



Cell and gene therapy

# Forma Steri-Cult CO<sub>2</sub> Incubator CTS Series

Excellent performance  
for high-value cultures

# For cell and gene therapy research and manufacturing

Thermo Scientific™ Forma™ Steri-Cult CO<sub>2</sub> Incubator Cell Therapy Systems (CTS™) Series consists of our popular Steri-Cult models with enhanced features, extensive documentation, and certifications. Our compliance services support your Good Manufacturing Practice (GMP) needs.

The CTS Series helps you get up and running faster, stay compliant, navigate regulatory audits, and stay on schedule as you take your cell therapy from discovery to clinical research and commercial manufacturing.



**Product**



**Documentation  
package**



**Compliance  
services**



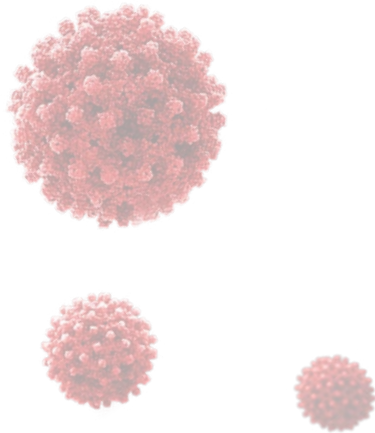
# Forma Steri-Cult CO<sub>2</sub> Incubator CTS Series

## Excellent protection for high-value cultures

Thermo Scientific™ Forma™ Steri-Cult CO<sub>2</sub> Incubators are designed to meet the needs of today's rapid-fire discoveries. Starting with the quality you've come to depend on from Thermo Fisher Scientific products, Steri-Cult CO<sub>2</sub> incubators have added features that can help take your work to the next level. Known for unique features ideally suited for manufacturing, Steri-Cult CO<sub>2</sub> incubators offer proven contamination control features, fast recovery and excellent uniformity that help reduce downtime and improve quality.

### Features

- Ultimate contamination control: proven 12-log 140°C sterilization for high-value cultures, in-chamber HEPA filtration enabling ISO Class 5 conditions, and an external active humidification system
- Largest stackable culturing capacity available ideal for high-volume culturing
- Active humidification system and IR CO<sub>2</sub> sensor with in-chamber fan for fast recovery and outstanding uniformity to support optimum cell viability
- Designed for easy cleaning with electropolished stainless steel inner chamber to reduce microscopic structures where microorganisms could hide
- Proven compatible with common cGMP facility protocols and clean room procedures such as STERIS vaporized hydrogen peroxide (VHP) biodecontamination technology
- 4-20 mA data output







# Support tomorrow's breakthroughs today

## Contamination control and cleanability

### Ultimate contamination control

The risk of contamination is ever-present. Grice EA et al. 2008 showed that humans carry 10,000 microbes/cm<sup>2</sup> on skin, and Armstrong SE et al. 2010 showed that even biopharma cultures were contaminated at a rate of 8.45%.

Steri-Cult CO<sub>2</sub> incubators offer the ultimate protection for high-value cultures with every element of their design, from the in-chamber ISO Class 5 HEPA filtration system to the easily cleaned electropolished chamber 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 minimize 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” vaporized hydrogen peroxide (VHP), 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™ Pro Remote Monitoring System provides external sensors and CFR-21 compliant software packages ideal for GMP environments. The Smart-Vue Pro system offers a customizable and scalable architecture that is compatible across multiple brands and equipment types, offering self-installation and long range capabilities.



Learn more at [thermofisher.com/smart-vuepro](http://thermofisher.com/smart-vuepro)





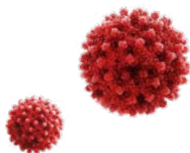
# Product documentation package

## Certifications and protocols to help with validation

Binder element	Description
<b>Product support documents</b>	
Design qualification (technical data sheet, drawings) <sup>1</sup>	Basic specification descriptions of the product and may include some summary drawings
Recommended maintenance schedule	User-based recommended maintenance and schedule
Consumables and customer-replaceable parts	Replaceable parts based upon usage or wear
Recommended cleaning procedures	Effective and typical procedures
<b>Regulatory and compliance certifications</b>	
Declaration of conformity with EU laws (CE)	CE certificate proof
CSA certificate	CSA certificate proof
Certificate of environmental status	Regulatory certificates for various sustainability items
Quality Management System (QMS) certificate	Factory/site-based quality system description
<b>Traceability/ validation documents</b>	
Certificate of conformance	Production certificate
FAT report <sup>2</sup>	End-of-line test summary with checklist of performance
Key material of construction specifications	Technical specifications
STERIS™ VHP compatibility certificate	Test certificate for vaporized hydrogen peroxide cleaning
HEPA filter certificate <sup>2</sup>	Certificate of filter performance
Temperature sensor calibration document <sup>2</sup>	Certificate from supplier on calibration
RH sensor calibration document <sup>2</sup>	Certificate from supplier on calibration
CO <sub>2</sub> sensor calibration document <sup>2</sup>	Certificate from supplier on calibration
CO <sub>2</sub> valve certificate of compliance <sup>2</sup>	Certificate from supplier on compliance
Certificate of electropolishing <sup>2</sup>	Material certificate of surface finish

1) These documents are available from the factory prior to purchase upon request (in addition to CAD format drawings).

2) These are serialized documents.





# Compliance services<sup>1</sup>

## On-site qualification

Unity™ Lab Services, as part of Thermo Fisher Scientific, offers on-site qualification services that help ensure your laboratory equipment meets global standards and mitigates the risk of regulatory non-compliance. Our full-range compliance portfolio offers improved productivity, single-vendor convenience, a no-charge requalification guarantee,<sup>2</sup> and comprehensive documentation reports that give you peace of mind by supporting your quality management system, traceability, and audit readiness. Our standardized field qualifications for CO<sub>2</sub> incubators include IQ, OQ and temperature mapping services. Semi-customized protocols are available. Contact your local sales or service team for services in your location.

### Qualification services

Installation qualification (IQ) <sup>3</sup>
Component verification
Assembly verification
Installation verification
Site verification

Operational qualification (OQ)
<b>System configuration</b>
Set points
Alarms and safety
<b>System functionality</b>
All functional attributes
<b>Reference measurements for</b>
CO <sub>2</sub>
Temperature
Humidity



### Mapping services<sup>4</sup>

	Description
Temperature mapping	Manufacturing performance specifications verified via a multi-point temperature mapping with recommended test profile and probe configuration.
Door open recovery	Temperature map during door open recovery.
Power failure recovery	Temperature map during power failure.

Selecting the right compliance services solution is a significant part of your quality system. Our factory-trained, highly skilled field service engineers will support your project from the time of order until regulatory sign-off to help you pass qualifications. Our best practices ultimately help you reduce costs and maintain operational uptime.

1. Compliance services are only available in select locations including the United States, Germany, France, the United Kingdom, Ireland, Spain, Portugal, Italy, Austria, Switzerland, Norway, Sweden, Denmark, Belgium and the Netherlands. For more information, contact your local sales or service representative.
2. Our no-charge requalification guarantee for laboratory equipment applies only to equipment under a qualifying Unity Lab Services equipment service plan or warranty and includes requalification on covered corrective maintenance repair at no additional charge. [Terms and conditions apply: https://www.unitylabservices.com/content/dam/uls/support/terms-conditions/BN20201026-1220-TsCs-Requalification%20Guarantee-FINAL.pdf](https://www.unitylabservices.com/content/dam/uls/support/terms-conditions/BN20201026-1220-TsCs-Requalification%20Guarantee-FINAL.pdf)
3. Installation of equipment is not included within our IQ services. Additional fees apply for inside delivery shipping method or for full installation and setup of equipment.
4. Key offerings may vary by region.

# Order details

## Product and documentation package

Product description	Voltage	Cat. No.
Forma Steri-Cult CO <sub>2</sub> incubator, electropolished stainless steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation	115 V	3307E
Forma Steri-Cult CO <sub>2</sub> incubator, electropolished Stainless Steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation	230 V	3308E
Forma Steri-Cult CO <sub>2</sub> incubator, electropolished Stainless Steel 11.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation	115 V	3310E
Forma Steri-Cult CO <sub>2</sub> incubator, electropolished Stainless Steel 1.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation	230 V	3311E

All models in the CTS Series come complete with IR CO<sub>2</sub> sensor, 4-20mA data output, and electropolished stainless steel interior.

## Accessories

Product description	Cat. No.
Electropolished stainless steel reinforced shelf 11.4 cu. ft. (322.8 L)	192104
Roller dolly for one or two (stacked) model 3307E (3308E)	1900162
Roller dolly for one or two (stacked) model 3310E (3311E)	1900163

## Compliance services\*

Qualification service	Cat. No.
On-site IQ/OQ + temperature mapping service	IOPQPCKE89003500
On-site IQ/OQ service	IOQPCKE89003500
On-site temperature mapping service	TEMPMAP

\* See page 6 for details and availability.



## Remote monitoring\*

	Product description	Region	Cat. No.
<b>Module (Duo)</b>	Smart-View Pro Duo 915MHz only. Delivered with two 3.6 V lithium batteries, one sensor mounting kit, one mounting holder, one antenna and one 1.5 m/5 ft. flat cable.	USA, Canada	SVPHWRMOD012
	Smart-View Pro Duo 868MHz only. Delivered with two 3.6 V lithium batteries, one sensor mounting kit, one mounting holder, one antenna and one 1.5 m/5 ft. flat cable.	Europe	SVPHWRMOD022
<b>Module (Quatro)</b>	Smart-View Pro Quatro 915MHz only. Delivered with two 3.6 V lithium batteries, two sensor mounting kit, one mounting holder, one antenna and two 1.5 m/5 ft. flat cables.	USA, Canada	SVPHWRMOD014
	Smart-View Pro Quatro 868MHz only. Delivered with two 3.6 V lithium batteries, two sensor mounting kit, one mounting holder, one antenna and two 1.5 m/5 ft. flat cables.	Europe	SVPHWRMOD024
<b>Gateway</b>	Smart-View Pro LoRaWAN 915 MHz platform-enabled Ethernet/Wi-Fi connectivity receiver with universal power supply	USA, Canada	SVPHWRLGW001
	Smart-View Pro LoRaWAN 865-868* MHz platform-enabled Ethernet/Wi-Fi connectivity receiver with universal power supply	Europe	SVPHWRLGW002
<b>Sensor (CO<sub>2</sub>/temp/rH)</b>	OCEASOFT Smart Triple Point Sensor for CO <sub>2</sub> , temperature, and relative humidity, CO <sub>2</sub> : 0.5/9.9%. Temp: 0/+50°C, RH: 0/99%, calibrated at 5% CO <sub>2</sub> /37°C/80% RH	All regions	SVPSENCCS001

\* Not available in all countries or regions. Frequencies that are approved for use are country-specific. 865–868 MHz is approved for use in most European markets, and 915 MHz is approved for use in North American markets. Please consult your local representative for more details.



Learn more at [thermofisher.com/ctsforma](https://thermofisher.com/ctsforma)

**thermo** scientific