

**INNOVHEART S.R.L.**  
**CODE OF ETHICS**



## I. INTRODUCTION

InnovHeart S.r.l. (hereinafter, also "**InnovHeart**" or, the "**Company**") pays great attention to the ethical aspects of the Company and considers legality and correctness necessary conditions for conducting business.

As InnovHeart operates in a particularly sensitive and important sector of natural science and engineering research and development, it is committed to making a decisive contribution to protecting the health of citizens.

In carrying out its business, the Company intends to observe not only the laws and provisions in force pertaining to the countries in which it operates, but also its high ethical standards, principles detailed within this Code of Ethics.

The Code of Ethics is an integral part of the Organization, Management and Control Model adopted by the Company on March 29, 2021 (hereinafter, the "**231 Model**") pursuant to Legislative Decree 231, June 8, 2001, and defines the ethical principles that the Company considers fundamental in carrying out its business and setting the rules of conduct to be respected by all who act in the name of the Company.

The Company monitors the effectiveness of the Code of Ethics, preparing adequate information, training, prevention and controls and commits to the transparency of the conduct implemented and sanctions when conduct does not comply with the Code of Ethics.

## II. GENERAL PROVISIONS

### *A. Purpose and applicability*

The Code of Ethics expresses the ethical principles with which the Company complies in the context of business and company activities, defining the set of rights, duties and responsibilities that derive from these principles and which are assumed by the Company in the exercise of its corporate activities.

The purpose of the Code of Ethics is to summarize the Company's ethical principles and rules of conduct in which those who work for, collaborate with, or have relationships with the Company, for any reason, must comply.

Those responsible for complying with the Code of Ethics ("recipients") include the following:

- a) Members of the Board of Directors (hereinafter, the "**BoD**"), the liquidators in the event of liquidation of the Company and those who perform, even de facto, management, administration, direction or control functions within the Company or in one of its autonomous organizational units;
- b) Members of the Company Supervisory Body (hereinafter, the "**SB**")<sup>1</sup>;
- c) Managers;
- d) Employees of the Company<sup>2</sup>;
- e) All who, although external to the Company, operate directly or indirectly, permanently or temporarily on its behalf (such as collaborators in any capacity, attorneys, distributors, agents, consultants, suppliers, business partners etc.)<sup>3, 4</sup>

Those responsible for compliance with the Code of Ethics are required to observe and, to the extent of their competencies, enforce the provisions of the Code and its principles.

Under no circumstances may recipients adopt behaviors in the pursuit of the Company's interest that conflict with the provisions of the Code of Ethics.

The Code of Ethics applies to all activities carried out by the Company, even when performed abroad.

Compliance with the Code of Ethics is an integral part of the contractual obligations of employees pursuant to the provisions of art. 2104 and following the Civil Code.

Compliance with the Code of Ethics is also an integral part of the contractual obligations of third-party recipients. In the absence of an express commitment to comply with the Code of Ethics, the Company will not continue the third-party relationship. To this end, specific clauses are aimed at third-party recipient compliance with the 231 Model and Code of Ethics, and penalties and termination of the contractual relationship applied in case of violation.

Code of Ethics violations affect the relationship of trust established with the Company and can lead to disciplinary actions and compensation for damage without prejudice to the respect for employees of the provisions in this regard by art. 7 of the law n. 300/1970 and collective agreements applied to employment

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<sup>1</sup> The subjects referred to in points **a)** and **b)** below, collectively, "**Corporate Bodies**".

<sup>2</sup> The subjects referred to in points **c)** and **d)**, hereinafter "**employees**".

<sup>3</sup> The subjects referred to in point **e)**, hereinafter "**third-party recipients**".

<sup>4</sup> The subjects mentioned in points **a)**, **b)**, **c)**, **d)**, and **e)**, hereinafter, "**recipients**".

relationships.

Code of Ethics violations must be immediately brought to the attention of the Company via the channels and methods defined in order to timely report offenses and irregularities.

### *B. Distribution of the Code of Ethics*

The Company guarantees dissemination of the Code of Ethics both internally and externally via distribution to the Corporate Bodies, employees and third-party recipients. The Code is published on the Company's website <https://www.innovheart.com/> as well as on the Company intranet, which is easily accessible by clicking on the link sent to employees via email.

The Company, with the help of the SB, is responsible for:

- a) Specific training and periodic awareness-raising activities regarding issues covered within the Code of Ethics are administered in order to prevent Legislative Decree 231/2001 crimes from occurring. Course participation is compulsory and includes questionnaires to verify the degree of knowledge and understanding. Evidence of training course participation is retained;
- b) Performing periodic checks in order to monitor the degree of compliance with the Code of Ethics provisions;
- c) Updates/revisions to the Code of Ethics related to economic, financial, commercial and geographical evolution of the Company or changes in organizational / management structures, as well as with reference to the types of violations detected throughout the business and regulatory changes;
- d) Providing adequate prevention tools, implementing appropriate sanction measures and timely applying measures in the event of an ascertained violation of the Code of Ethics;
- e) Preparation of all tools that assist in the application of the Code of Ethics.

### *C. Recipient Obligations*

The Code of Ethics binds recipients at all levels of the Company.

Recipients are required to know the provisions contained within the Code of Ethics as well as the applicable laws and regulations.

Recipients are also obliged to:

- a) Refrain from conduct, including omissions, contrary to the Code of Ethics provisions and applicable laws and regulations;
- b) Contact their superiors or the SB for the necessary clarifications on the application methods of the Code of Ethics and / or applicable laws and regulations;
- c) Report Code of Ethics violations, even if potential, to the SB in the manner defined by the Company;
- d) Cooperate in the event of an investigation carried out by the Company, the SB or public authorities in relation to alleged violations of the 231 Model and / or the Code of Ethics.

*D. Further obligations for the heads of company functions*

In addition to the previous provisions, each company functional manager is obliged to perform the following:

- a) Be an example to subordinates through their behavior;
- b) Ensure subordinate compliance with the Code of Ethics;
- c) Make every effort to ensure that their subordinates understand that the provisions contained in the Code of Ethics are an integral part of work performance;
- d) Prevent all forms of retaliation within their functions to the detriment of the recipients who have collaborated in order to ensure compliance with the Code of Ethics;
- e) Promote and ensure Code of Ethics compliance by all third-party recipients with whom he/she operates.

### III. ETHICS PRINCIPLES

#### *A. Ethics in the context of business and company activities*

In the interest of patient safety and well-being, InnovHeart is committed to the research and experimental development of high-quality medical technologies.

The Company commits to compliance with applicable laws and regulations.

Behavioral ethics not only includes strict observance, but also extends to the will to adopt the highest standards of behavior in different situations. Compliance with applicable laws and regulations and ethical standards is important for close collaboration between the medical technology sector research and experimental development and healthcare professionals (defined below).

This collaboration may take place in the form of the following:

- a) Research and experimental development of medical technologies;
- b) Provision of training, education, service and support to ensure effective and safe use of medical technologies;
- c) Support for medical research, education and enhancement of professional skills.

These activities are necessary for the advancement of medical science and the improvement of patient care, but must take place through transparent, fair and ethical interactions.

InnovHeart commits to acting in a correct and transparent way, avoiding misleading information and behaviors such taking undue advantage of positions of weakness or lack of knowledge. The Company is committed to respecting free private initiative, affirming the social function of the free market, maximizing economic financial companies through correct commercial relationships with customers and suppliers and adequate recognition of the contribution of their collaborators.

InnovHeart also takes specific precautions (as illustrated below) in Public Administration relations.

#### *B. Work ethics: human resource protection*

The Company recognizes that human resources and its internal and external collaborators are fundamental factors for its development.

In particular, the Company:

- a) Promotes the value of human resources in order to improve and increase its assets and each recipient's competitive skills;
- b) Commits to the health, safety and physical and mental integrity of its employees, collaborators and consultants, as well as the working conditions that respect individual dignity, in compliance with applicable legislation;
- c) Refuses all forms of irregular work<sup>5</sup>;
- d) Ensures that hierarchical authority is exercised with equity and correctness, avoiding abuse of powers.

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<sup>5</sup> By irregular work is meant an employment relationship not compliant with the Law.

As work health and safety is the Company's primary objective, it commits to the dissemination of a culture of safety among all recipients, aimed at increasing sensitivity and awareness of possible risks as well as promoting responsible and respectful behavior and conduct towards one's own safety and that of others.

Consistently with this objective, all recipients involved in health and safety-related tasks in the workplace (competent doctor, head of the prevention and protection service) collaborate to eliminate or progressively reduce risks at source and improve working conditions in compliance with the principles set out below, in particular when decisions or choices must be made and, subsequently, implemented.

### *C. Information ethics*

InnovHeart's communication is expressed, above all, in scientific information, which must be accurate, balanced, correct, objective, unambiguous and never misleading, documented and documentable.

The information must be produced and disclosed in compliance with the related provisions.

## IV. RULES OF CONDUCT

### *A. Competition*

InnovHeart is aware that the free market presumes autonomy of its actors in determining and pursuing corporate goals.

The Company firmly believes in competition and the free market, assets that must be defended from any undue pressure both internally from the same players in the affected markets and externally from third parties, whatever the role.

InnovHeart conducts its commercial activities in compliance with competition laws and supply contracts undertaken to observe by adopting all the most appropriate measures.

InnovHeart condemns any initiative or contact between competitors that is contrary to the principles of competition, including, for example: discussions on prices or quantities, subdivision of markets, production or sales restrictions, agreements to share customers, exchanges of pricing information, etc.

### *B. Conflicts of interest*

Recipients are forbidden to carry out or facilitate conflict of interest operations, even if potential, as well as activities that could interfere with the ability to make, impartially, decisions in the best interest of the Company and in full compliance with the Code of Ethics.

Recipients are required to communicate all conflicts of interest including third party conflicts, even if only potential, to the SB so that the existence and severity can be assessed, and the consequent effects excluded or mitigated.

### *C. Payments and illegal practices*

Recipients are prohibited from directly or indirectly offering, conducting or authorizing monetary (or anything of significant value) payments in order to illegally achieve the following:

- a) Influence the judgment or conduct of any person, customer or company;
- b) Win or maintain commercial activities;
- c) Influence public official actions or decisions;
- d) Derive advantages. Not only direct but also indirect incentives of any form, through agents, distributors, consultants or other third parties. For this reason, InnovHeart commits to applying all laws, regulations and regulations that prohibit or limit incentives aimed at influencing healthcare professionals (as defined below) or customers.

Recipients are also forbidden to perform or omit acts following the allocation of or the promise of monetary funds or other benefits, for themselves or for others, in violation of the obligations inherent in their office or the obligations of loyalty.

### *D. Confidentiality*

InnovHeart ensures the confidentiality of the information in its possession and refrains from using confidential data, except for in the case of express authorization from the owner and in compliance with the applicable

laws.

Recipients are prohibited from using, disclosing or communicating confidential information received or obtained in relation to the functions and duties carried out at the Company. "Confidential information" is defined as "all information, data or news that has been communicated confidentially or is confidential in nature and related to activities, future activities, or the Company's business."

#### *E. Behavior towards competition*

The Company's behavior in the market is based on the utmost fairness towards competitors. In particular, InnovHeart commits to refraining from engaging in unfair and damaging behavior towards the image of its competition.

#### *F. Sustainable development and community responsibility*

Within its development programs, InnovHeart is committed to taking into consideration the needs of the community in which the Company is located in order to contribute to its economic, social and civil development.

#### *G. Healthcare professionals, organizations and third-party relationships*

InnovHeart recognizes that ethical standards and compliance with applicable laws and regulations are essential to the research and experimental development of medical technologies and the collaboration with public and / or private healthcare professionals (doctors, nurses, laboratory personnel, researchers, technicians, administrative staff in the field of health facilities, etc.), who purchase, rent, recommend, manage, use, supply, procure medical technologies or related services (hereinafter "**healthcare professionals**").

The Company commits to ethical business practices and continuity of socially responsible conduct related to interactions with healthcare professionals, respecting their obligation to make independent decisions related to clinical and diagnostic practices.

The Code of Ethics establishes the appropriate standards for various types of relationships with healthcare professionals in compliance with laws, regulations and professional codes / regulations of the bodies to which the professional belongs. The healthcare sector imposes specific conditions on companies or professionals within the sector when carrying out their activities.

Therefore, InnovHeart commits to interacting with healthcare professionals by respecting the laws, regulations and professional codes of reference.

In general, any relationship between recipients and employees of the Public Administration or professionals of private and public healthcare sectors must be legitimate, transparent, and ethically professional.

Thus, recipients are prohibited from promising or providing monetary funds, granting goods of any kind, utility or other benefits to public employees and / or similar subjects, public and private healthcare professionals, or who in any title intervene in a purchase process, even on a personal basis, aimed at promoting or favoring his/her own interests or those of the Company.

During relations with the Public Administration, it is forbidden to directly or indirectly partake in the following activities through third parties:

- a) Hire someone from a previously terminated public relationship within three years following the termination or assign work to former Public Administration employees who exercised authoritative or negotiation powers towards the Company (art. 53, paragraph 16-ter of Legislative Decree 165/2001);
- b) Offer or provide gifts that are not of modest value or that could be perceived as advantageous;
- c) Solicit or obtain confidential information beyond that permitted by law;
- d) Perform activities that unduly interfere with the Public Administration's tender decision.

Conversely, certain interactions with healthcare professionals are permitted and considered positively in order to contribute to the advancement of medical science by improving diagnosis and patient care, including the following:

- a) Progress of medical technology: Research and development of innovative medical technologies and the improvement of existing products as a result of collaboration between companies within the sector and healthcare professionals. Innovation and creativity are essential for the development and evolution of medical technologies and often occur through collaboration of various bodies, institutions, and people outside the structures of companies in the sector;
- b) Safe and effective use of medical technology: Usually requires companies within the sector to offer healthcare professionals adequate instructions, training, services and technical support. Regulatory bodies may also require this type of training as a condition for product approval;
- c) Research and education: In support of medical research, education on the appropriate use of technologies and the growth of professional skills contribute to patient safety and increase access to new technologies and the most advanced and effective therapies.

Without prejudice to authorization obligations, recipients involved in interactions with healthcare professionals and the transfer of value or potential conflicts of interest must inform the healthcare professional's head of hospital administration.

InnovHeart adopts specific precautions, when interacting with health organizations (legal persons or entities, regardless of form or legal organization), associations or health, medical or scientific organizations through which one or more professionals provide services or has the ability to exercise direct or indirect influence on prescriptions, recommendations, purchases, orders, supplies, use, sales or rentals of medical technologies or related services (e.g., hospitals, centralized purchasing offices, clinics, laboratories, pharmacies, research institutes, associations, foundations, universities, scientific societies or other educational or professional institutions) (hereinafter "**healthcare organizations**").

Interactions with healthcare organizations or third parties should be handled by subjects meeting specific compliance requirements, namely:

- Carry out adequate due diligence on the individuals and legal entities including non-profit entities with whom they collaborate to ensure that no benefits are illegally offered to employees or public officials, customers or other entities;
- Ensure that individual and legal entity, including non-profit entities with whom they collaborate comply with current anti-corruption legislation;
- Are equipped with ISO 9001 certification and / or other similar valid certifications;

- Have an Organizational Model pursuant to Legislative Decree 231/2001 and the SB;
- Have a defined Code of Ethics in place;
- Themselves or their representatives are not under investigation, have no proceedings underway, or have not undergone precautionary measures or non-definitive convictions for relevant crimes pursuant to Legislative Decree 231/2001 or art. 356 and 356-bis c.p.

The Company commits to refraining from directly or indirectly organizing or participating in conferences, workshops, and the like in which:

- a) Tourist-recreational aspects prevail over the technical-scientific ones;
- b) Hospitality and travel expenses are extended to the guests accompanying them;
- c) Hospitality and travel expenses are extended to a period of time, prior to the start and / or after the end of the event, exceeding 24 hours;
- d) Principles of sobriety related to the following points I and J is not respected

InnovHeart adopts independent internal processes based on objective criteria in order to evaluate requests for contributions.

#### *H. Training, educational, and promotional activities of company products*

The following initiatives organized directly or through a third party are permitted:

- a) Scientific-clinical updates related to products, clinical procedures and business;
- b) Higher or advanced level training updates on technical, regulatory, organizational-managerial (healthcare management) and / or political-social issues related to the reference sector;
- c) Protection of the health and psycho-physical well-being of the person, as well as the culture of prevention.

#### *I. Donations*

The purpose of donations is to support social, humanitarian, philanthropic or charitable projects. In particular, donations should be aimed at the following:

- Care of the poor;
- Patient education (including awareness campaigns);
- Improvement of patient conditions;
- Public education;
- Humanitarian projects and donations in the event of natural disasters;
- Support of events whose proceeds go to charity.

The Company intends to contribute concretely to the social development of the community in which it operates and therefore intends to donate to foundations operating in the field of research and to entities active in the charity sector.

Donations are characterized by the absence of any commercial interest and should be made in favor of

organizations and entities that have the right to receive them pursuant to the applicable laws, regulations and regulations. Donations are subject to verification of the absence of conflicts of interest.

Donations to individuals are strictly prohibited.

Donations of monetary value, goods, equipment, etc. must be carried out in compliance with current legislation based on the beneficiary and must be authorized in advance in accordance with the approved delegations and powers.

Evidence of the destination and use of the donation must then be requested from the beneficiary.

Transparency procedures referred to in Chapter V below are required.

#### *J. Healthcare professional tasks, consultancy and studies*

Healthcare professionals may provide, in good faith and in compliance with current legislation, freelance consultancy activities for the Company, as well as collaborate in product research, development and use.

Relations with healthcare workers and Public Administration employees during InnovHeart's typical business operations must be carried out fairly and transparently and should be based on compliance with current regulations and internal company protocols.

For uncertainties regarding the appropriate behaviors, recipients should refrain from carrying out further activities and immediately inform their superior and the SB.

A consulting agreement between the Company and public and private healthcare professionals is done in good faith if supported by the following elements:

- a) Stipulated only where the scientific interest of the Company is preliminarily identified and consistent with the skills of the healthcare professional;
- b) Formalized, duly signed by all parties, specifies the activities and services to be provided, and encompasses all costs;
- c) Complies with laws, regulations and the rules of the country in which the healthcare professional practices. Includes prior authorizations issued by the competent top management;
- d) Compensation to healthcare professionals providing services to the Company is predetermined according to objective fair market value criteria and based on the qualification and experience of the professional;
- e) Payment is made based on adequate documentation certifying the execution of the services and an invoice issued by the professional, payable by traceable means.

The Company may pay reasonable expenses to consultants for carrying out the activities within the consultancy agreement.

Consultant selection must be based on qualifications and experience through an internal evaluation and selection process to fulfill the purpose of the services.

Meeting locations and circumstances between the Company and consultants must be appropriate. Where needed, travel and hospitality expenses are subject to the agreement duration and should aid in the purpose of the meeting according to the parameters referred to in point G.

Compliance with the transparency procedure in Chapter V below is required.

#### *K. Research projects*

Research projects in collaboration with public or private bodies, in the case of scientific research or experiments promoted respectively by the Company or by the bodies to which the Company provides external support, must always be inspired by a genuine scientific interest aimed at the development of clinical procedures or product evaluation.

The decision to carry out or research carried out by an institution must be documented, clearly foresee the scientific objectives that the research aims to achieve and the benefit that the Company can achieve.

Collaborative relationships with both public and private entities for research purposes must follow a research protocol approved or reported to the competent ethics committee, from the stipulation of a research contract or convention with the institution involved and from carrying out the research itself in compliance with all applicable laws and regulations.

Fees paid to the body conducting research on behalf of the Company must be determined based on fair market value.

If the research promoter is a healthcare professional, the Company ensures that the collaborative relationship exists with the utmost transparency and follows the professional's institutional authorizations and permits.

All medical devices instrumental to the execution of research must be included within the contract and should be delivered to and withdrawn from the researcher through the institution to which it belongs.

In any case, compliance with the transparency procedure referred to in Chapter V below is necessary.

#### *L. Gifting to healthcare professionals*

Modest gifts to healthcare professionals are occasionally permitted.

The gifts should be for promotional purposes only and related to the healthcare professional's activity or for the benefit of patients.

Gifts in the form of cash or cash equivalents (e.g. vouchers, book vouchers, fuel vouchers, prepaid cards, etc.) are strictly prohibited.

The foregoing provisions do not apply to the legitimate practice of providing appropriate product samples and opportunities for their evaluation.

#### *M. Quality assurance*

InnovHeart bases its reputation on the highest quality of its medical devices and related services in order for patients to benefit from the best possible results.

The Company's commitment is not limited to quality and safety standard compliance required by law but, where possible, further ensures increasingly effective products and services.

## V. EXECUTION OF THE CODE OF ETHICS

### *A. Disciplinary code*

Violations of the Code of Ethics could constitute Company sanctions based on the Company's disciplinary code.

Failure to report facts and / or circumstances contributing to violations of the Code of Ethics constitutes as a violation subject to Company sanctions.

The disciplinary code details the ethical violations, rules of conduct set out in the 231 Model and, within the Code of Ethics, the subjects required to comply and the related applicable sanctions.

### *B. Whistleblowing*

In order to facilitate reports and communication by all recipients, the Company has implemented measures aimed at identifying the emergence of offenses and irregularities described in the 231 Model.