



Thermo Scientific
Critical Environment Products and Services



Where clean is critical
every container - every time

Thermo
SCIENTIFIC

The only thing in your container is what you add

Thermo Scientific™ Clean Process Products and Services for Critical Environments

Low Particle Cleaning

- Provided as standard products or custom services
- Designed to exceed USP <788>
- Containers and closures cleaned in proprietary HEPA filtered washing/drying equipment
- Clean packaged in class 10 HEPA filtered workstations inside our class 100 clean room
- Glass certified to contain as few as 5 particles/mL larger than 0.5 microns
- Plastic certified to contain as few as 20 particles/mL larger than 0.3 microns
- Certificate of analysis or cleaning certificates are available with each lot

Chemical Cleaning for Trace Analysis

- Provided as standard products or custom services. Choice of combination of several cleaning methods
- Test include removal of trace inorganics (metals), trace volatile organic compounds, trace semivolatile organic compounds, total organic carbon, particle counting and trace pesticides/herbicides
- Available with cleanroom or standard packaging
- Certificate of analysis or cleaning certificates available with each lot

Depyrogenation

- Provided as standard products or custom services
- To meet endotoxin-free container needs for terminal sterilization or endotoxin-limited environments
- Testing performed according to USP<85>
- Endotoxin levels of less than 0.06 EU/mL (USP standard is 0.25 EU/mL for WFI)
- Containers and closures cleaned in proprietary HEPA filtered washing equipment with endotoxin-free water followed by 250°C depyrogenation cycle
- Clean packaged in class 10 HEPA filtered workstations inside our class 100 clean room
- Certificate of analysis or cleaning certificates are available with each lot

Silanization

- Provided as standard products or custom services
- Available as vials and culture tubes to minimize waste costs for quantitative analysis
- Treatment inhibits materials from adhering to the surface of the container, allowing for maximum recovery of trace analytes
- A methylsilylating agent is introduced by vapor phase deposition onto the surface of the disposable glassware
- Silylating agent reacts with active groups on surface of glass effectively making them less reactive to stored non-aqueous materials
- Environmentally-friendly method of surface modification
- Certificate of conformance provided for the treated product



Total Organic Carbon

Total organic carbon (TOC) certified vials

Trust our low-level certified vials for Total Organic Carbon testing and sampling. Several sizes of containers are available including the popular 40 mL autosampler vials cleaned, certified, and ready to use. Each lot of vials is tested and certified to contribute < 10 ppb or < 20 ppb TOC as background. A certificate of analysis is included.

Applications:

- USP Method 643 testing
- Off-line and grab sampling of high purity water
- 40 mL vials fit most automated TOC instruments
- Low background is perfect for preparation and storage of standards
- Simplify and reduce cost of cleaning validation

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
CT18-TOC	Screw thread glass tube (round bottom) silanized 16 x 125 (certified for less than 20 ppb for TOC)	0.6 (18)	15-425	PTFE / Silicone Septa	0.563 x 5.00	14.30 x 127	255
CT18-TOC/LL	Screw thread glass tube (round bottom) silanized with closure 16 x 125 (certified for less than 10 ppb for TOC)	0.6 (18)	15-425	PTFE / Silicone Septa	0.563 x 5.00	14.30 x 127	255
SCT-18100/TOC	Clear glass flat bottom tube with closure 18 x 100 (less than 20 ppb for TOC)	0.58 (17)	15-425	PTFE / Silicone Septa	0.938 x 6.00	23.83 x 152.40	200
3115-OTWS-2	30mL Polysulphone Tube, TOC cleaned only, no C of A	1 (30)	20-400	PTFE / Silicone Septa	1.02 x 3.74	26 x 95	100
24-414/TS/WS-2	24-414 Polypropylene cap, pre-cleaned	N/A	24-414	PTFE / Silicone Septa	N/A	N/A	72
40C-TOC	Clear glass vial with closure, dust covers (certified for less than 20 ppb for TOC)	1.35 (40)	24-414	PTFE / Silicone Septa	1.125 x 3.75	28.58 x 95.25	72
40A-TOC/DB/LL	Amber glass vial with closure, dust covers (certified for less than 10 ppb for TOC)	1.35 (40)	24-414	PTFE/Silicone Septa	1.125 x 3.75	28.58 x 95.25	144
40C-TOC/DB	Clear glass vial with closure, dust covers (certified for less than 20 ppb for TOC)	1.35 (40)	24-414	PTFE / Silicone Septa	1.125 x 3.75	28.58 x 95.25	144
40C-TOC/DB/LL	Clear glass vial with closure, dust covers (certified for less than 10 ppb for TOC)	1.35 (40)	24-414	PTFE / Silicone Septa	1.125 x 3.75	28.58 x 95.25	144
40C-TOC/LL	Clear glass vial (certified for less than 10 ppb for TOC)	1.35 (40)	24-414	PTFE / Silicone Septa	1.125 x 3.75	28.58 x 95.25	72
40C-TOC/LL/VKS	Clear glass vial (certified for less than 10ppb TOC)	1.35 (40)	24-414	PTFE / Silicone Septa	1.125 x 3.75	28.58 x 95.25	9
S114-125A/TOC	Amber glass Boston round with closed top closure	4 (125)	22-400	PTFE / Silicone	1.875 x 4.375	47.63 x 111.13	12
S114-250A/TOC	Amber glass Boston round with open-top polypropylene closure	8 (250)	24-414	PTFE / Silicone Septa	2.375 x 5.375	60.33 x 136.53	12
S114-250C/TOC	Clear glass Boston round, open-top polypropylene closure	8 (250)	24-414	PTFE / Silicone Septa	2.375 x 5.375	60.33 x 136.53	24
1000C/TOC	Clear Boston round bottle with closed top closure	32 (1000)	33-400	PTFE	3.75 x 8.5	95.25 x 215.90	12
1000A/TOC	Amber Boston round glass bottle with closed top closure	32 (1000)	33-430	PTFE	3.75 x 8.5	95.25 x 215.90	12

TOC water and other specialty waters

High-purity specialty water exceeds 17 MegaOhm resistivity with low organic and inorganic impurities at the time of packaging. Processing includes reverse osmosis, activated carbon and ultraviolet TOC reduction. Specialty waters are packaged in pre-cleaned amber glass containers. Our specialty waters are final filtered to 0.05 micron through hydrophobic membrane filters and certified to contain < 50 ppb Total Organic Carbon.

Applications:

- Sample and standards dilution
- Lab blank determination
- Equipment rinsing

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
112-01A/CTOC	Amber glass bottle with closure	32 (1000)	33-430	PTFE / Silicone	3.70 x 8.10	93.98 x 205.74	12
111-04A/C-TOC	Amber jug with closure	128 (4000)	38-430	PTFE / Silicone	6.25 x 13.25	158.75 x 336.55	4



Low Particle Containers

Particle-certified glass containers

Protect the quality of your products or laboratory samples by using low particulate containers which are tested and certified to meet the low particle criteria of group L as described in the table on page 11. The containers are assembled to contain as few as 5 particles per milliliter > 0.5 microns. Assembled with low-shedding polypropylene closures with chemically inert PTFE faced liners that do not contain adhesives. Both clear and amber glass products are available.

Applications:

- Bulk intermediate, etc. storage in cleanroom or controlled environment use
- Pharmaceutical, biotech and medical use

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
130-005/LP	Amber glass wide mouth bottle with closed top polypropylene closure	0.5 (15)	28-400	PTFE	1.14 x 1.75	29 x 44.5	57
140-40C/LP	Clear glass vial with open-top closure, particulate cleaned	1.35 (40)	24-414	PTFE / Silicone Septa	1.125 x 3.75	28.58 x 95.25	90
114-060A/LP	Amber glass Boston round bottle with open-top closure	2 (60)	20-400	PTFE / Silicone Septa	1.875 x 4.375	47.63 x 111.13	24
120-02A/LP	Amber glass packer bottle with lined closure	2 (60)	33-400	PTFE	1.75 x 3.00	44.45 x 76.20	24
114-125CT/LP	Clear glass Boston round bottle with closed top closure	4 (125)	24-414	PTFE / Silicone	1.875 x 4.375	47.63 x 111.13	12
114-125A/LP	Amber glass Boston round bottle with closed top closure	4 (125)	24-414	PTFE / Silicone	1.875 x 4.375	47.63 x 111.13	12
120-04A/LP	Amber glass packer bottle with PTFE lined closure	4 (125)	38-400	PTFE	2.00 x 3.75	50.80 x 95.25	12
114-250C/LP	Clear glass Boston round bottle with closed top closure	8 (250)	24-414	PTFE / Silicone	2.375 x 5.375	60.33 x 136.53	24
114-250A/LP	Amber glass Boston round bottle with closed top closure	8 (250)	24-414	PTFE / Silicone	2.375 x 5.375	60.33 x 136.53	12
121-08A/LP	Amber glass wide mouth packer bottle with closure	8 (250)	45-400	PTFE	4.75 in x 2.5	120.65 x 63.50	12
132-16C/LP	Clear glass jar, wide mouth, with closure	16 (500)	89-400	PTFE	3.5 x 3.875	90 x 98.4	12
133-32C/LP	Clear glass jar, wide mouth with closure	32 (1000)	89-400	PTFE	3.75 x 6.625	95.25 x 168.28	12
113-500A/LP	Amber glass Boston round bottle with closure	16 (500)	28-400	PTFE	3.00 x 6.625	76.20 x 168.28	12
122-16A/LP	Amber glass wide mouth packer bottle with closure	16 (500)	53-400	PTFE	5.80 x 3.18	147.32 x 80.77	12
112-01A/LP	Amber glass Boston round bottle with closure	32 (1000)	33-430	PTFE / Silicone	3.75 x 8.50	95.25 x 215.90	12
110-80A/LP	Amber fluorinated glass jug with closure	80 (2500)	38-430	PTFE / Silicone	5.25 x 12.00	133.4 x 305	6
123-80A/LP	Amber glass wide mouth packer bottle with closure	84 (2500)	70-400	PTFE	5.50 x 9.375	139.70 x 238.13	4
111-04A/LP	Amber glass jug with closure	128 (4000)	38-430	PTFE / Silicone	6.25 x 13.25	158.75 x 336.55	4



Particle-certified HDPE containers

Consistent quality and reliability are guaranteed when you use Thermo Scientific particulate-cleaned bottles for storage of your product or high purity samples. Narrow mouth HDPE bottles with polypropylene closures are leak-proof and suitable for use in sampling packaging and may be used with combination packaging for hazardous shipping. Bottles are double-bagged and ready to take into your cleanroom with no extra preparation. Low metals certification includes aluminum, calcium, copper, iron, potassium, magnesium, manganese, sodium, and zinc at less than 10 ppb. A certificate of analysis is included with each lot.

Applications:

- Bulk intermediate, etc. storage in cleanroom or controlled environment use
- Pharmaceutical and biotech use

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
156-125W/N/LP	HDPE Narrow mouth Nalgene bottle with closure	4 (125)	24-415	N/A	2.00 x 4.00	50.80 x 101.60	24
156-125W/N/LPM	HDPE Narrow mouth Nalgene bottle with closure, low metals	4 (125)	24-415	N/A	2.00 x 4.00	50.80 x 101.60	24
157-250W/N/LP	HDPE Narrow mouth Nalgene bottle with closure	8 (250)	24-415	N/A	2.50 x 5.25	63.50 x 133.35	24
157-250W/N/LPM	HDPE Narrow mouth Nalgene bottle with closure, low metals	8 (250)	24-415	N/A	2.50 x 5.25	63.50 x 133.35	24
150-01W/N/LP	HDPE Narrow mouth Nalgene bottle with closure	32 (1000)	38-430	N/A	3.625 x 8.50	92.08 x 215.90	12
150-01W/N/LPM	HDPE Narrow mouth Nalgene bottle with closure, low metals	32 (1000)	38-430	N/A	3.625 x 8.50	92.08 x 215.90	12

Besides more than 80 standard products, we offer custom cleaning of your containers.

See pages 8-9 for a wide variety of processing services for Thermo Scientific and other containers you may send in for cleaning.



Depyrogenation

Depyrogenated glass

Save the need to invest in expensive capital equipment with ready-to-use depyrogenated glassware in a wide variety of sizes and configurations. The containers have been specially prepared to meet endotoxin levels of less than 0.06 EU/mL. A certificate of analysis is included with each lot.

Applications:

- Packaging and storing articles that will be terminally sterilized
- Storage of laboratory reagents and medias
- Sample storage
- Water sampling

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
23-CTP4/PF	Clear glass vial with urea closure	0.12 (4)	13-425	PTFE	0.591 x 1.77	15.01 x 44.96	72
139-20C/CT/LP/PF	Clear glass vial with closed top black polypropylene closure	0.75 (22)	24-400	PTFE / Silicone	1.125 x 2.25	28.6 x 57.15	72
130-02C/PF	Clear wide mouth glass straight side jar with closure	2 (60)	53-400	PTFE	2.25 x 1.875	57.15 x 47.63	24
C20-02A/PF	Amber wide mouth glass jar with closure	2 (60)	33-400	PTFE	1.625 x 3.00	41.28 x 76.20	24
130-04A/PF	Amber wide mouth short glass straight side jar with closure	4 (125)	58-400	PTFE	2.25 x 2.75	57.15 x 69.85	24
130-04C/PF	Clear wide mouth short glass straight side jar with closure	4 (125)	58-400	PTFE	2.375 x 2.625	60.33 x 66.68	24
130-04C/TL/PF	Clear tall wide mouth glass jar with closure	4 (125)	48-400	PTFE	2.00 x 4.00	50.80 x 101.60	24
C20-04A/PF	Amber glass wide mouth packer bottle with closure	4 (125)	38-400	PTFE	2.125 x 3.75	53.98 x 95.25	24
121-08A/PF	Amber glass wide mouth packer bottle with closure	8 (250)	45-400	PTFE	4.75 in x 2.5	120.65 x 63.50	12
131-08A/PF	Amber glass straight side wide mouth jar	8 (250)	70-400	PTFE	2.875 x 3.5	73.03 x 88.90	24
131-08C/PF	Clear glass straight side wide mouth jar	8 (250)	70-400	PTFE	2.875 x 3.5	73.03 x 88.90	24
122-16A/PF	Amber glass wide mouth packer bottle with closure	16 (500)	53-400	PTFE	5.80 x 3.18	147.32 x 80.77	12
132-16C/PF	Clear glass straight side wide mouth jar	16 (500)	89-400	PTFE	3.5 x 3.875	88.9 x 98.43	12
123-32A/PF	Amber glass wide mouth packer bottle with closure	32 (1000)	53-400	PTFE	3.87 x 7.25	98.30 x 184.15	12
133-32C/PF	Clear glass wide mouth bottle with closure	32 (1000)	89-400	PTFE	3.75 x 6.625	95.25 x 168.28	12
123-40A/PF	Amber glass wide mouth packer bottle with closure	40 (1200)	70-400	PTFE	7.500 x 4.125	190.50 x 104.78	24
117-2L/PF	Clear glass wide mouth bottle	64 (2000)	83-400	PTFE	5.00 x 8.50	127.00 x 215.90	6
123-80A/PF	Amber glass wide mouth packer bottle with closure	84 (2500)	70-400	PTFE	5.50 x 9.375	139.70 x 238.13	4
117-4L/PF	Clear glass wide mouth bottle	128 (4000)	89-400	PTFE	6.25 x 10.00	158.75 x 254	4

Depyrogenated, sterile vials

Certified both depyrogenated and sterile and available in sizes from 1 mL to 100 mL. Sterile vials are Type 1 borosilicate, assembled with butyl stoppers and aluminum seals. Certificates of Sterility and Pyrogen Test Included.

Applications:

- Suitable for the same applications as above, but where an aseptic protocol is required

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
ST1-11	Clear glass vial pre-assembled with stopper and aluminum crimp seal	0.034 (1)	11	Butyl Rubber Stopper	0.469 x 1.188	11.91 x 30.18	100
ST2-13	Clear glass vial pre-assembled with stopper and aluminum crimp seal	0.068 (2)	13	Butyl Rubber Stopper	0.50 x 1.313	12.70 x 33.35	100
ST2-13A	Amber glass vial pre-assembled with stopper and aluminum crimp seal	0.068 (2)	13	Butyl Rubber Stopper	0.50 x 1.313	12.70 x 33.35	100
ST5-13	Clear glass vial pre-assembled with stopper and aluminum crimp seal	0.17 (5)	13	Butyl Rubber Stopper	0.594 x 2.00	15.09 x 50.80	50
ST5-20	Clear glass vial pre-assembled with stopper and aluminum crimp seal	0.17 (5)	20	Butyl Rubber Stopper	0.781 x 1.50	19.84 x 38.10	50
ST5-20A	Amber glass vial pre-assembled with stopper and aluminum crimp seal	0.17 (5)	20	Butyl Rubber Stopper	0.781 x 1.50	19.84 x 38.10	50
ST10-20	Clear glass vial pre-assembled with stopper and aluminum crimp seal	0.34 (10)	20	Butyl Rubber Stopper	0.813 x 2.00	20.65 x 50.80	50
ST10-20A	Amber glass vial pre-assembled with stopper and aluminum crimp seal	0.34 (10)	20	Butyl Rubber Stopper	0.813 x 2.00	20.65 x 50.80	50
ST20-20	Clear glass vial pre-assembled with stopper and aluminum crimp seal	0.68 (20)	20	Butyl Rubber Stopper	0.969 x 2.313	24.61 x 58.75	50
ST30-20	Clear glass vial pre-assembled with stopper and aluminum crimp seal	1.014 (30)	20	Butyl Rubber Stopper	1.313 x 2.50	33.35 x 63.50	50
ST30-20A	Amber glass vial pre-assembled with stopper and aluminum crimp seal	1.014 (30)	20	Butyl Rubber Stopper	1.313 x 2.50	33.35 x 63.50	50
ST50-20	Clear glass vial pre-assembled with stopper and aluminum crimp seal	1.7 (50)	20	Butyl Rubber Stopper	1.50 x 2.688	38.1 x 68.28	50
ST50-20A	Amber glass vial pre-assembled with stopper and aluminum crimp seal	1.7 (50)	20	Butyl Rubber Stopper	1.50 x 2.688	38.1 x 68.28	50
ST100-20	Clear glass vial pre-assembled with stopper and aluminum crimp seal	3.4 (100)	20	Butyl Rubber Stopper	1.75 x 3.75	44.45 x 95.25	50
ST100-20A	Amber glass vial pre-assembled with stopper and aluminum crimp seal	3.4 (100)	20	Butyl Rubber Stopper	1.75 x 3.75	44.45 x 95.25	50

Silanization

Thermo Scientific silanized glassware products

Save time and minimize waste costs when performing quantitative analysis or storing materials. Surface deactivation treatments such as silanization may play an important role in preserving the integrity of certain materials or extracts stored in glass containers. It also helps to avoid alkalization of contents which may occur as carbonates leach from the glass with normal weathering. Pre-processed with a silanized surface deactivation treatment, these products are offered in convenient, ready-to-use clean packs.

Applications:

- Trace organic analysis
- Processing of materials prone to adhering to glass
- Extraction glassware
- Non-aqueous material storage



Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
SAA-SV2-2	Amber glass vial 12 x 32 screw thread closure	0.068 (2)	8-425	PTFE / Silicone	0.472 x 1.26	11.99 x 32.00	100
SCA-SV2-2	Clear glass vial 12 x 32 closed top closure	0.068 (2)	8-425	PTFE	0.472 x 1.26	11.99 x 32.00	100
SCA-SV2-CT	Amber glass vial 12 x 32 closed top closure	0.068 (2)	8-425	PTFE	0.472 x 1.26	11.99 x 32.00	100
EP608154-S	Amber glass vial with closure	0.12 (4)	13-425	PTFE / Foam	0.591 x 1.772	15.01 x 45.01	100
SAA-SV4-2	Amber glass vial 15 x 45 closed top closure	0.12 (4)	13-425	PTFE	0.591 x 1.772	15.01 x 45.01	100
SCA-SV4-2	Clear glass vial 15 x 45 closed top closure	0.12 (4)	13-425	PTFE	0.591 x 1.772	15.01 x 45.01	100
EP608158-S	Amber glass vial with closure	0.27 (8)	15-425	PTFE / Foam	0.669 x 2.362	16.99 x 59.99	100
239-20A/CT-S	Amber vial with closed top polypropylene closure	0.68 (20)	24-414	PTFE / Silicone	1.125 X 2.25	28.58 x 57.15	72
C39-20A/CT-S	Amber glass vial with solid closed top septa closure	0.68 (20)	24-414	PTFE / Silicone	1.083 x 2.244	27.51 x 57.00	72
C39-20C/CT-S	Clear glass vial with solid closed top septa closure	0.68 (20)	24-414	PTFE / Silicone	1.083 x 2.244	27.51 x 57.00	72
212-01A-S	Amber glass Boston round bottle with black closure	32 (1000)	33-430	PTFE / Silicone	3.70 x 8.10	93.98 x 205.74	12

Glassware culture tubes, disposable

Type 1 borosilicate glass sold 1000 per case, 250 per inner pack.

Cat. No.	Description	Capacity oz. (mL)	Closure Size (mm)	Closure Liner	O.D. x H, in.	O.D. x H, mm	Qty/Cs
CTS-1275	Clear glass culture tubes 12 x 75 (closures are not included)	0.20 (6)	N/A	N/A	0.438 x 2.938	11.13 x 74.63	1000
STT-13100-S	Screw thread glass tube 13 x 100 (closures are not included)	0.27 (8)	13-415	N/A	0.500 x 3.938	12.70 x 100.03	1000
CTS-13100	Clear glass culture tubes 13 x 100 (closures are not included)	0.34 (10)	N/A	N/A	0.500 x 3.938	12.70 x 100.03	1000
STT-16100-S	Screw thread glass tube 16 x 100 (closures are not included)	0.44 (13)	15-415	N/A	0.563 x 4.000	14.30 x 101.60	1000
CTS-16100	Clear glass culture tubes 16 x 100 (closures are not included)	0.51 (15)	N/A	N/A	0.563 x 4.000	14.30 x 101.60	1000
STT-16125-S	Screw thread glass tube 16 x 125 (closures are not included)	0.54 (16)	15-415	N/A	1.500 x 4.938	38.01 x 125.43	1000
CTS-16125-2	Clear glass culture tubes 16 x 125 (closures are not included)	0.85 (20)	N/A	N/A	1.500 x 4.938	38.10 x 125.43	1000





Custom services

If you can't find what you need within more than 80 standard items, we'll tailor a solution just for you!

We have the capability to clean glass or plastic containers, as well as closures or other component parts. All cleaning and packaging services are carried out in our class 10 HEPA filtered workstations inside our class 100 clean room with full product traceability. We can service containers from 100 μ L to 10L. Any of our cleaning methods may be provided as a service for custom cleaning of non-standard containers.

Critical Environment Products and Services Feature

- Flexibility – Small or large quantities with scale up planning
- Full customization – Cleaning, packaging and certification for specific needs
- Cleanroom Facilities – Products handled and packaged in class 10 HEPA filtered workstations inside our class 100 clean room
- Full traceability – Including archival services

Focus on what you do best and **leave the cleaning to us**

Class 100/10 cleaning services

- State-of-the-art water purification system used for rinse water meets USP requirements for Water for Injection (WFI)
- Colorless or amber glass or plastics
- Closures and components
- 100 µL to 10L
- Performed in class 10 HEPA filtered workstations inside our class 100 clean room with full traceability

Sterilization methods

- Dry heat
- Gamma irradiation
- Moist heat/autoclave
- Certificate of analysis included – meets USP criteria
- Meets USP sterilization criteria

Custom clean packaging

Our process cleaned containers are packaged in a variety of materials selected to maintain the integrity of our process right up to the point of use. The selection of packaging can be affected by the intended use of the product as well as the level of certification provided.

Our standard product packaging options include:

Cleanroom bag (polyethylene)

- Non-breathable polyethylene bags manufactured in a Class 10 clean room
- Individual item per bag, multi-units per bag, tray pack shrink-wrapped
- Single, double, or triple bags available
- Heat-sealed or twist-tied

Autoclaveable bag

- Breathable Tyvek®/polyethylene pouch
- Manufactured in a Class 10 clean room
- Single, double, or triple bags available

Foil-wrap

- Cleanroom grade aluminum foil
- Single, double, or triple layers of foil available

Autoclave wrap

- Non-shedding woven polypropylene
- Used for tray pack vials that are steam sterilized
- Must have at least one heat sealed autoclave bag over the autoclave wrap to form a microbial barrier
- Single, double, or trip wrap bags available



Critical Environment Supporting Information

Process Definitions

Process	Definition	Common Applications	Typical Certifications
Depyrogenation, validated 3-log reduction	The destruction and removal of endotoxins. Endotoxins are fever producing substances commonly found in the cell wall of certain bacteria. Depyrogenated products have reduced endotoxin content by at least 99.9% or 3 logs.	Injectable or parenteral drugs, lyophilization, final packaging prior to drug delivery, stability studies, clinical trials	Certificate of Process, Certificate of Analysis (USP 85)
Silanization	Silanized products have been treated to neutralize active sites in glassware. This process allows materials to remain stable and prevents them from reacting with the glass surface. It also prevents the components of the glass from leaching into the samples.	Proteins, assays of blood serum, pharmacological assays of therapeutic drugs	Certificate of Conformance, Certificate of Process
TOC process	Total organic carbon (TOC) is a measure of the amount of carbon covalently bound in organic molecules in a water sample. Thermo Scientific TOC vials are cleaned and certified to contain fewer than 10 ppb TOC as background.	Validation of water systems, equipment validations, cleaning validations, and monitoring low levels of organic contaminants in numerous applications	Certificate of Analysis -TOC
Particulate cleaning	We use high-purity 17 Meg-ohm, electronics-grade water filtered to sub-micron levels for the particulate cleaning process. This highly aggressive, low particle water is heated and used for cleaning processes.	Numerous applications in the pharmaceutical, biotech, medical, semiconductor industries, and anywhere cleanrooms or controlled environments are utilized	Certificate of Analysis (USP 788)
Irradiation	Application of a radiation dose sufficient to destroy all viable forms of life. A radiation dose sufficient to destroy all viable forms of life including bacterial spores, is applied to an acceptable sterility level (SAL). A typical radiation dose is 25-40 kGy, which produces the required SAL of 10^{-6} . Thermo Scientific gamma sterilizes glassware, stoppers, seals and certain closures and plastic bottles.	Injectable or parenteral drugs, lyophilization, final packaging prior to drug delivery, stability studies, clinical trials	USP Sterility, Certificate of Process
Sterile foil-wrap	Sterile processing is designed to destroy all living organisms. We sterilize glassware via a validated dry-heat, foil-wrap method.	Proteins, assays of blood serum, pharmacological assays of therapeutic drugs	Certificate of Analysis-Endotoxins, USP Sterility, USP Particulates
USP purified water and WFI rinses	We use state-of-the-art water purification system which far exceeds the USP specifications for TOC, conductivity, bacterial, and endotoxin levels to provide a final product that meets FDA requirements.	Various cleanroom applications in the pharmaceutical, biotech and medical industries.	Certificate of Process
TOC process	Total organic carbon (TOC) is a measure of the amount of carbon covalently bound in organic molecules in a water sample. Thermo Scientific TOC vials are cleaned and certified to contain fewer than 10 ppb TOC as background.	Validation of water systems, equipment validations, cleaning validations, and monitoring low levels of organic contaminants in numerous applications	Certificate of Analysis -TOC
Steam sterilization	The sterilization involves the application of steam, heat and pressure to destroy all viable forms of life, including bacterial spores, to an acceptable sterility assurance level (SAL) of 10^{-6}	Numerous applications in the pharmaceutical, biotech, medical, and anywhere cleanrooms or controlled environments are utilized	USP Sterility, Certificate of Process

Process Specifications

Critical environment final rinse water specifications

USP purified water: Container sizes > 250 mL

	USP Specifications	Typical EP Values
TOC	< 500 ppb	10-20 ppb
Conductivity	< 1.3 μ S/cm	0.06 μ S/cm
Bacteria	100 cfu/mL	0 cfu / 100 mL

USP water for injection (WFI): Containers \leq 250 mL

	USP Specifications	Typical EP Values
TOC	< 500 ppb	10-20 ppb
Conductivity	< 1.3 μ S/cm	0.06 μ S/cm
Bacterial	10 cfu / 100 mL	0 cfu / 100 mL
Endotoxin	< 0.25 EU/mL	< 0.06 EU/mL

Critical environment processing group specifications

Particulates glass or plastic Group L	
Compound	Spec
Particulates general 1	< 5 pcs/mL @ 0.5 μ m
Particulates general 2	< 10 pcs/mL @ 0.5 μ m
Particulates general 3	< 20 pcs/mL @ 0.5 μ m
Particulates general 4	< 50 pcs/mL @ 0.5 μ m
Particulates general 5	< 20 pcs/mL @ 0.3 μ m

Low-particle / metals combination (μ g/L) plastics only Group E			
Compound	Spec	Compound	Spec
Aluminum	< 10	Potassium	< 10
Calcium	< 10	Magnesium	< 10
Copper	< 10	Manganese	< 10
Iron	< 10	Sodium	< 10
Particulates	<50pcs/ml @ 0.2 μ m		

TOC glass Group M	
Compound	Spec
TOC general 1	< 10 ppb
TOC general 2	< 20 ppb

Endotoxin glass Group N	
Compound	Spec
Endotoxin	< 0.06 EU/mL



Custom Cleaning Specification Sheet

When an application requires customization of one or more products and services, fill out our Custom Cleaning Specification Sheet providing as much detail as possible. This sheet can be found via the QR code, on the Thermo Scientific website at www.thermoscientific.com/cleanrequest or from your local sales specialist.

If you need assistance with further information or a quote, our customer service department is a phone call away.

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ANZ: Australia: 1300 735 292, New Zealand: 0800 933 966; **Asia:** China Toll-free: 800-810-5118 or 400-650-5118; India: +91 22 6716 2200, India Toll-free: 1 800 22 8374; Japan: +81-3-5826-1616; Other Asian countries: 65 68729717
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 countries: +358 9 329 10200; Russia/CIS: +7 (812) 703 42 15; Spain/Portugal: +34 93 223 09 18; Switzerland: +41 44 454 12 22; UK/Ireland: +44 870 609 9203
North America: USA/Canada +1 585 586 8800; USA Toll-free: 800 625 4327
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