

## Who are we?

### We are Thermal Compliance, specialists in temperature mapping and autoclave validation.

Founded in 2007, we are an independent validation service provider to the pharmaceutical, biotechnology and healthcare sectors internationally.

We provide validation, calibration, equipment hire and temperature mapping services.

Our autoclave validation services include:

- EN285 testing
- HTM2010 testing
- installation qualification
- operational qualification
- cycle development
- performance qualification
- troubleshooting.

Our temperature mapping and validation services are used for equipment and environments such as:

- fridges
- freezers
- incubators
- ovens
- warehouses
- storage rooms
- humidity cabinets
- stability rooms.

We have a wide range of equipment available to hire including Kaye Validator 2000s and thermal testing equipment.

We also offer products including the 3M Electronic Test System, biological indicators, thermocouples, and autoclave tape.



## Temperature mapping

### **We provide temperature mapping, thermal validation and humidity mapping services for temperature critical equipment.**

We perform testing over a range of -196 to 400°C, and 0 to 95% RH.

We use GE Kaye Validator 2000 and wireless data loggers capable of logging every second to give a detailed analysis of your temperature critical environment, performing work to either our Standard Operating Procedures (SOPs) and protocols, or your own documentation.

We also offer onsite calibration services for temperature and pressure.

Our knowledge of US and EU industry guidelines – such as the Orange guide, ICH guidelines and ASTM E2500 – is key to providing you with a clear and compliant validation approach.

We perform temperature mapping on various healthcare, process, laboratory and storage equipment, including:

- Laboratory: incubators; ovens; humidity chambers; autoclaves
- Process: freeze driers; steam-in-place; depyrogenation tunnels; autoclaves
- Product storage: fridges; freezers; cold stores; warehouses; liquid nitrogen tanks; stability rooms





## Autoclave validation

**At Thermal Compliance we specialise in autoclave validation to UK, EU and international standards for the pharmaceutical, biotechnology and healthcare sectors.**

Our experience and expertise will give you a clear, compliant and transparent autoclave validation package. Awareness of current EU and US regulatory requirements is essential.

We can qualify your autoclave to EN 285:2006, EN 17665 and PDA Technical Report 01 to meet MHRA, IMB and FDA expectations.

Validation Services:

- Installation/Operation Qualification (IQ, OQ)
- Cycle/Load Development (CD)
- Performance Qualification (PQ) and Re-Qualification (RQ)
- EN 285:2006 testing
- Pressure and temperature air detector setup
- Audits and consultancy support
- Steam quality testing
- HTM 01-05 testing
- HTM 2010 testing.





## Equipment hire

**Our GE Kaye Validator thermal validation systems are available for hire with current calibration certificates.**

We also offer thermal baths from -80°C to 400°C and IRTD-400s.

There is no minimum hire period; all of our equipment is delivered in protective cases with current calibration certificates; additional validation accessories are also available.

Items for hire include:


- Kaye Validator 2000 (versions 3.6, 3.5, 3.1, 2x) including 3 Sensor Input Modules (SIMS), power lead, serial cable, USB cable, and calibration certificates
- Kaye LTR-140 (-40), temperature range -40°C to 140°C
- Kaye LTR-140 (-25), temperature range -25°C to 140°C
- Kaye M2801 / IRTD-400,

temperature range -196°C to 400°C

- Kaye HTR-400, temperature range 50°C to 400°C, accuracy  $\pm 0.2^\circ\text{C}$  to  $\pm 0.4^\circ\text{C}$ .

Other equipment that we have available to hire includes: entry glands, pressure transmitters and temperature and humidity dataloggers.





## Products

**At Thermal Compliance, our approach is to identify and embrace forward-thinking solutions.**

We find innovative solutions to improve performance through timesaving, and by increasing quality of data and ease of use. Our products include:

### 3M™ Electronic Test Systems (ETS)



We distribute the 3M™ Electronic Test System (ETS) a paper free electronic Bowie & Dick Test.

We provide validation support to assist your move to a paperless system.

ETS provides comprehensive, objective, independent information about the critical variables of the steam sterilization process.





## Biological indicators



- 3M™ Attest™ Biological Indicators for Ethylene Oxide (EtO) Sterilization.
- 3M™ Attest™ Rapid Readout Biological Indicator for Steam.
- 3M™ Attest™ Biological Indicators for Steam Sterilization.



## Autoclave tape

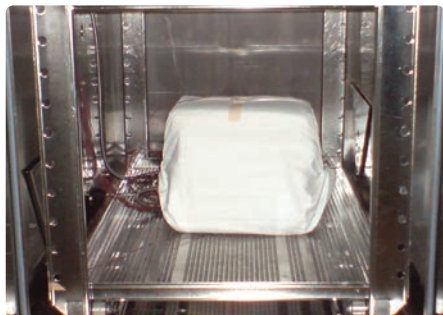


- 3M™ Comply™ Steam Indicator Tape. Individually wrapped.
- 3M™ Comply™ Ethylene Oxide Indicator Tape. Individually wrapped.



## Standard Towel Packs

- For use in HTM2010 & EN285 Testing.



## Bespoke Thermocouples

- Bespoke for use with Kaye Validator
- Class 1 (Premium) Type T cable
- Colour coded to IEC 584-3
- FEP Encapsulation & Welded Tips
- Numbered.





## Contact us:

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