

# Product approval and certification in Canada and the United States (U.S.)

**INTEGRA Biosciences** is recognized for delivering high-quality laboratory equipment focused on liquid handling and media preparation. Our commitment to innovation ensures that we meet the diverse needs of customers in research, diagnostics, and quality control across the life sciences and medical sectors.

All our products comply with the IEC61010 standards family, which the U.S. adopts with minor differences as UL61010, and Canada recognizes as CAN/CSA-C22.2 No.61010-1-04. This compliance underscores our dedication to safety and reliability in laboratory environments.

Product approval and certification in Canada and the United States involve specific regulatory processes to ensure safety, efficacy, and compliance with relevant standards.

## 1 INTEGRA Biosciences approach

Both above-mentioned countries prioritize safety and efficacy in laboratory products through rigorous approval and certification processes, ensuring that they meet established safety standards before being marketed.

**INTEGRA Biosciences** takes a comprehensive approach to product development, certification, and compliance, ensuring that its laboratory tools meet the highest standards of safety, quality, and innovation. Here are the key aspects of INTEGRA Biosciences' approach:

### **1. Commitment to Quality and Safety**

**Rigorous testing:** All products undergo extensive testing to meet international safety standards, including UL61010 and CAN/CSA-C22.2 No.61010-1-04, ensuring laboratory safety. We maintain constant communication with local authorities, accredited testing laboratories, and specialists to provide the highest safety standards for our customers.

The 61010-1 standard is a comprehensive safety standard that applies to electrical devices used in laboratories as well as in industrial and commercial environments. Here are the key aspects in detail:

#### **1. Scope**

The standard applies to a wide range of electrical devices, including Measuring instruments, Control devices, Laboratory equipment, Test and inspection devices

#### **2. Electrical Safety**

**Isolation:** The standard requires specifications for the insulation of electrical parts to ensure that no hazardous voltages are present on accessible parts.

**Overcurrent Protection:** Devices must be designed to safely shut down in the event of overload or short circuits to prevent fire or shock hazards.

**Overvoltage Protection:** Measures must be taken to minimize overvoltages from external sources (e.g., lightning).

#### **3. Mechanical Safety**

**Structural Integrity:** Devices must be stable and resistant to mechanical stresses, such as impacts or vibrations.

**Protection Against Hazardous Movements:** Moving parts must be designed to pose no danger to the user.

#### **4. Environmental Protection**

**Operating Conditions:** Devices must operate safely under various environmental conditions (temperature, humidity, dust).

**Corrosion Protection:** Materials must be corrosion-resistant to ensure their integrity over time.

#### **5. User-Friendliness**

**Controls and Displays:** These should be clearly and intuitively designed to minimize the risk of user error.

Safety Markings: All safety-related information must be clearly visible and understandable.

## 6. Testing and Certification

To confirm compliance with the 61010-1 standard, INTEGRA must subject their devices to a series of tests. These include:

Functional Tests: Verification of basic operational functions.

Safety Tests: Inspections for electrical isolation, overcurrent protection, and mechanical safety.

Environmental Tests: Evaluation of performance under various environmental conditions.

## 7. Risk Management

The standard requires manufacturers to conduct a risk analysis to identify potential hazards and implement appropriate safety measures.

The 61010-1 standard is crucial for ensuring the safety and reliability of electrical devices in laboratories and other applications. It not only protects users but also supports manufacturers in providing high-quality and safe products.

*If you need more information on specific tests or aspects of the standard, feel free to ask!*

**NRTL Compliance:** INTEGRA ensures that its electrical equipment receives certification from recognized NRTLs, such as TÜV SÜD and CSA, to guarantee adherence to safety regulations. For specific products (see below for listed products) INTEGRA has a NRTL certification.

## 2. Regulatory Compliance

**Adherence to Standards:** The company closely follows relevant regulations in both the U.S. and Canada, including OSHA and Health Canada requirements, to maintain compliance and avoid legal issues.

**Environmental Responsibility:** INTEGRA is committed to environmental sustainability, ensuring that its products comply with Canadian environmental regulations concerning waste disposal and hazardous materials.

## 3. Innovation and Customer-Centric Solutions

**Continuous Improvement:** INTEGRA invests in research and development to create innovative solutions that address the evolving needs of customers in the life sciences, diagnostics, and quality control sectors.

**Feedback-Driven Design:** The company actively seeks feedback from users to enhance product functionality and usability, ensuring that solutions are tailored to customer requirements.

## 4. Education and Support

**Technical Support:** The company offers robust technical support to assist customers in navigating compliance and operational challenges.

## 5. Collaboration with Accredited Bodies

**Partnerships:** INTEGRA collaborates with accredited certification bodies like TÜV SÜD to streamline the certification process and maintain high standards of quality assurance.

**INTEGRA Biosciences'** approach integrates rigorous testing, regulatory compliance, innovative design, customer support, and collaboration with accredited bodies to deliver high-quality laboratory tools. This comprehensive strategy ensures that the company meets safety standards while addressing the dynamic needs of its customers in the life sciences and medical industries.

**INTEGRA Bioscience Products** MEDIACLAVE 10 and 30, as well as VIAFLO 96 and 384, are additionally marked with the cTÜVus label, indicating that they can be operated in Canada and the U.S. without any additional testing. This additional certification signifies that these devices have undergone thorough testing by TÜV SÜD Product Services, an organization accredited by both the Standards Council of Canada (SCC) and the Occupational Safety and Health Administration (OSHA).

**INTEGRA Biosciences** ensures that its MEDIACLAVE and VIAFLO products are compliant with safety regulations in Canada and the U.S. through rigorous testing and certification. The cTÜVus label, regular factory inspections by TÜV SÜD, and the certification of power supplies reflect the company's commitment to quality and safety. Additionally, the option for field inspections allows customers to further verify compliance as needed.

## 2 U.S. legal situation

**UL Certification:** For electrical safety, products must meet UL standards. UL (Underwriters Laboratories) tests and certifies products to ensure they comply with safety standards, often referencing UL61010 for laboratory equipment. UL certification is essential for ensuring the electrical safety of laboratory equipment. Underwriters Laboratories (UL) conducts rigorous testing to verify that products meet specific safety standards. For laboratory equipment, this often involves compliance with UL61010, which focuses on safety requirements for electrical equipment used in laboratories.

Key Aspects of UL Certification:

1. **Safety Testing:** Products undergo various tests to evaluate risks such as electric shock, fire hazards, and mechanical hazards.
2. **Compliance with Standards:** UL61010 outlines requirements for design, construction, and performance to ensure safe operation in laboratory environments.
3. **Labeling:** Certified products receive a UL mark, indicating compliance with safety standards, which can enhance customer trust and marketability.
4. **Periodic Inspections:** UL conducts regular audits and inspections to ensure ongoing compliance with safety standards, even after initial certification.
5. **Market Access:** UL certification can facilitate market entry in the U.S. and Canada, as many customers and regulatory bodies require it for electrical products.

In summary, UL certification plays a crucial role in ensuring that laboratory equipment is safe and reliable for users, ultimately contributing to the integrity of research and diagnostics in the life sciences

**ANSI Compliance:** Many products must also comply with American National Standards Institute (ANSI) standards, which may relate to specific industry practices.

ANSI compliance is vital for ensuring that products meet established safety and quality standards across various industries. The American National Standards Institute (ANSI) oversees the development of consensus standards that address numerous aspects of product design, manufacturing, and performance.

Key Aspects of ANSI Compliance:

1. **Standard Development:** ANSI collaborates with industry experts, organizations, and stakeholders to develop standards that reflect best practices in safety, performance, and efficiency.
2. **Variety of Standards:** ANSI standards cover a wide range of areas, including laboratory equipment, safety protocols, and quality assurance processes. This ensures that products are reliable and suitable for their intended applications.
3. **Enhanced Safety:** Compliance with ANSI standards helps reduce risks associated with product use, ensuring that equipment operates safely in laboratory environments.
4. **Quality Assurance:** ANSI standards often include requirements for testing and validation, promoting consistent quality across products and manufacturers.
5. **Market Recognition:** ANSI compliance can enhance a product's credibility and acceptance in the marketplace, as many organizations and regulatory bodies recognize ANSI standards as benchmarks for safety and quality.

In summary, ANSI compliance is essential for manufacturers to ensure their products meet rigorous industry standards, ultimately fostering trust and safety in laboratory practices. The federal legal requirements for electrical products in the workplace are outlined in the **Code of Federal Regulations (CFR)**, specifically under **Title 29 CFR 1910.303**.

This regulation mandates that electrical equipment operating at 50 volts or more must have approval from a **Nationally Recognized Testing Laboratory (NRTL)** to ensure safety and compliance.

Key Points are:

1. **NRTL Approval:** NRTL approval is crucial for ensuring that electrical equipment meets safety standards, particularly in workplace environments. This requirement helps protect employees from potential hazards associated with electrical equipment.
2. **Occupational Safety and Health Administration (OSHA):** OSHA is the federal agency responsible for overseeing workplace safety, including the accreditation and auditing of products to ensure they meet specific safety standards. OSHA maintains a list of recognized NRTLs on its website <http://www.osha.gov>, which manufacturers can reference.
3. **Recognized NRTLs for Laboratory Devices:** For laboratory instruments adhering to the UL61010 standard series, several NRTLs are recognized for testing, including:
  - o Bureau Veritas
  - o CSA Group
  - o FM Approvals
  - o Intertek
  - o MET Labs
  - o Nemko
  - o NSF International
  - o QAI (Quality Auditing Institute)
  - o QPS (Quality Products Services)
  - o SGS
  - o TÜV Rheinland
  - o TÜV SÜD
  - o TÜV SÜD Product Services
  - o UL (Underwriters Laboratories)
4. **Local Regulations:** While federal regulations set the baseline for safety standards, local regulations may also exist. These are often aligned with federal regulations, and INTEGRA Biosciences is not aware of any instances where a manufacturer has faced ruling against them for compliance with federal standards.

Compliance with Title 29 CFR 1910.303 and obtaining NRTL approval is essential for manufacturers of electrical equipment, particularly in laboratory settings. This ensures that products meet safety requirements, helping to protect workers and maintain a safe laboratory environment.

## 3 Canadian legal situation

### CSA Certification and Environmental Compliance in Canada

- **CSA Certification:** The Canadian Standards Association (CSA) provides critical certification for safety standards, including those specified in **CAN/CSA-C22.2 No.61010-1-04**, which focuses on electrical safety for laboratory equipment. This certification is essential for ensuring that products are safe for use in laboratory settings.
- **Environmental Compliance:** In Canada, products must also adhere to environmental regulations concerning waste disposal and hazardous materials. This compliance is crucial for promoting sustainability and ensuring public health and safety.

### Accreditation and Oversight

- **Standards Council of Canada (SCC):** The SCC is the federal agency responsible for accrediting certification bodies to ensure they meet specific safety standards. The SCC maintains a list of accredited certification bodies on its website ([scc.ca](http://scc.ca)), detailing their scope of recognition and the standards they can certify against.
- **TÜV SÜD Product Services:** INTEGRA Biosciences chooses TÜV SÜD Product Services as its certification body for lab instruments in Canada. This choice reflects a commitment to quality and safety, as TÜV SÜD is recognized for its rigorous testing and certification processes.

### Common Misconceptions

- **CSA as the Sole Body:** There is a common misconception that the CSA is the only accredited certification body in Canada. While the CSA plays a significant role, especially with its publication of the Canadian Electrical Code (CEC), which defines requirements for the installation and maintenance of electrical equipment, several other accredited bodies, including TÜV SÜD, also provide important certification services.

In Canada, CSA certification and compliance with environmental regulations are essential for the safety and sustainability of laboratory equipment. The Standards Council of Canada oversees the accreditation of various certification bodies, ensuring a robust framework for product safety. INTEGRA Biosciences, by selecting TÜV SÜD for certification, underscores its commitment to high safety standards while navigating the diverse landscape of regulatory requirements

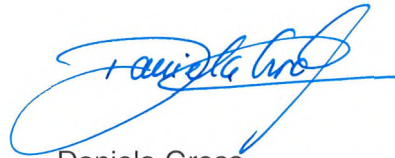
All **INTEGRA Biosciences** products comply with applicable and mandatory regulations and have been fully tested for product safety.

## 4 Signature

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If you have any further specific questions, please feel free to contact us. We are happy to support you in this context.

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