

# Our Promise to Quality and Safety

INTEGRA Biosciences is certified according to ISO 9001 (Quality Management) and ISO 14001 (Environmental Management) standards. Additionally, INTEGRA is actively pursuing ISO 17025 accreditation to further strengthen its commitment to technical competence and measurement accuracy.

INTEGRA Biosciences is committed to provide reliable, high-quality products which are safe and compliant with relevant regulations worldwide.

INTEGRA Biosciences is committed to delivering high-quality laboratory instruments and accessories that are developed, manufactured, and distributed in accordance with their defined **intended use**.

Our products are intended exclusively for **general laboratory use and research purposes by trained professionals**. They are **not intended for medical, diagnostic, or therapeutic applications**. In line with this intended use, INTEGRA products **do not fall under the scope of medical device regulations**, such as the EU Medical Device Regulation (MDR), the In Vitro Diagnostic Regulation (IVDR), or pharmacopoeial standards.

INTEGRA products are classified as **laboratory equipment** and are **subject to the requirements of the Low Voltage Directive (2014/35/EU)**, where applicable. They do not fall under the scope of the Machinery Directive (2006/42/EC).

Despite not being classified as medical devices, INTEGRA maintains a strong commitment to **regulatory compliance, product safety, and quality**. Our processes and products are designed to meet all applicable legal and safety requirements for laboratory equipment, ensuring reliability and trust for laboratories worldwide.

## 1 INTEGRA Biosciences Compliance with IEC 61010 Safety Standards

INTEGRA Biosciences instruments comply with the internationally recognized IEC 61010 standard series, which governs safety aspects of laboratory equipment such as mechanical safety, emissions, pressure, and ergonomics. Part 1 of the standard outlines general requirements, while Part 2-81 specifically applies to automatic laboratory instruments that operate without manual intervention—covering **INTEGRA Bioscience's** relevant products.

Risk mitigation is ensured through comprehensive Failure Mode and Effects Analysis (FMEA) and adherence to IEC 61010 guidelines, including sensor systems that limit speed and force to maintain the lowest risk category. Additional safety features such as warnings, audible/visual signals, and clear instructions enable safe operation without protective enclosures. All products have successfully passed internal and TÜV SÜD safety tests.

### 1.1 Product Safety and Certifications of INTEGRA Biosciences in North America

INTEGRA Biosciences ensures product safety and regulatory compliance in the U.S. and Canada through rigorous testing and certification processes. All laboratory instruments are tested to meet international safety standards such as UL61010 and CAN/CSA-C22.2 No.61010-1-04. Certification by recognized Nationally Recognized Testing Laboratories (NRTLs), including TÜV SÜD and CSA, confirms adherence to these standards.

The company also complies with OSHA and Health Canada regulations and integrates environmental responsibility into its processes. Products such as MEDIACLAVE 10/30 and VIAFLO 96/384 are marked with the cTÜVus label, allowing them to be used in both the U.S. and Canada without additional testing.

INTEGRA Biosciences emphasizes continuous improvement through customer feedback, strong technical support, and collaboration with accredited certification bodies. Regular factory inspections and field audit options underscore the company's commitment to maintaining the highest safety and quality standards.

## 2 EMC and Safety Requirements for Electrical Devices in the EU and the USA

In the European Union, non-medical electrical devices must comply with several directives:

- **EMC Directive 2014/30/EU**: Ensures that devices do not cause or suffer from unacceptable electromagnetic interference. The harmonized standard **EN 61326-1** applies to laboratory, measuring,

control, and regulation equipment.

- **Radio Equipment Directive (RED) 2014/53/EU:** Applies to devices with wireless technologies (e.g., WLAN, Bluetooth). It requires compliance with safety, EMC, and efficient spectrum use standards.
- **Low Voltage Directive (LVD) 2014/35/EU:** Covers electrical safety for devices operating between 50–1000 V AC or 75–1500 V DC, aiming to protect people and property.

In the **United States**, the **Federal Communications Commission (FCC)** regulates electromagnetic compatibility via **FCC Part 15** of Title 47 CFR. This primarily covers **electromagnetic emissions**. For wireless devices, additional rules under **Part 15 Subpart C** or other applicable sections must be followed.

### 3 Measures to Ensure Animal-Free and Safe Products

**INTEGRA Biosciences** ensures that its products are free from animal-derived components through comprehensive measures. These include the analysis of all ingredients, obtaining certificates of conformity from suppliers, and clear work instructions for relevant departments. These actions minimize the risk of TSE/BSE transmission and ensure product safety. Although not a manufacturer of medical devices, **INTEGRA Biosciences** complies with the relevant EU regulations (2003/32/EC, 722/2012) and continuously works to optimize its quality standards.

### 4 INTEGRA Biosciences Material Compliance and Environmental Responsibility Statement

**INTEGRA Biosciences** is committed to providing safe, high-quality, and environmentally friendly products. As part of its mission, the company ensures compliance with international environmental and material regulations throughout the entire product life cycle—from raw material sourcing to end-of-life disposal. This includes adherence to laws such as **RoHS (EU and China), REACH, WEEE, California Proposition 65, and conflict minerals regulations (Dodd-Frank Act and EU Regulation 2017/821)**. **INTEGRA Biosciences** regularly monitors legal updates to maintain ongoing compliance and minimize its environmental footprint.

### 5 Health, Safety, and Well-being in the Workplace at INTEGRA Biosciences

**INTEGRA Biosciences** prioritizes the health, safety, and well-being of its employees through continuous training, thorough qualification checks, and adherence to all relevant health and safety regulations. The company maintains safe and comfortable work environments, including adapted operating rooms and ergonomic workstations, while managing workload to prevent stress and accidents. **INTEGRA Biosciences** fosters a respectful workplace free from harassment and discrimination and provides special protection for vulnerable groups such as pregnant women and employees recovering from illness. The company strictly prohibits drug and alcohol use during work and offers support for addiction. To promote employee health, **INTEGRA Biosciences** encourages participation in wellness activities and ensures access to proper personal protective equipment and first aid. Overall, **INTEGRA Biosciences** commits to creating a safe, healthy, and supportive work environment aligned with legal requirements.

### 6 Supply Chain Ethics and Anti-Slavery Commitment

**INTEGRA Biosciences** is actively committed to upholding ethical labor practices throughout its supply chain. Through comprehensive risk assessments and a binding code of conduct, the company ensures the prevention of modern slavery. Suppliers are carefully vetted before onboarding and must demonstrate measures to comply with labor rights. Employees receive training to raise awareness of modern slavery, and a whistleblowing policy enables confidential reporting. Regular audits and collaboration with industry partners help maintain high ethical standards.

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Urs Hartmann

CEO

INTEGRA Biosciences AG



Daniela Gross

Head of Corporate Quality

INTEGRA Biosciences AG

If you require further information or a more detailed explanation on a specific aspect, please do not hesitate to contact us!

**INTEGRA Biosciences AG**  
7205 Zizers, Switzerland  
T +41 81 286 95 30  
info@integra-biosciences.com

**INTEGRA Biosciences Corp.**  
Hudson NH 03051, USA  
T +1 603 578 5800  
info-us@integra-biosciences.com

**INTEGRA Biosciences Deutschland GmbH**  
35444 Biebertal, Deutschland  
T +49 6409 81 999 15  
info-de@integra-biosciences.com

**INTEGRA Biosciences SAS**  
95062 Cergy-Pontoise Cedex 1, France  
T +33 1 34 30 76 76  
info-fr@integra-biosciences.com

**INTEGRA Biosciences Ltd.**  
Thatcham Berkshire RG194EP, UK  
T +44 1635 797 00  
info-uk@integra-biosciences.com

**INTEGRA Biosciences (Shanghai) Co., Ltd.**  
上海自由贸易试验区 201315, 中国  
T +86 21 5844 7203  
info-cn@integra-biosciences.com

**INTEGRA Biosciences KK**  
ちよだ一く、ときよ 101-0031、じゃぼん  
T +81 3 5962 4936  
info-jp@integra-biosciences.com

**INTEGRA Biosciences Nordic ApS**  
2605 Brøndby, Denmark  
T +45 3173 5373  
orders-nordic@integra-biosciences.com

**INTEGRA Biosciences Ireland Limited**  
Blanchardstown, Dublin 15, Ireland  
T +44 1635 797000  
info-ie@integra-biosciences.com

**INTEGRA Biosciences Pty Ltd**  
Brendale QLD 4500, Australia  
T +61 7 3497 5800  
info-au@integra-biosciences.com

**INTEGRA Biosciences Benelux B.V**  
4814 DB Breda, Netherlands  
T +32 78 48 66 75  
orders-benelux@integra-biosciences.com