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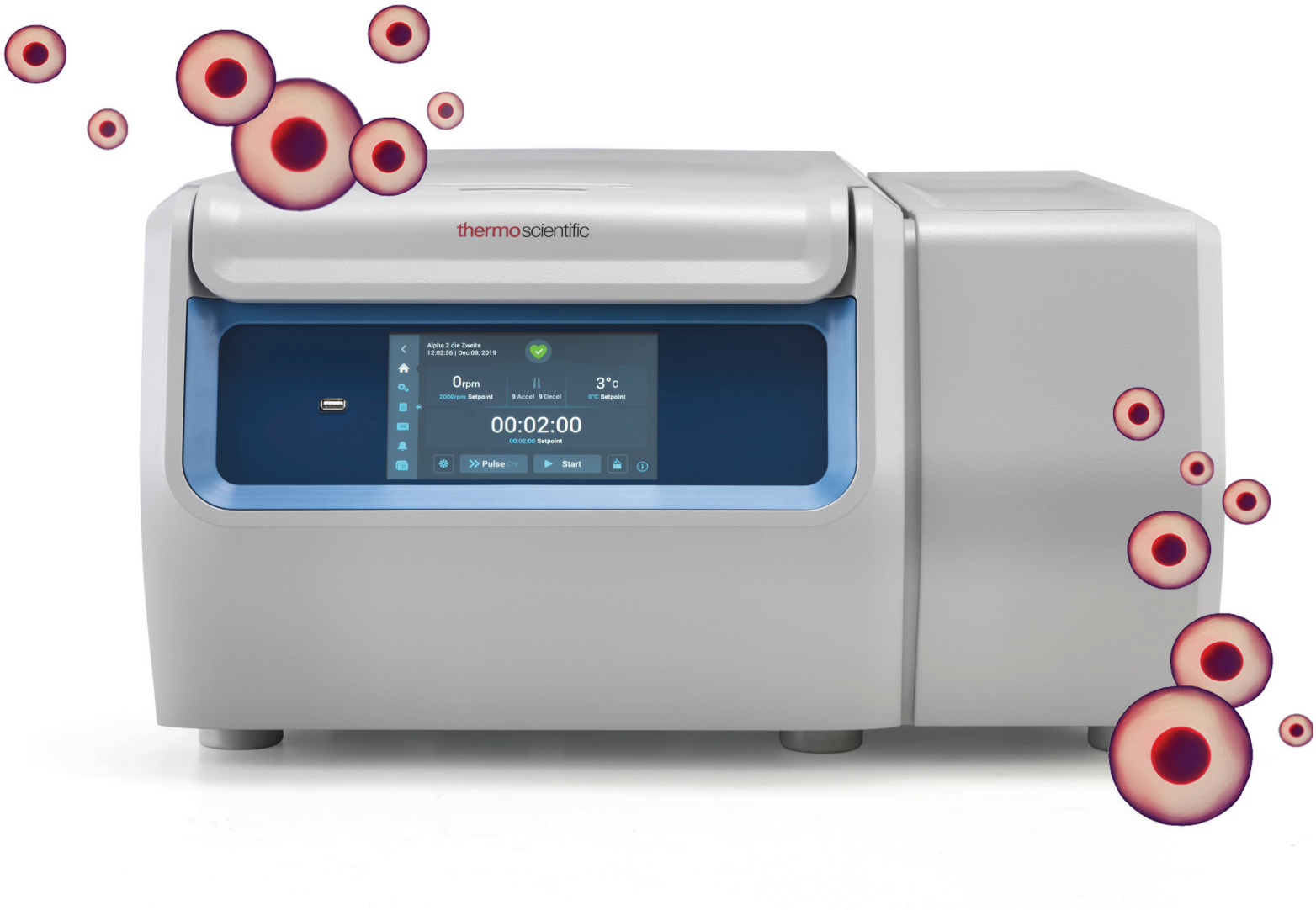


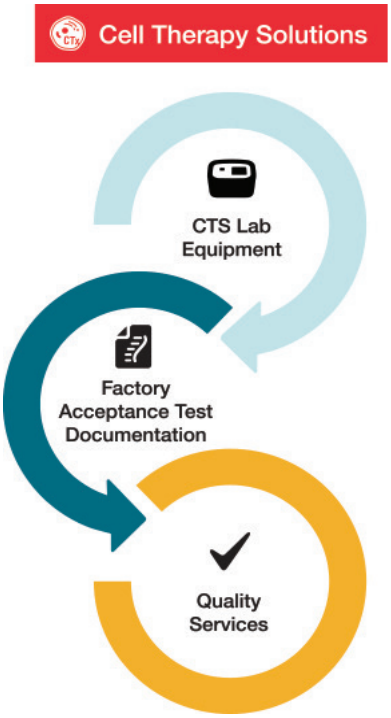

# Thermo Scientific™ General Purpose Pro Centrifuges – CTS Series

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

ThermoFisher SCIENTIFIC

# Thoughtfully designed for your cell and gene therapy needs.

Explore integrated solutions that support your GMP and cleanroom needs for cell and gene therapy — from $CO_2$ incubators and centrifuges to cold storage, biological safety cabinets, and beyond. Our product innovations are supported by high-quality materials, factory acceptance testing documentation, and on-site compliance services. They help you get up and running faster, stay compliant, support regulatory audits, and stay on schedule — as you translate your cell therapy from discovery to clinical research and commercial manufacturing.



General Purpose Pro Centrifuges are designed to meet the needs of today's rapid-fire discoveries, with updates to help you get your research done more quickly, consistently, and with powerful reliability.

Built on the foundation of quality and dependability you expect from Thermo Scientific products, General Purpose Pro Centrifuges have features that can take your work to the next level.

- User-intuitive screen enables easy access and programming for faster results
- TX-1000 swinging bucket rotor provides an unprecedented 4 L capacity in a 3 L footprint with the ability to hold up to 40 x 50 mL conical tubes, 96 x 15 mL conical tubes, and 4 x 500 mL conical bottles in one run
- Scheduling features and preventative maintenance queues help reduce downtime to avoid delay of cell processing to lower the impact on cell viability
- ClickSeal ™ Biocontainment Lids help prevent contamination
- Compatible with common cGMP and cleanroom disinfecting procedures such as Steris VHP dry heat sterilization
- Front USB port for easier plug in and data transfer in non-altered (PDF) format
- Compliance with the most recent applicable regulatory and safety standards *

*Compliance packages are only available in select locations including the United States, Germany, France, the United Kingdom, Ireland, Spain, Portugal, Italy, Austria, Switzerland, Norway, Sweden, Denmark, and the Netherlands. For more information, contact your local representative.

# Order details

## Thermo Scientific General Purpose Pro Centrifuges – CTS Series

**Complete validation packages ***

| Cat. No. | Product description | Voltage and frequency |
|---|---|---|
| 75009014 | Thermo Scientific™ Sorvall™ X4R Pro Cell Therapy Centrifuge CTS Series, Factory Acceptance Test Documentation, IQ/OQ Field Services | 220-240 V, 50/60 Hz |
| 75009015 | Thermo Scientific Sorvall X4R Pro Cell Therapy Centrifuge CTS Series, Factory Acceptance Test Documentation, IQ/OQ Field Services | 220 V, 60 Hz |
| 75009016 | Thermo Scientific Sorvall X4R Pro Cell Therapy Centrifuge CTS Series, Factory Acceptance Test Documentation, IQ/OQ Field Services | 120 V |
| 75009017 | Thermo Scientific Sorvall X4R Pro Cell Therapy Centrifuge CTS Series, Factory Acceptance Test Documentation, IQ/OQ Field Services | 100 V |
| 75009023 | Thermo Scientific™ Multifuge™ X4R Pro Cell Therapy Centrifuge CTS Series, Factory Acceptance Test Documentation, IQ/OQ Package | 220-240 V, 50/60 Hz |

**Factory acceptance compliance packages**

| Cat. No. | Product description | Voltage and frequency |
|---|---|---|
| 75009018 | Thermo Scientific Sorvall X4R Pro Cell Therapy Package CTS Series, Factory Acceptance Test Documentation | 220-240 V, 50/60 Hz |
| 75009019 | Thermo Scientific Sorvall X4R Pro Cell Therapy Package CTS Series, Factory Acceptance Test Documentation | 220 V, 60 Hz |
| 75009020 | Thermo Scientific Sorvall X4R Pro Cell Therapy Package CTS Series, Factory Acceptance Test Documentation | 120 V |
| 75009021 | Thermo Scientific Sorvall X4R Pro Cell Therapy Package CTS Series, Factory Acceptance Test Documentation | 100 V |
| 75009022 | Thermo Scientific Multifuge X4R Pro Cell Therapy Package CTS Series, Factory Acceptance Test Documentation | 220-240 V, 50/60 Hz |

* 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

## Support a timely and rapid validation process with our comprehensive documentation package

Products manufactured within the reliable ISO 13485 certified environment are provided with comprehensive FAT documentation to support timely validation.

### Regulatory certificates

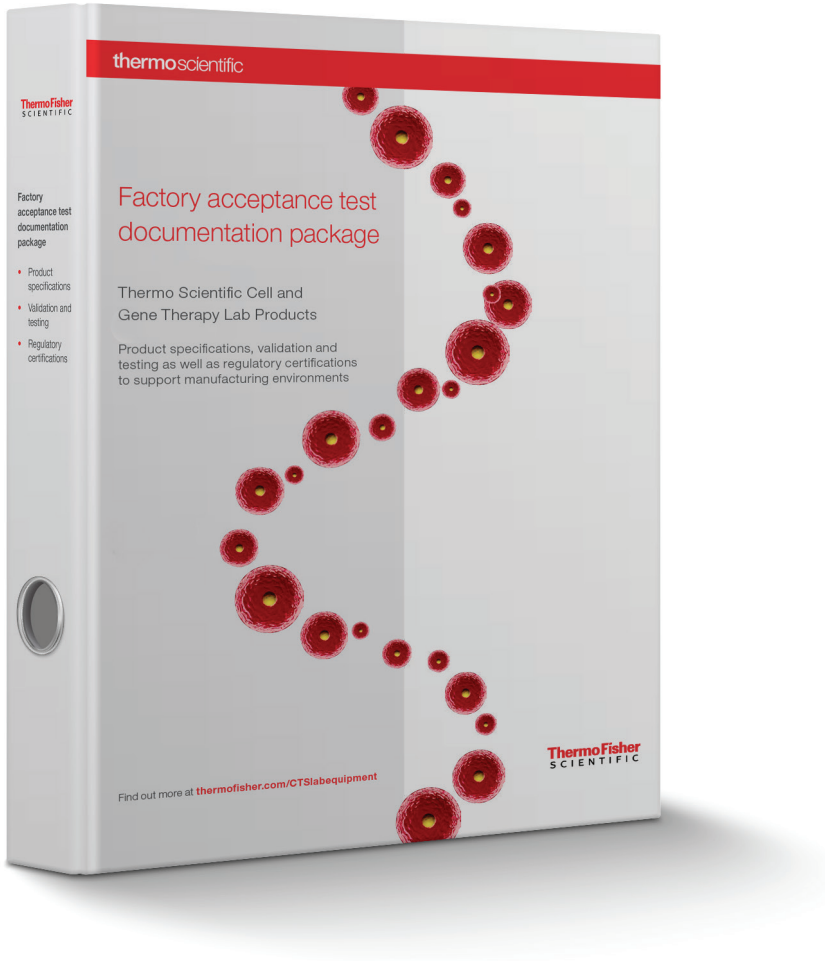
- Declaration of Conformity (CE) with EU law
- CSA and QMS Certificates
- Certificates of Environmental Status

### Recommended protocols

- Suggested customer maintenance schedule
- Recommended cleaning and disinfecting solutions

### Product-specific factory documentation and specification

- Certificate of Conformance
- Technical specifications
- Equipment drawings
- Porton Down Certificate
- Steris VHP Disinfection Certificate



# Qualification services

## Gain confidence with our requalification service 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.

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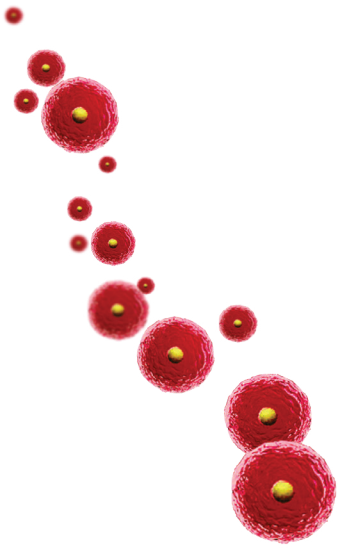
# Service solutions

| 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.<br>• 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.<br>• OQ limits: Records a list of manufacturer-recommended limits for ensuring that the system is operating as expected.<br>• 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.<br>*Key tests: Min/Max Speed, Brief/Extended Time, Temperature for Refrigerated Models* |
| Cycle Testing | • Point-in-time test: Exercise of pre-defined duration that surpasses singular calibration and routine speed, time, and temperature monitoring activities for ensuring that the equipment is performing in accordance with the intended use of the system. |

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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