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), and **MEDIAJET** (Part No. 103xxx).

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 **U**nited **S**tates of **A**merica (USA), EN 61010 in the **E**uropean **U**nion (EU) or GOST 61010 in the **E**ur**a**sian **E**conomic **C**ommunity (EAEC).

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 above mentioned **INTEGRA Biosciences** instruments are thus clearly in the scope of IEC EN 61010-1 and IEC EN 61010-2-81.

2 Risk mitigation

INTEGRA Biosciences equipment was carefully designed with respect to handling safety. A thorough risk analysis was performed with **F**ailure **M**ode and **E**ffects **A**nalysis (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 TÜV SÜD Product Services safety tests were passed successfully.

3 Legal considerations EU

The European version of IEC 61010-1, EN 61010-1 is harmonized under the **L**ow **V**oltage **D**irective (**LVD**, see https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en). Alternatively equipment in the scope of EN 61010-1 could be declared compliant with the **M**achinery **D**irective (**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**. By EU law conformity can only be declared to either the **LVD** or the **MD**. In the absence of an official ruling, **INTEGRA Biosciences** decided that its equipment is best and most strictly covered by requirements of the IEC 61010 series of standards harmonized under the **LVD**. This opinion is shared by a majority of manufacturers with similar equipment.

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