

INTEGRA

Dear valued Customer,

Dear Madam / Sir

Thank you for your request and your interest in our products.

Due to the tremendous number of quality-related inquiries we receive, we regret to inform you that we cannot answer every single questionnaire. Therefore, we are attaching all available information and documentation on our INTEGRA products to this statement as a summary. Further helpful information is available on our webpage [INTEGRA Biosciences](#).

If your request concerns Product Description, Part Number or Related Product – *please see on our webpage [INTEGRA Products](#)*. If INTEGRA Biosciences product is defined as an accessory or spare part, the corresponding product refers to the instrument to which this accessory or spare part belongs. The application of the (related) product, as defined by INTEGRA Biosciences, is openly communicated through the description of the product or its related product, its intended use - as published in the Operating Instructions - and on the related CE certificate when applicable.

Intended use of our INTEGRA products

The products we supply are intended for general and wide-ranging use as laboratory equipment or accessories for professionals in the laboratory field. Since our products are defined as laboratory equipment, our INTEGRA products do not have to comply with medical or pharmacopeial requirements and guidelines.

Users who intend to certify our INTEGRA products for internal purposes and analysis-dependent certification processes must perform their own internal tests and controls and ensure that they comply with applicable international and local regulations.

Please see our CE Marking of general laboratory use pipettes [INTEGRA CE Marking of general laboratory use pipettes](#)

Quality system

INTEGRA Biosciences' manufacturing facilities are ISO 9001 certified. Attached is the latest version of our ISO 9001:2015 certificates:

Please see our [INTEGRA ISO 9001 Certificate US and CH](#)

General information

Founded in 1965, INTEGRA is active worldwide in the field of laboratory equipment manufacturing and consumables production. With more than 500 employees, INTEGRA is represented all over the world with two main manufacturing locations in Hudson, NH and our corporate offices in Zizers, Switzerland.

For you as a customer, a competent quality team is available. The proportion of quality employees at Integra is in the range of 3 – 6 percent.

At INTEGRA, we recognize that preserving high legal, ethical and moral standards is paramount for our success. The purpose of our Code of Conduct (*Integrity, passion, excellence, inspiration, entrepreneurship*) is to outline the general standards of business conduct and behaviours expected from INTEGRA employees, as well INTEGRA's business partners.

Our company has defined job descriptions, standard operating procedures (SOP) and process forms as part of our quality system. Internal Audits are conducted regularly to ensure our quality requirements are being met. Customer audits are allowed at INTEGRA. Depending on the effort required, this is subject to a fee.

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Documented processes for product development, product and material testing, as well as change management are also part of our quality management system. To manufacture our products, we apply only qualified personnel, equipment and suitable facilities.

Our Head of Corporate Quality is part of the management and responsible for quality-related topics in our company. Our competencies within the company are organized in such a way that responsibility is defined for quality management in the USA and Switzerland, respectively.

More information about the company can be found using the following links:

1. On this page, [About INTEGRA](#) you will find more about the *Integra locations* and the *Integra Code of Conduct*. The company brochure presents the *core values of the company*, that the company was founded in 1965 and other helpful information.
2. Download flyers, instruction manuals, certificates, software and much more at the [INTEGRA Download Center](#)
3. Furthermore, we have set up a Compliance and Certificate Center on our webpage [INTEGRA Compliance and Certificate Center](#)
Here you will find among other helpful information our safety regulations of automated laboratory equipment, Product approval and certification, CE Statement and Environmental and Material Compliance Regulations.
4. INTEGRA sets high standards with low environmental impact; you will find on this page valuable information about our sustainability [INTEGRA Sustainability Overview](#)
We would like to inform you about our good business practices and share the sustainability profile [IntegrityNext INTEGRA](#).

If you have further questions, don't hesitate to contact us.

Best regards

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Attachment

- *ISO 9001 Certificate* INTEGRA Biosciences
- *Quality Manual (Table of contents)*

INTEGRA

Quality manual Switzerland

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Quality manual US

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