thermoscientific

Instructions for Use

These instructions are valid for:

CE 2797 IVD

- **Nalgene™ Specimen Cryogenic Vial, 15 mL externally-threaded**

REF

- **5005-0015**

GTIN

- **10850016058673**

GMDN

- **47775**

Intended Use

Intended Purpose/Use	These polypropylene containers are covered specimen receptacles and are intended to be used for the collection, and preservation and/or transport, of any type of tissue specimen (e.g., biopsy tissue) collected from any body part for in vitro diagnostic investigation. They do not contain patient-contact specimen sampling/extraction devices such as swabs/brushes. The container can be used to store samples down to the vapor phase of liquid nitrogen temperatures. The containers are disposable and for single use only. Intended for laboratory and healthcare professional use.
Indications for Use	To be used when a healthcare professional determines an area of tissue in the body is not presenting as normal and biopsy is recommended.
Intended User Group	Healthcare and laboratory professionals.
Use Environment	Operating rooms of hospitals and associated laboratories.
Intended Patient Population	Patients with a medical or clinical condition that require a biopsy for in vitro diagnostic investigation, diagnosis, and possible medical treatment.
Contraindications	No known contraindications have been identified.

Instructions for Use

1. Specific instructions for use of these containers 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.
2. If used with liquid nitrogen (LN_2), only place these cryogenic containers in the vapor phase of the LN_2.

Conditions of Use (without Specimen)

Nalgene™ Specimen Cryogenic Vial, 15 mL externally-threaded	
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 the collection and preservation and/or transport, of any type of tissue specimen (e.g., biopsy tissue) collected from any body part for *in vitro* diagnostic investigation.

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. Nalgene™ Specimen Cryogenic Vial, 15 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.

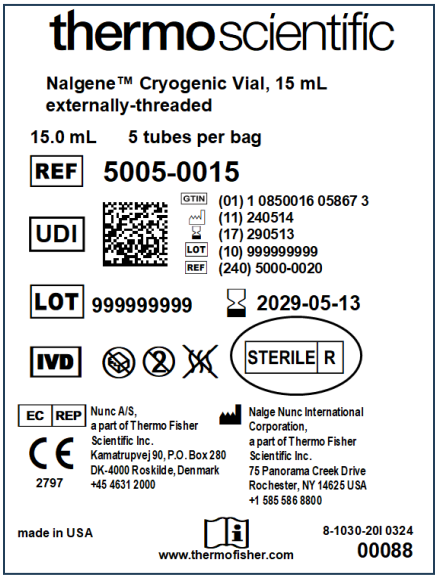
Report to the manufacturer and local competent authority if you experience unexpected operation or serious incident with the device during or because of its use. The manufacturer will support and if relevant report it to the competent authorities.

Quality Assurance Release Specifications

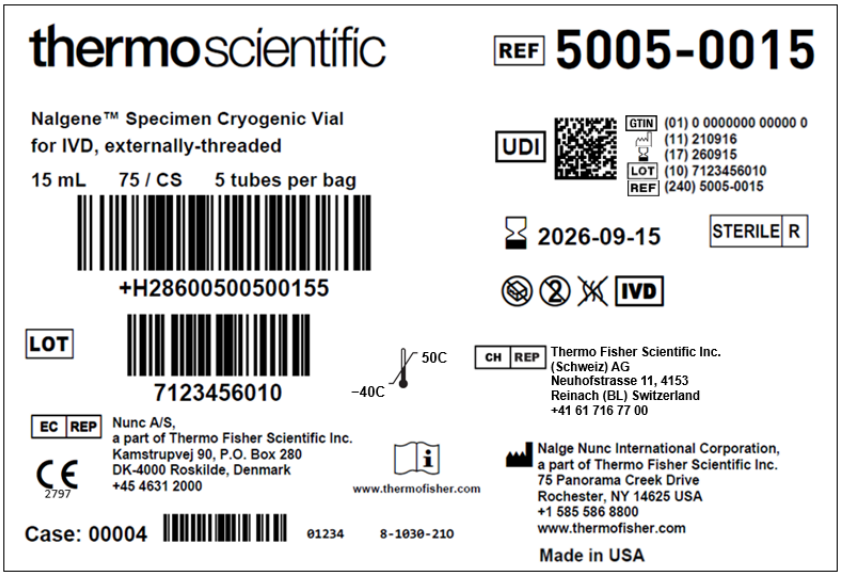
5005-0015

Parameter	Specification
Pyrogen (endotoxin)	< 0.5 EU/mL
Irradiation Certificate of Processing Review	19.0 - 28.0 kGy

Pack Label



Case Label



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 Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
EC REP	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
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
STERILE R	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 *sterile* 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
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an *in vitro* 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

Contact Information

Legal Manufacturer 

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This is revision B01 of this IFU. This revision updated the following information:

- Updated the pack label image.