

1.8 mL 480 / CS 48 tubes per bag

**REF 374506-WP1D**

**UDI**  **GTIN** (01) 2 0850016 05860 9  
(11) 251015  
(17) 271015  
(10) 185300  
(240) 374506-WP1D

**LOT** 185300 **2027-10-15** **STERILE R**

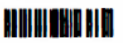
**IVD** 

**CH REP** Thermo Fisher Scientific (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland CRN-AR-20001963 +41 61 716 77 00

**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000


**CE** 2797

Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800 www.thermofisher.com


Case: 00004  00004 8-1030-210 0825 **Made in USA**

**thermo scientific**  
 Nunc™ Universal Tri-coded Tubes  
 1.8mL Ext Sharp V-bottom Bulk  
 1.8 mL 48 tubes per bag

**REF** SP374506-WP1D


**UDI**  (01) 0 000000 00000 0  
 (11) YYMMDD  
 (17) YYMMDD  
 (10) 123456789  
 (240) SP374506-WP1D

**LOT** 123456789  YYYY-MM-DD

   **IVD** 


**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +45 4631 2000





**EC REP** Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800


Made in USA  8-1030-211 0324 **01234**  
[www.thermofisher.com](http://www.thermofisher.com)


**thermo scientific** **REF** SP374506-WP1D

Nunc™ Universal Tri-coded Tubes  
 1.8mL Ext Sharp V-bottom Bulk  
 1.8 mL 480 / CS 48 tubes per bag

**UDI**  (01) 2 0850016 05807 6  
 (11) 251015  
 (17) 271015  
 (10) 185229  
 (240) SP374506-WP1D

 2027-10-15 **STERILE R**    **IVD**


**LOT**  +H286SP374506WP1D5

**LOT**  185229





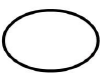


**EC REP** Nunc A/S, a part of Thermo Fisher Scientific Inc. Kamstrupvej 90, P.O. Box 280 DK-4000 Roskilde, Denmark +46 46312000 [www.thermofisher.com](http://www.thermofisher.com)









**EC REP** Thermo Fisher Scientific (Schweiz) AG Neuhofstrasse 11, 4153 Reinach (BL) Switzerland CRN-AR-20001963 +41 61 716 77 00

**EC REP** Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625 USA +1 585 586 8800 [www.thermofisher.com](http://www.thermofisher.com)

**Case: 00001**  00001 8-1030-210 0825 Made in USA

**Symbols Glossary in accordance with ISO 15223-1:2021 and other references**

| Symbol  | Title of Symbol                                     | Description of Symbol  | Reference Number |
|---|---|--|------------------|
|   | Manufacturer  | Indicates the medical device manufacturer as defined in EU MDR 2017/745 and EU IVDR 2017/746.                      | 5.1.1            |
| <b>EC REP</b>   | Authorized representative in the European Community | Indicates the authorized representative in the European Community.   | 5.1.2            |
|  | Date of Manufacture                                 | Indicates the date the medical device was manufactured.  | 5.1.3            |
|  | Use-by date   | Indicates the date after which the medical device is not to be used.   | 5.1.4            |
| <b>LOT</b>  | Batch code  | Indicates the manufacturer's batch code so that the batch or lot can be identified.                                | 5.1.5            |
| <b>REF</b>  | Catalogue number                                    | Indicates the manufacturer's catalogue number so that the medical device can be identified.                        | 5.1.6            |
| <b>STERILE R</b>  | Sterilized using irradiation                        | Indicates a medical device that has been sterilized using irradiation.   | 5.2.4            |
|  | Do not use if package is damaged                    | Indicates a medical device that should not be used if the package has been damaged or opened.                      | 5.2.8            |
|  | Single <i>sterile</i> barrier system                | Indicates a single barrier system.   | 5.2.11           |
|  | Temperature limit                                   | Indicates the temperature limits to which the medical device can be safely exposed.                                | 5.3.7            |
|  | Do not re-use                                       | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. | 5.4.2            |

|   |   |   |               |
|---|---|---|---------------|
|  | Consult instructions for use              | Indicates the need for the user to consult the instructions for use.  | 5.4.3         |
|  | Caution                                   | Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions | 5.4.4         |
|  | <i>In vitro</i> diagnostic medical device | Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device                      | 5.5.1         |
|  | Non-pyrogenic                             | Indicates a medical device that is non-pyrogenic.   | 5.6.3         |
|  | Unique Device Identifier                  | Indicates a carrier that contains Unique Device Identifier information.   | 5.7.10        |
|  | European Conformity Mark                  | Indicates European technical conformity.  | (EU) 2017/746 |
|  | Authorized representative in Switzerland  | Indicates the authorized representative in Switzerland.   | IvDO          |
|  | GTIN (Global Trade Item Number)           | Uniquely identifies the item all over the world.  | GS1           |

## Contact Information

### Legal Manufacturer

Nalge Nunc International Corporation,  
a part of Thermo Fisher Scientific Inc.  
75 Panorama Creek Drive  
Rochester, New York 14625 USA  
Phone: +1 585 586 8800  
[www.thermofisher.com](http://www.thermofisher.com)

### UK Responsible Person (UKRP)

Life Technologies Ltd,  
a part of Thermo Fisher Scientific Inc.  
3 Fountain Drive, Inchinnan Business Park  
Paisley, PA3 9RF, United Kingdom  
Phone: +44 (7826) 908289  
[www.thermofisher.com](http://www.thermofisher.com)

### EU Representative

Nunc A/S,  
a part of Thermo Fisher Scientific Inc.  
Kamstrupvej 90  
DK-4000 Roskilde, Denmark  
Phone: +45 4631 2000  
[www.thermofisher.com](http://www.thermofisher.com)

### Swiss Representative

Thermo Fisher Scientific (Schweiz) AG  
Neuhofstrasse 11, 4153  
Reinach (BL) Switzerland  
+41 61 716 77 00  
[www.thermofisher.com](http://www.thermofisher.com)

This is revision G00 of this IFU. This revision updated the following information:

- Added Nunc™ Universal Tri-coded Tubes, 1.8 mL Ext Sharp V-bottom Bulk, SKUs 374506-WP1D and SP374506-WP1D.
- Added corresponding GTINs for SKUs 374506-WP1D and SP374506-WP1D.
- Added Quality Assurance Release Specifications for SKUs 374506-WP1D and SP374506-WP1D.
- Added labels for SKUs 374506-WP1D and SP374506-WP1D.