



Cell and gene therapy

## Herasafe 2030i Biological Safety Cabinet CTS Series

Smart protection that never takes a day off

thermo scientific

# For cell and gene therapy research and manufacturing

Thermo Scientific<sup>™</sup> Herasafe<sup>™</sup> 2030i Biological Safety Cabinets Cell Therapy Systems (CTS<sup>™</sup>) Series consists of equipment, documentation, and certifications, as well as compliance services that 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.





## Herasafe 2030i Biological Safety Cabinet Smart technology and user comfort

Our most technologically advanced Class II cabinets available, Thermo Scientific Herasafe 2030i Biological Safety Cabinets (BSCs) CTS Series optimize contamination prevention, convenience, and information management. Designed for performance and precision, they are equipped with smart self-monitoring safety features, an intuitive touchscreen, and built-in connectivity. They are ideal for demanding cell culture applications in the biopharma and other industries that require safe handling of products and protection of personnel and the environment.

The cabinets are manufactured and certified according to regional regulatory bodies for biological safety (NSF ANSI 49 and EN 12469).



#### Features

#### Touchscreen interface

Intuitive operation and indicates clear status and performance. Easy navigation and convenient illustration of airflow safety and usage data to address any lingering user concerns about the cabinet functioning properly to protect them and their valuable samples.

Performance details such as user interaction logs, errors and event logs are easily identified to drive continuous process improvement and reproducibility of results.



#### Information management

Standard USB data outputs enable download of the event log to a memory stick. Embedded capability to be connected to the Thermo Fisher Scientific cloud by Wi-Fi. In regions where service is available, you can connect remotely via our app, to check the equipment status, and for alerts, alarms and the user log. Please check availability with your Thermo Fisher Scientific sales representative.





## Setting the standard for class II biological safety cabinets

### Ultimate contamination control and cleanability



#### Electronic front sash

With push button simplicity, the cabinet's front window automatically opens to the correct aperture mandated by regional regulation to help ensure proper working conditions. The sloped position enables fatigue-free work. When closed, the window provides an aerosol-tight seal.

#### High grade 316 L stainless steel interior

Stainless steel interior with "brushed and sanded" finish provides maximum scratch resistance, non-reflective properties and cleanability.

#### SmartFlow Plus technology

Through a proprietary Thermo Scientific<sup>™</sup> SmartFlow<sup>™</sup> Plus Auto Compensation design, unique energy-saving dual DC blower motors automatically adjust to maintain proper airflow during the loading of protective HEPA filters.

#### SmartClean Plus hinged front window

Our Thermo Scientific<sup>™</sup> SmartClean<sup>™</sup> Plus fully opening front hinged window design enables easy cleaning and full access to the cabinet interior work space for thorough cleaning/disinfection and incorporation of ancillary work tools and equipment as desired.

#### Self-adjusting germicidal UV light intensity

If you apply UV germicidal light to your work surface at the end of each work day, Herasafe 2030i Biological Safety Cabinets feature time-sensitive auto shut-off to preserve bulb life. Our exclusive self-adjusting exposure capability enables reproducible germicidal effectiveness with every use and ensures performance at consistent levels to protect your important work.





## Product documentation package Certifications and protocols to help with validation

Binder element	Description			
Product support documents				
Design qualification (technical data sheet, drawings) <sup>1</sup>	Basic spec descriptions of the product and may include some summary drawings			
Consumables and customer-replaceable parts	Replaceable parts based upon usage or wear			
Recommended cleaning procedures	Effective and typical procedures to keep product clean			
Regulatory and compliance certifications				
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			
REACH statement	Regulatory certificates for various sustainability items			
DIN EN12469 TÜV certification	Regulatory compliance certificate			
DIN ISO 14644-1 cleanroom compatibility certificate	Regulatory compliance certificate			
Traceability/ validation documents				
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			
HEPA filter certificate <sup>2</sup>	Certificate of filter performance			
1) These documents are available from the factory prior to purchase upon request (in addition to CAD format drawings)				

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2) These are serialized documents.









## Compliance services<sup>1</sup> On-site qualification

Unity<sup>™</sup> 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 provides improved productivity, single-vendor convenience, a no-charge requalification quarantee,<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 biosafety cabinets include IQ and OQ 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>	Operational qualification (OQ)		
Component verification	System configuration		
Assembly verification	Set points		
Installation verification	Alarms and safety		
Site verification	System functionality		
	All functional attributes		
	System performance per factory specification		
	System alarms		
Part Contraction	Power failure		
AT AND A DO	Performance tests		
	HEPA filter leakage		
	Air velocity		
	Volumetric exhaust flow		
	KI-DISCUS <sup>™</sup> system		
	Electrical safety		
	Smoke pattern		

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 the first time. Our one-and-done 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.
- 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.

## **Order details**

#### Product and documentation package

Product name	Includes	Electrical	Cat. No.
Thermo Scientific Herasafe 2030i, 0.9 m Class 2 A2 Biological Safety Cabinet	Cross Beam UV-C, Product Documentation Package	230 V, 50/60 Hz	51033758
Thermo Scientific Herasafe 2030i, 1.2 m Class 2 A2 Biological Safety Cabinet	Cross Beam UV-C, Product Documentation Package	230 V, 50/60 Hz	51033759
Thermo Scientific Herasafe 2030i, 1.5 m Class 2 A2 Biological Safety Cabinet	Cross Beam UV-C, Product Documentation Package	230 V, 50/60 Hz	51033760
Thermo Scientific Herasafe2030i, 1.8 m Class 2 A2 Biological Safety Cabinet	Cross Beam UV-C, Product Documentation Package	230 V, 50/60 Hz	51033761
Thermo Scientific Herasafe 2030i, NSF-CTS Series, 4 ft.	Cross Beam UV-C; Factory Acceptance Test Documentation; Indented Single-Piece Work Tray; Prep for 3x Service Taps (Rear Wall)	120 V, 60 Hz	51033762
Thermo Scientific Herasafe 2030i, NSF-CTS Series, 6 ft.	Cross Beam UV-C, Factory Acceptance Test Documentation; Indented Single-Piece Work Tray; Prep for 3x Service Taps (Rear Wall)	120 V, 60 Hz	51033763

Stand	options
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We recommend ordering a base stand to ensure a robust and stable installation of the BSC. All of our base stands have been tested with our units for stability and functionality. Choose between a fixed height, manually adjustable working height, or electrically adjustable working height. Please consider the total height of the room when choosing the right working height. Footrest and castor options are available for added convenience.

EN 12469

Fixed height stand charcoal grey	Acc.	50155665	50155666	50155667	50155668	50155666	50155668
Provides work height of 750mm							
Adjustable height stand charcoal grey	Acc.	50155688	50155689	50155690	50155691	50155689	50155691
Provides work height of 750-950mm							
Electric adjustable stand charcoal grey	Acc.	50117449	50109314	50117450	50109325	50109314	50109325
Footrest bar (for non-electric floorstand)	Acc.	50051982	50051983	50051984	50051985	50051983	50051985
Castor-Set for stand (4 pcs.)	Acc.						
Provides work height of 850 mm (for fixed		50109977 50109977			)9977		
stands only)							

#### **Compliance services\***

Qualification service	Certification standard	Cat. No.
On-site IQ/OQ service	NSF 49 (United States)	IOQPCKE89003610
	EN 12469 (Europe)	IOQPCKE89003488
	DIN 12980 (Germany)	IOQPCKG89003613

\* See page 6 for details and availability.



NSF/ANSI 49





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