

## WHY SHOULD I CARE ABOUT REGULATORY MARKING AND COMPLIANCE OF LAB PRODUCTS?



The purchase of laboratory equipment can be a complex process involving technical, economic, and operational considerations. Equally important, but sometimes taken for granted, are safety and regulatory compliance requirements. Be sure to know the facts before making a purchase decision.

### **Who is legally responsible for ensuring that products conform to relevant regulations?**

In North America, employers are responsible for ensuring that products meet all regulatory requirements to ensure a safe workplace. In the US, this is enforced by OSHA; in Canada, HECS serves a similar role. Use of products that are not suitably certified would constitute a workplace safety violation according to OSHA or HECS statutes.

In Europe (the EEA), the manufacturer is legally responsible for ensuring compliance through CE marking. However, the customer bears the actual risk associated with using an unsafe or non-compliant product.

## What are the requirements for certification?

The requirements vary by national jurisdiction but generally fall into two major categories.

### US and Canada

Approval is required by a licensing body, which are referred to generally as nationally recognized testing laboratories, or NRTL's. Well known examples of NRTL's are UL or Intertek; these are two companies that provide a similar service. This marking can be obtained for a product in general through rigorous testing and scrutiny of the product design by the authorizing body. For a product that has not undergone this design-level scrutiny, a site audit can be performed to provide validation for a specific device, located in a specific lab. These site audits are performed after installation and typically cost \$5,000 or more for each device.

### Europe

Certification is self-administered by manufacturers through application of the CE mark, which is required to sell indicated products in the EEA.

## How can I tell that a manufacturer's CE mark self-certification was rigorous?

The requirements vary by national jurisdiction but generally fall into two major categories.

A manufacturer that is committed to product safety will seek **external validation** of their design. Two common forms of external validation are NRTL marking, and/or the CB scheme. While NRTL marking is not required for sale of products in Europe, it does reflect rigor in product design and safety.

The CB scheme is a voluntary certification of safety and certainty that is endorsed by the International Electrotechnical Commission (IEC). The IEC is a not-for-profit organization of experts who participate in technical and conformity assessment activities – including writing standards – to make common processes and benchmarks for compliance regulations. **CB Certification is based on the successful completion of third-party testing against relevant Harmonized Standards and technical assessment of an accredited Certification Body.**

### COUNTRIES PARTICIPATING IN THE CB SCHEME ARE:

Argentina • Australia • Austria • Bahrain  
• Belarus • Belgium • Brazil (suspended)  
• Bulgaria • Canada • China • Colombia  
• Croatia • Czech Republic • Denmark •  
Finland • France • Germany • Greece •  
Hungary • India • Indonesia • Ireland • Israel  
• Italy • Japan • Kazakhstan • Kenya • Korea,  
Republic Of • Libya • Malaysia • Mexico  
• Netherlands • New Zealand • Norway •  
Pakistan • Poland • Portugal • Romania •  
Russian Federation • Saudi Arabia • Serbia  
• Singapore • Slovakia • Slovenia • South  
Africa • Spain • Sweden • Switzerland  
• Thailand • Turkey • Ukraine • United  
Arab Emirates • United Kingdom • USA •  
Vietnam

Product safety is too important to cut corners. A manufacturer that is taking shortcuts by skipping external validation is putting your lab at risk.

## **What is the risk of using a non-compliant product?**

In the US and Canada, the employer may be subject to a workplace safety violation according to OSHA or HECS statutes.

Unfortunately, the risk in all jurisdictions is greater than legal, it is a risk of safety. Regulatory compliance marks exist to ensure that manufacturers have “done their homework” to ensure that their product conforms to all relevant safety and compliance standards. A product without rigorous third-party validation may not meet those safety requirements.

The safety standards at risk are most commonly electrical safety and interference. A non-compliant device may interfere with – or be interfered by – neighboring electronic devices. Examples of electrical interference include:

- screen flicker in displays
- unstable power supply, which can lead to device malfunction or even fire
- interference with data transfer and storage.

Affected devices could be those in the lab (instruments, computers) or even those in or near the lab but not associated with the lab directly such as watches, phones, pacemakers, insulin pumps or other nearby electronics.

## **Isn't this a formality? Everything is pretty safe, right?**

That is not true. Electromechanical systems are complex, especially those systems that push the limits of sensitivity and resolution as in analytical instrumentation. Interference is common and may lie undetected for a long time. But consequences are severe when they emerge. It is not worth the risk.

## **What about RoHS?**

The other significant risk that is posed by incomplete or counterfeit CE certification is one of hazardous materials. A key requirement of CE marking is conformity to the RoHS directive (Restriction of Hazardous Substances). A product that is not truly compliant may contain hazardous substances. This hazard is especially acute in the event of an emergency – a fire could generate chemicals that are extremely toxic. The most likely risk is in disposal at the end of product life. These restricted substances are toxic to groundwater and cannot be placed in landfills. The consumer could be liable for incorrectly disposing of substances that require special handling.

## **Is counterfeit CE marking a real problem?**

Yes. Recent examples have shown that both European, and external manufacturers have been found to apply CE marks negligently. Enforcement is increasing, but there are still products on the market that bear the CE mark without fully complying to the requirements of the mark.

## How can I be certain that a product is compliant and safe?

Demand verification. A manufacturer should be able to provide their certificates to mark for both the CE mark and their NRTL approval. You should also ask for third-party validation documentation, such as the widely recognized CB scheme of IEEE/IEEC. Many manufacturers will post this information on their websites to simplify verification.

## How does Micromeritics approach regulatory compliance?

Micromeritics is absolutely committed to customer safety, and to documenting that commitment through rigorous external validation. Products are appropriately certified for the jurisdiction in which they are sold and our products are externally validated through Intertek and the CB-scheme.

Certificates of compliance are available through our [Declarations of Conformity page](#) or on request. Please request these documents from us, and from any vendor you are considering doing business with.

