

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

**INTEGRA Biosciences** is a leading provider of high-quality laboratory tools for liquid handling and media preparation. We are committed to create innovative solutions which fulfill the needs of our customers in research, diagnostics and quality control within the life science markets and medical industry.

**INTEGRA Biosciences** products are fully compliant with the **IEC61010** standards family which the U.S. have adopted with minor national differences as **UL61010**, Canada as **CAN/CSA-C22.2 No.61010-1-04**.

## 1 U.S. legal situation

The federal legal requirements for products are defined in the **Code of Federal Regulations (CFR)**. Title **29 CFR 1910.303** defines that **Nationally Recognized Testing Laboratory (NRTL)** approval is required for electrical equipment operating at 50 V or more when they are used in the workplace. In addition to federal regulation, local regulations do exist. However, these are closely tied to federal regulations and no ruling against a manufacturer following federal regulations is known to **INTEGRA Biosciences**.

The federal agency responsible for accreditation and auditing to specific safety standards is the **Occupational Safety and Health Administration (OSHA)**. **OSHA's** web page <http://www.osha.gov> lists **NRTL's** and their scope of recognition. For laboratory devices and instruments (**UL61010** standard series) the following **NRTLs** are recognized for testing at the time of writing: Bureau Veritas, CSA, FM approvals, Intertek, MET, Nemko, NSF, QAI, QPS, SGS, TÜV Rheinland, TÜV SÜD, TÜV SÜD Product services, UL.

## 2 Canadian legal situation

The federal agency responsible for accreditation and auditing to specific safety standards is the **Standards Council of Canada (SCC)**. SCC accredited certification bodies are listed on <http://www.scc.ca> with their scope of recognition.

TÜV SÜD Product services is one of the accredited bodies for lab instruments and **INTEGRA Biosciences** choice when it comes to product certification for Canada. Sometimes it is thought that **Canadian Standards Association (CSA)** is the only accredited certification body which may stem from the fact that the requirements pertaining to the installation and maintenance of electrical equipment in Canada are defined in the **Canadian Electrical Code (CEC)** which is published by CSA.

## 3 INTEGRA Biosciences approach

**INTEGRA Biosciences MEDIACLAVE 10 and 30, VIAFLO 96 and 384** marked with the cTÜVus label can be operated without any additional testing in Canada and the U.S. These devices were tested by TÜV SÜD Product services which is both accredited by SCC and OSHA. As part of the cTÜVus certification, TÜV SÜD Product services also inspects **INTEGRA Biosciences** factories on a regular basis.

All external power supplies for **INTEGRA Biosciences** products are CSA and UL certified by their manufacturers, which means that these products are also fully compliant with Canadian and U.S. regulations. Field inspections to confirm compliance by CSA or UL are available upon request for **INTEGRA Biosciences** products like e.g. **MEDIAJET** at the customer's expense.