

**INNOVHEART S.R.L.**

**ORGANIZATIONAL MODEL**

**ACCORDING TO LEGISLATIVE DECREE NO. 231/2001**

**Approved by the Board of Directors  
with a resolution dated March 29<sup>th</sup>, 2021**

**Summary**

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## 1. THE LEGISLATIVE DECREE NO. 231/2001

This document represents the Organizational Model (below, “**the Model**”) according to Legislative Decree no. 231/2001 and subsequent additions (below, “**the Decree**”) adopted in the current version by the Board of Directors of InnovHeart S.r.l. (below, “**the Company**” or “**InnovHeart**”) with resolution-dated March 29<sup>th</sup>, 2021.

The Legislative Decree no. 231 of 8 June 2001 which title is “*Regulatory framework of the administrative liability of legal entities, Companies and associations without legal status, according to the article no. 11 of the Law no. 300 of 29 September 2000*”, has introduced for the first time within the national legal system the administrative liability for those who are not single individuals (below, “**Entities** or **Institutions**”).

The Legislative Decree no. 231/2001 operates in a framework of international obligations and – aligning itself with many legal systems of other countries – establishes the liability for entities, considered “*as an independent center of interests and legal relationships, a landmark for different precepts, and a matrix of decisions and activities of those subjects that operate in the name, on behalf or in any case in the interest of the entity*”.

The original text, which referred to a series of offences committed against the Public Administration, has been supplemented by subsequent legislative measures which have extended the range of offences whose commission may entail the administrative liability of the Entity.

The Entity's liability - similar to the criminal liability – arises in connection with the commission, by a person linked by a functional relationship with the Entity itself, of one of the crimes specifically provided for by the Legislative Decree.

The responsibility of the Entity may exist if the Crimes are committed in its interest or to its advantage, while it is not configurable in the case in which the author of the same has acted in the exclusive interest of himself or of third parties.

The functional relationship linking the perpetrator to the legal entity may be one of representation, subordination or collaboration, within the limits provided by the Legislative Decree.

If the author of the crime is an individual who holds functions of representation, administration, management or control of the Entity or of one of its organizational units with financial and functional autonomy, as well as a person who exercises, also de facto, the management and control of the Entity, a presumption of responsibility is established for the latter. This is in consideration of the fact that the individual expresses, represents and implements the management policy of the Entity.

There is no presumption of liability borne by the Entity if the perpetrator of the Offence is a person that is subject to the management or supervision of one of the people mentioned in the previous paragraph, or that, in this case, the fact of the subordinate person entails the liability of the Entity only if it turns out that its perpetration was made possible by the failure to comply with the obligations of management and supervision.

The administrative liability of the Entity is additional to the criminal liability of the individual and not a substitute for it. From the substantial autonomy of this liability derives the circumstance that the Entity is called to answer for the crime even when the perpetrator has not been identified or cannot be charged, or if the crime is extinguished for reasons other than amnesty. The criminal liability of the natural person remains regulated by common criminal law.

The legislator has envisaged a system of sanctions which is characterized by the application to the legal person of a sanction, which normally is a pecuniary one.

Together with the pecuniary sanction, in some cases, interdiction sanctions may also be applied, such as the prohibition to carry out the activity, the suspension or revocation of authorizations, licenses or concessions functional to the commission of the offence, the prohibition to contract with the Public Administration, the exclusion from facilitations, financing, contributions or subsidies, the possible revocation of those already granted, the prohibition to advertise goods or services.

In addition to the above-mentioned pecuniary and prohibitory sanctions, the confiscation (always ordered with the conviction) of the price or of the profit of the crime (also "for equivalent") and, in certain cases, the publication of the conviction is added.

Moreover, the Legislator has foreseen that such interdictory measures - if there are serious indications of the Entity's liability and there are grounded and specific elements that make it appear that there is a concrete danger of the commission of offences of the same nature – can be applied, upon request of the Public Prosecutor, also as a precautionary measure already during the investigation phase.

If specific conditions are met, the Judge, when applying a disqualification penalty that would lead to the interruption of the Entity's activity, has the right to appoint a commissioner to supervise the continuation of the activity itself, for a period corresponding to the duration of the disqualification penalty that would have been applied.

Foreign companies operating in Italy are also subject to the regulations set forth in the Legislative Decree, regardless of the existence or otherwise in the country of origin of regulations governing the same matter in a similar manner.

## 2. THE ORGANIZATIONAL MODEL

The Legislative Decree provides for a specific **form of exemption from liability** for the Entity if:

- a) the management body has adopted and effectively implemented an “Organizational Model” suitable for preventing offences;
- b) the task of supervising the functioning of the Organizational Model and its compliance, as well as ensuring that it is updated, has been entrusted to a body of the entity, the so-called Supervisory Body, which has autonomous powers of initiative and control;
- c) those who have committed an offence have acted by fraudulently evading the Organizational Model;
- d) there was no omitted or insufficient supervision by the Body referred to in letter b) above.

The Organizational Model is the set of rules, reported in the Special Parts and in the Protocols, both of a behavioral nature ("Principles of Conduct") and operational ("Operational Modalities") whose observance - in the execution of activities inherent the Risk Processes - makes it possible to prevent illicit, incorrect or irregular conduct.

Failure to comply with the Principles of Conduct present in the Special Parts and in the Operative Modalities by the Addressees is punishable.

### **3. DESCRIPTION OF THE COMPANY**

InnovHeart S.r.l. started its activity on November 26, 2015 in the field of research, development, qualification of innovative implantable prosthetic devices for clinical use and related transcatheter implantation procedure, aimed at the treatment of mitral heart valve pathologies with the so-called, replacement modality.

InnovHeart S.r.l. holds a 100% interest in the share capital of its U.S. subsidiary InnovHeart US Inc., located at the 55 Chapel St Ste 010, Newton, MA, USA, 02458, which performs for the parent company the activities of design, development and manufacture of the device for the delivery of the prosthesis, so-called delivery system of the device.

The operational structure of InnovHeart S.r.l. consists of:

- INNOVHEART - Milano: Via Giovannino De Grassi 11 – Milano (MI);
- INNOVHEART - Colleretto Giacosa: Via Ribes 5 – Colleretto Giacosa (TO).

The branch of Milan is identified by the Company as its registered office; the branch of Colleretto Giacosa, on the other hand, is the place where the Company carries out its main activity, and therefore where the activities relating to research, development, qualification, devices and procedures are carried out, as well as the administrative and management activities in support of the Company.

#### **4. CODE OF ETHICS OF INNOVHEART S.r.l.**

At the same time as the approval of the Organization Model, InnovHeart S.r.l. adopted its own Code of Ethics, which defines the values by which the Company is inspired in the performance of its activities and constitutes an integral part of the Organizational Model itself.

The Code of Ethics is an official corporate document and, as such, illustrates the rights and duties as well as the responsibilities of the Company towards its stakeholders.

In particular, the Code of Ethics contains the ethical principles and rules of conduct that Top Management, employees, consultants, collaborators and all those who operate in the name of or on behalf of InnovHeart are required to respect and/or share (suppliers and business partners).

In this perspective, the principles contained in the Code of Ethics also constitute a useful interpretative reference in the concrete application of the Model in relation to company dynamics.

The Organizational Model meets the need to prevent, as far as possible, the commission of the offences established by Legislative Decree 231/01 by identifying specific rules of conduct. From this point of view arises the difference between the Code of Ethics and the Model; the Code of Ethics, in fact, is a general instrument aimed at promoting a "company deontology" but lacks a specific proceduralisation.

The provisions of the Organizational Model are inspired by the ethical principles and rules of conduct contained in the Code of Ethics and are integrated and compatible with it.

The Code of Ethics is therefore binding on the recipients.

## **5. ADDRESSEES**

This Organizational Model is intended for:

- directors and managers with functions of representation, administration or management of the Company;
- employees or other people, regardless of the relationship that binds them to the Company, who are subject to the management or supervision of one of the aforementioned subjects.

The respect of the provisions of the Legislative Decree, as well as the respect of the principles of conduct set forth in the Code of Ethics, is also required of third parties operating on behalf of InnovHeart, through the provision of appropriate contractual clauses.