TECH SHEET Certified Clean Containers

## Thermo Scientific Nalgene Certified Clean Biotainer Carboys

How can low particulate carboys help improve my biopharmaceutical and vaccine production?

# Less chance of contamination to maintain product integrity

- Inspection procedures throughout manufacturing include leak testing, dimensional testing, visual inspection for particulates and release testing to ensure the carboy meets all specifications
- Clean room-produced in ISO Class 7 to limit particulates during molding
- All container/closure systems certified leakproof\* to protect valuable contents
- Robust, PC can be used from -100°C to 100°C, allowing for both heated mixing and frozen storage or shipment. It is recommended to always test in actual use conditions, as results may vary depending upon application.

#### Clean containers in bioproduction

Sterile containers, free from added interfering chemicals and low in particulates, are required to maintain both cleanroom as well as product integrity.



### **Key Features**

- Certified to meet USP <788> low particulate requirements
- Sterile, ready-to-use products with robust triple-layer packaging for clean room use
- Certified low endotoxin (0.50 EU/mL) according to USP <85> to limit pyrogens
- Products can be supplied with forced extraction studies\*\*, validation binders\*\* and certificates



# Manufactured, Tested and Supported for Critical Applications

- Products are certified sterile and meet the particulate matter limits specified in USP <788>, low endotoxin according to USP <85> and in heat-sealed packaging ready for clean room use
- All packs are in double heat-sealed clean room bags and placed in a protective carton liner for cleanroom use
- High quality, USP 30 <661>-compliant, non-cytotoxic, non-mutagenic, resins with incoming quality control and ID confirmation on every lot to ensure consistent materials are delivered to you
- Support materials available upon request include forced extraction studies\*\*, validation binders\*\*, certificates and other documentation upon request
- Customer support includes our highly experienced commercial specialist teams, regulatory team, quality team and regional technical support

## Thermo Scientific™ Nalgene™ Biotainer™ Polycarbonate (PC) Carboys

Cat. No.	Description	Volume	Width, mm (in)	Height with Closure,	Closure		No. per Pack/
				mm (in)	Size	Material	Case
383405-16	Square Biotainer Carboy with attached Handle	5L	166 (6.55)	299 (11.76)	48mm	white PP w/ silicone closure	1/6
383405-42	Square Biotainer Carboy	5L	166 (6.55)	299 (11.76)	48mm	white PP w/ silicone closure	1/6
383410-08	Square Biotainer Carboy with attached Handle	10L	255 (10.05)	337 (13.26)	48mm	white PP w/ silicone closure	1/2
383410-42	Square Biotainer Carboy	10L	255 (10.05)	337 (13.26)	48mm	white PP w/ silicone closure	1/2
383423-42	Square Biotainer Carboy with attached Handle	20L	255 (10.05)	495 (19.50)	48mm	white PP w/ silicone closure	1/3

#### Disclaimer:

\*Our guarantee for a leakproof seal is subject to our standard product warranty, as set forth in the Thermo Fisher Scientific Terms and Conditions of Sale. Our products are leakproof at ambient temperature and pressure when used with their corresponding closures. However, to ensure safe usage, customers are advised to test our containers and closures under conditions of their planned applications. Please contact technicalsupport@thermofisher.com if you need additional information about our products.

Asia: Australia: 1300-735-292; New Zealand: 0800-933-966; China +86-21-6865-4588 or +86-10-8419-3588; China Toll-free: 800-810-5118 or 400-650-5118; Singapore +65-6872-9718; Japan: +81-3-5826-1616; Korea +82-2-2023-0640; Taiwan +886-2-87516655; India: +91-22-6680-3000 Europe: Austria: +43-1-801-40-0; Belgium: +32-2-482-30-30; Denmark: +45-4631-2000; France: +33-2-2803-2180; Germany: +49-6184-90-6000; Germany Toll-free: 0800-1-536-376; Italy: +39-02-95059-554; Netherlands: +31-76-571-4440; Nordic/Baltic/ClS countries: +358-10-329-2200; Russia: +7-(812)-703-42-15; Spain/Portugal: +34-93-223-09-18; Switzerland: +41-44-454-12-12; UK/Ireland: +44-870-609-9203

North America: USA/Canada +1-585-586-8800; USA Toll-free: 800-625-4327

**South America:** USA sales support: +1-585-586-8800 **Countries not listed:** +49-6184-90-6000 or +33-2-2803-2000





<sup>\*\*</sup>Forced extraction studies and validation binders from Thermo Fisher Scientific, where available, are provided under a confidentiality agreement to assist customers in product selection. Customers are responsible for determining what studies are recommended for its specific applications. Forced extraction studies and validation binders may be requested by contacting us at ROCregSupport@thermofisher.com.