

	Quality Policy Biocompatibility Innovation S.r.l.	Rev. 5 02/04/2026
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To be global leaders in innovation in the field of biocompatibility, setting new standards for the future of medical devices and improving patient care.

This is our VISION!

To transform the biomedical sector through the continuous integration of technologies that enhance the biocompatibility and durability of medical devices, eliminating the main causes of malfunction and extending their lifespan. We are committed to improving clinical outcomes, expanding access to medical solutions that enhance quality of life, and equipping the healthcare system with reliable, safe, and sustainable technologies.

This is our MISSION!

At BCI, we are committed to ensuring the safety and quality of medical devices and, consequently, the well-being of patients by developing advanced technologies for biomedical materials to improve the biocompatibility and durability of medical devices, without altering their design, performance, or mechanical properties. Our solutions, developed based on clinical needs, are intended to meet critical requirements across various medical fields.

The Biocompatibility team is composed of scientists and managers whose ultimate goal is to make their expertise and knowledge available for the benefit of the patient. Achieving our objectives is possible only by ensuring:

- a) a positive and supportive working environment for our employees, appropriate recognition of their work, and opportunities for professional growth;
- b) continuous training for all collaborators, including participation in training courses, conferences, and scientific meetings, to enhance competence;
- c) the support of a network of qualified professionals actively contributing to the company's success;
- d) long-term financial stability.

	Quality Policy Biocompatibility Innovation S.r.l.	Rev. 5 02/04/2026
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Within this framework, Biocompatibility Innovation Srl, through the commitment and determination of its Management, establishes the Quality Policy as a fundamental tool for the continuous improvement of its Management System, which is essential to providing customers and, ultimately, society with innovative products and services to increase satisfaction and trust.

By aligning its Management System with UNI EN ISO 9001, UNI EN ISO 13485, and UNI ISO 55001 standards, the Management of Biocompatibility Innovation S.r.l. aims to continuously pursue the following objectives:

- Operate in compliance with the applicable standards in their current revisions, respecting and applying the requirements of Inspection and Control Bodies;
- Promote to customers, as part of its external image, the company's choice to operate under an integrated Quality Management System, ensuring competence in the field of Medical Devices and the safe management/protection of both internal and external know-how;
- Ensure adequate resources in terms of personnel, scientific knowledge, and equipment necessary to carry out its activities;
- Guarantee the impartiality of personnel, ensuring independence in technical decisions and the financial resources needed to pursue them, in line with the company's strategic direction;
- Involve personnel in the Management System to promote awareness of the importance of Quality, know-how, and customer satisfaction;
- Focus internal resources primarily on the prevention of Non-Conformities, ensuring that corrective actions eliminate the root causes of identified issues;
- Operate with a continuous improvement approach to the Management System.

The criteria for verifying the achievement of, or deviation from, the objectives set in the Quality Policy are based on indicators directly related to key management parameters.

	Quality Policy Biocompatibility Innovation S.r.l.	Rev. 5 02/04/2026
---	---	---

Main performance indicators include:

- Customer reports, complaints, and claims;
- Non-Conformities;
- Customer feedback (e.g., satisfaction);
- Achieved scientific results.

Indicators are monitored through:

- Internal audits;
- Customer audits;
- Audits conducted by Inspection and Control Bodies.

To achieve the objectives described in this Quality Policy and throughout the Management System documentation, Top Management—holding primary responsibility for achieving these objectives—delegates activity/function managers to implement and verify the Management System within their areas of responsibility, and technical/administrative staff to correctly and consistently apply the Management System, as well as to collaborate constructively with managers to improve the system itself.

We develop innovative methods and systems and are committed to protecting their intellectual property, including through patent filings, in order to safeguard their value, while also acting as active contributors within the scientific community.

Continuous technical updating and ongoing dialogue with the scientific community enable Biocompatibility Innovation to identify and address the needs and expectations of stakeholders (pharmaceutical companies, medical professionals, patients, etc.), and the entire management team is committed to meeting them.

	Quality Policy Biocompatibility Innovation S.r.l.	Rev. 5 02/04/2026
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STATEMENT OF COMPLIANCE WITH THE COMPANY CODE OF CONDUCT

Biocompatibility Innovation Srl

DECLARES

to adopt, implement, and maintain a Company Code of Conduct in line with international principles on human rights, working conditions, ethics, and social responsibility. In particular, Biocompatibility Innovation Srl is committed to respecting and promoting the principles set out in the eight fundamental conventions of the International Labour Organization (ILO), namely:

- Freedom of association and the right to collective bargaining;
- Elimination of all forms of forced or compulsory labour;
- Effective abolition of child labour;
- Elimination of discrimination in respect of employment and occupation;

Biocompatibility Innovation Srl also declares that it operates in accordance with the principles established by the United Nations, including the Universal Declaration of Human Rights, and commits to:

- Ensuring decent, safe, and healthy working conditions, in compliance with applicable occupational health and safety regulations, with particular attention to the management of chemical, biological, and laboratory risks, through appropriate prevention measures, staff training, and risk control;
- Ensuring compliance with working hours in accordance with applicable laws and national collective agreements, guaranteeing rest periods, holidays, and preventing excessive overtime;
- Ensuring fair and lawful remuneration, at least in line with the minimum standards set by applicable collective agreements, guaranteeing transparency in employment conditions and the principle of equal pay for work of equal value;
- Ensuring respect for the dignity, freedom, and fundamental rights of all workers;

	Quality Policy Biocompatibility Innovation S.r.l.	Rev. 5 02/04/2026
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- Preventing any form of abuse, harassment, coercion, or unfair treatment;
- Promoting ethical and responsible behavior throughout the supply chain, requiring suppliers and partners to comply with equivalent standards in terms of human rights, labor, and safety.

Biocompatibility Innovation Srl also undertakes to monitor the application of the above principles and to continuously improve its social, ethical, and occupational health and safety practices.

Este, 02 April 2026

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Alessandro Gandaglia, CEO

