

Safety regulations of automated laboratory equipment

INTEGRA Biosciences is committed to provide reliable, high quality products which are safe and environmental friendly – Compliance with relevant safety legislation worldwide is an important part of **INTEGRA Biosciences** mission. This document covers regulatory aspects of product safety of automated laboratory equipment produced by **INTEGRA Biosciences**.

Examples of such equipment are **ASSIST** (Part No 4500), **ASSIST PLUS** (Part No 4505), **VIAFLO 96** (Part No 6001), **VIAFLO 384** (Part No 6031), **WELLJET** (Part No 500x), **MINI 96** (Part No 480x) and **MEDIAJET** (Part No 1x300x).

INTEGRA Biosciences monitors changes and applicability of product safety regulations worldwide to ensure continued compliance. This document will be updated as required accordingly.

1 Applicable standards

The IEC 61010 standard series addresses all aspects of laboratory equipment safety, e.g. mechanical aspects, sound emissions, laser sources, pressure, fire and ergonomic aspects. This standard series is widely adopted throughout the world, e.g. as UL 61010 in the **United States of America (USA)**, EN 61010 in the **European Union (EU)** or GOST 61010 in the **EurAsian Economic Union (EAEU)**. This standard series also covers other **INTEGRA Biosciences** instruments like **MEDIACLAVE**, **FIREBOY**, **VACUSAFE**, **PIPETBOY** etc.

Part 1 of this standard series describes general requirements whereas Part 2 is divided into multiple sections describing specific aspects of particular equipment, e.g. automatic laboratory equipment for analysis (-2-81). The scope of IEC 61010-2-81 is defined as: “instruments or systems for measuring or modifying one or more characteristics or parameters of samples, performing the complete process or parts of the process without manual intervention”. The **INTEGRA Biosciences** instruments mentioned in the introduction are thus clearly in the scope of both IEC 61010-1 and IEC 61010-2-81.

2 Risk mitigation

All **INTEGRA Biosciences** instruments are carefully designed with respect to handling safety. A thorough risk analysis is performed with **Failure Mode and Effects Analysis (FMEA)** and methods described in IEC 61010 section 7 and Annex J covering all operational aspects and the entire product life cycle.

Limited speed and force range combined with sensors to detect blockage or user interference guarantee the lowest possible risk (category 1, “broadly acceptable”) as defined by IEC 61010. Additional measures such as warning markings, audible and visual signals and instructions for use allow to safely interact with the equipment without the need for protective hoods or cabinets. All in-house and independent TÜV SÜD Product Services safety tests were passed successfully.

3 Legal considerations EU

By **EU** law conformity can only be declared to either the **Low Voltage Directive (LVD)** or the **Machinery Directive (MD)**.

The current definition of “machinery” according to **MD** Article 2a is “an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application”. This scope covers almost any type of equipment with moving parts powered by stored energy, which in many cases (e.g. “ball pen”) was never intended to fall under the **MD**.

However, regarding other directives article 3 of the **MD** states “Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives”.

General laboratory equipment is covered in scope by standard EN 61010-1, the European version of IEC 61010-1. This standard is harmonized under the **LVD** (see https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en).

EN 61010-2-81 explicitly lists “automatic sampler / pipettor / aliquoter” in its extended scope definition. Its general scope is defined as “automatic and semi-automatic laboratory equipment for analysis and other purposes”. Therefore this standard specifically applies to instruments like **ASSIST**, **ASSIST PLUS**, **VIAFLO 96**, **VIAFLO 384**, **MINI 96**, **WELLJET** and **MEDIAJET**. EN 61010-2-81 is also harmonized under the **LVD**.

What’s more, to **INTEGRA Biosciences** knowledge there is no court decision setting a legal precedent favoring **MD** over **LVD** for aforementioned type of equipment.

Based on the above **INTEGRA Biosciences** laboratory instruments are most specifically covered by requirements of the IEC 61010 series of standards harmonized under the **LVD**. Conformity is therefore declared to the **LVD**, not the **MD**. This opinion is shared by a majority of manufacturers of similar equipment at the time of writing this statement.

4 Signatures

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