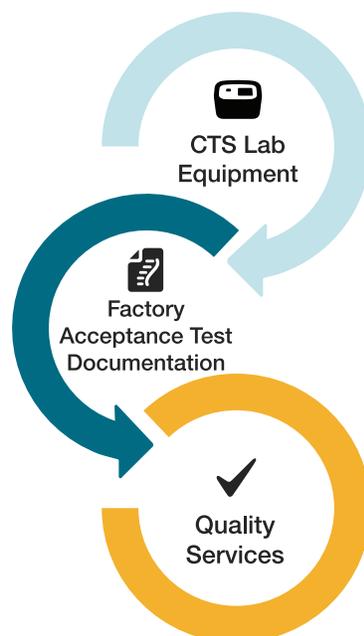# Thermo Scientific™ Steri-Cult™ CO_2 Incubators – CTS Series

Cell Therapy Systems (CTS) Series Lab Equipment provides you with proven solutions for commercial cell and gene therapy manufacturing

Thermo Fisher
SCIENTIFIC

Thoughtfully designed for your cell therapy needs now.

Thermo Fisher Scientific provides integrated solutions that support your GMP and clean room needs for cell and gene therapy — from CO_2 incubators and centrifuges to cold-storage, biological safety cabinets, and beyond — with innovations supported by high-quality products, factory acceptance testing documentation, and on-site compliance services. You get up and running faster, stay compliant, pass regulatory audits, and stay on schedule as you translate your cell therapy from discovery to clinical research and commercial manufacturing.

Cell Therapy Solutions

CTS Lab Equipment

Factory Acceptance Test Documentation

Quality Services

Thermo Scientific Forma Steri-Cult CO$_2$ incubators are designed to meet the needs of today's rapid-fire discoveries with updates that perform reliably and with minimal contamination risk to help speed up your work. Starting with the quality you've come to depend on from Thermo Fisher products, Steri-Cult incubators have added features that will take your work to the next level.

- Ultimate contamination control: proven 12-log sterilization for high-value cultures, in-chamber HEPA filtration enabling ISO Class 5 chamber conditions, and an external humidification system

- Largest stackable culturing capacity available ideal for high-volume culturing

- Active humidification system and IR CO$_2$ sensor with in-chamber fan for optimum cell viability

- Designed for easy cleaning with electropolished 100% stainless steel inner chamber

- Compatible with common cGMP facility protocols and clean room procedures such as STERIS vaporized hydrogen peroxide (VHP) biodecontamination technology

Support tomorrow's breakthroughs today.

Ultimate contamination control

The risk of contamination is ever-present. Grice EA et al. 2008 showed that humans carry 10,000 microbes/cm2 on skin, and Armstrong SE et al. 2010 showed that even biopharma cultures were contaminated at a rate of 8.45%.

Effective contamination control must be a key priority of every lab.

Steri-Cult CO_2 incubators offer the ultimate protection for high-value cultures with every element of their design, from the ISO Class 5 HEPA filtration system to their easily cleaned design and proven automated sterilization cycles.

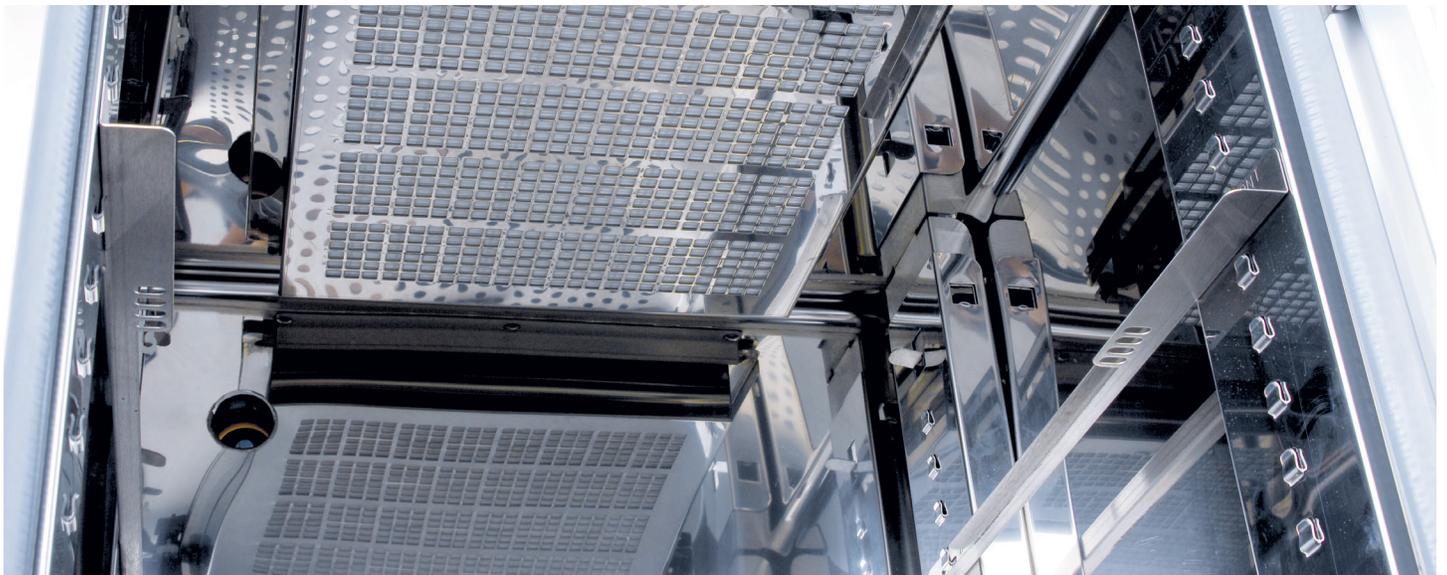## When cleanability is critical

Electropolished inner chamber
The high-quality, electropolished 100% stainless steel inner chamber assures a surface roughness (Ra) of less than 0.4 µm, more refined than the commonly accepted Ra≤ 0.8 µm. To help prevent the risk of unwanted microbial growth, this degree of precision reduces microscopic structures where microorganisms could adhere.

VHP compatibility test results
Proven compatibility with STERIS "dry process" systems, using vaporized hydrogen peroxide, a dry non-condensing vapor commonly used for biodecontamination of airborne and surface contaminants in clean rooms and production environments.

Remote monitoring
4-20mA signal output is included for interfacing with external data collection systems, such as the Thermo Scientific™ Smart-Vue™ remote monitoring system, which is ideal for GMP environments with external sensors and CFR-21 compliant software packages.

View of Electropolished Interior

Order details

Thermo Scientific Forma Steri-Cult CO_2 Incubators – CTS Series

Complete validation packages*

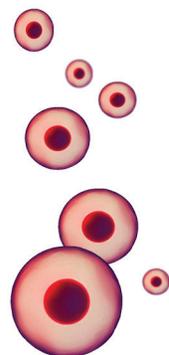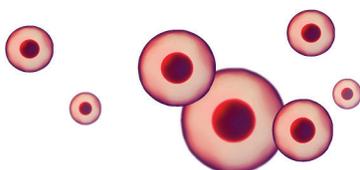| Cat. No.	Product Description	Voltage
3307CTS	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation, IQ/OQ Field Service	115V
3308CTS	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation, IQ/OQ Field Service	230V
3310CTS	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 11.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation, IQ/OQ Field Service	115V
3311CTS	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 11.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation, IQ/OQ Field Service	230V

Factory acceptance compliance packages

Cat. No.	Product Description	Voltage
3307E	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation	115V
3308E	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation	230V
3310E	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 11.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation	115V
3311E	Thermo Scientific Forma Steri-Cult CO2 Incubator – CTS Series, Electropolished Stainless Steel 1.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation	230V

Accessories

Cat. No.	Product Description
SV210-200-LSB	Smart-Vue Wireless Radio Module (North America Only)
SV406-200-LSB	Smart-Vue Temperature and CO_2 Sensor, 1m cable length
192104	Electropolished Stainless Steel Reinforced Shelf 11.4 cu. ft. (322.8 L)

All models in the CTS Series come complete with IR CO_2 sensor, 4-20mA data output, and electropolished stainless steel interior.

* Complete validation packages are only available in select locations including the United States, Germany, France, the United Kingdom, Ireland, Spain, Portugal, Italy, Switzerland, Norway, Denmark, the Netherlands, and certain APAC countries. For all other countries and for more information, contact your local representatives.

Factory Acceptance Test (FAT) documentation binder

Comprehensive documentation package that supports a timely and rapid validation process

Products manufactured within the ISO 13485 environment for reliability are provided with comprehensive FAT documentation to support timely validation.
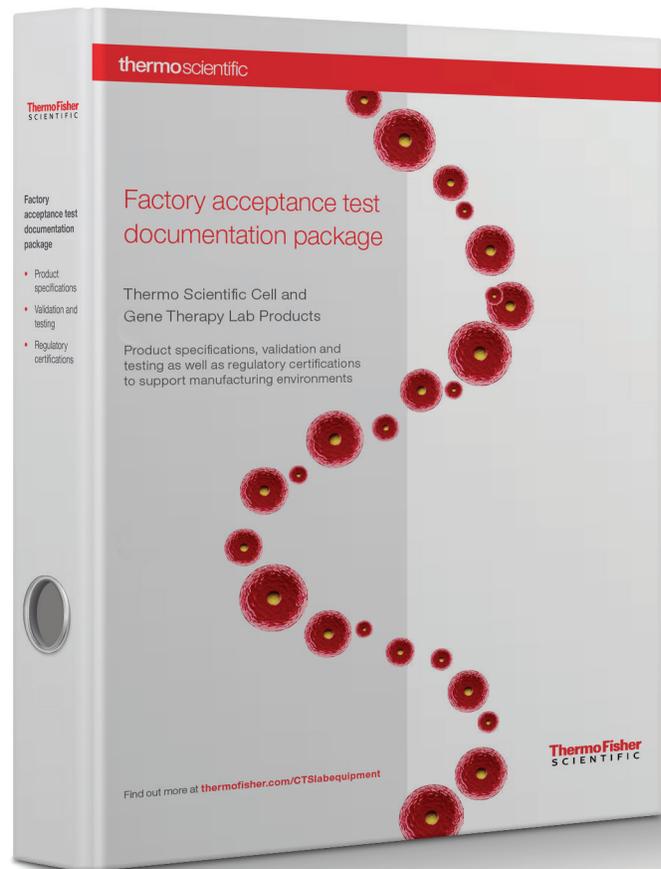
Regulatory certificates

- Declaration of Conformity (CE) with EU law
- CSA and QMS Certificates
- Certificates of Environmental Status

Recommended protocols

- User-replaceable parts and consumables lists
- Suggested customer maintenance schedule
- Recommended solutions and procedures

Product-specific factory documentation and specification

- Certificate of Conformance
- Certificate of Calibration
- Technical specifications
- Sensor calibration certificates
- Electropolishing certificate

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Factory
acceptance test
documentation
package

- Product specifications
- Validation and testing
- Regulatory certifications

Factory acceptance test documentation package

Thermo Scientific Cell and Gene Therapy Lab Products

Product specifications, validation and testing as well as regulatory certifications to support manufacturing environments

Find out more at thermofisher.com/CTSlabequipment

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Qualification services

Gain confidence with our requalification services that can help reduce your risk of non-compliant instruments

Stay compliant with our industry-exclusive, no-charge requalification guarantee*
With Unity™ Lab Services qualification services, you'll be confident that your instruments maintain compliance should an unexpected audit arise. Unlike other OEM service providers who charge for requalification services, we are the only provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying service instrument plan.

Pass audits the first time with our robust and easy-to-understand OEM qualification protocols and harmonized documentation
Our factory-developed qualification protocols are written to support accepted industry standards and regulatory requirements. Our qualification services provide consistent, audit-ready documentation that meets pre-determined and/or user specifications. In addition, our harmonization of qualification protocols and documentation across all instruments saves you administrative work, review time, and complicated approval processes, helping to ensure the best audit outcome.

Stay on schedule with our full-range, single-source support from experienced engineers
Unity Lab Services provides a full-service solution for installing, repairing, qualifying, and mitigating risks so your instruments (including other manufacturers' units) get up and running faster and your research stays on schedule. Our factory-certified validation engineers are product experts with experience in regulated environments, ensuring your qualifications are delivered efficiently and effectively to industry standards.

* Industry-exclusive, no-charge requalification guarantee

Unity Lab Services is the only OEM service provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying instrument service plan.

Service solutions

Qualification/service	Description
Installation Qualification (IQ)	• Unpacking, assembly, and installation: Verifies that the equipment, manuals, supplies, and any other accessories arrived undamaged as specified in the sales order. Verifies equipment is assembled and installed and any initial diagnostic tests have been performed. Documents any abnormal event(s) observed during assembly and installation. • Utility, facility, and environment: Verifies that the installation site satisfactorily meets manufacturer-specified environmental requirements.
Operation Qualification (OQ)	• System component information: Records detailed configuration information for each system component. • OQ limits: Records a list of manufacturer-recommended limits for ensuring that the system is operating as expected. • Equipment operational tests and results: Tests important equipment functions to verify that the equipment operates as intended by the manufacturer and required by the user. Includes a group of important equipment parameters selected for testing depending on the intended use of the equipment. *Key tests: Min/Max Speed, Brief/Extended Time, Temperature for Refrigerated Models*
Temperature Mapping	• Equipment capabilities tests: Tests important equipment capabilities for ensuring that the equipment is performing in accordance with the intended use of the system. • Multi-Point Temperature Mapping: Monitors temperature for a 24-hour period with 1-minute data collection intervals.

Visit **unitylabservices.com/complianceservices** to request a quote for service or to learn more.

Tips to stay compliant
To stay compliant with your standards, we recommend our annual calibration and preventative maintenance services. For more information, call Customer Care or contact your internal sales representative.

Find out more at **thermofisher.com/ctslabequipment**

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