



**ORGANIZATIONAL, MANAGEMENT AND CONTROL MODEL  
ACCORDING TO DECREE LAW NO. 231 OF 8TH JUNE 2001  
GENERAL PART**

<b>Rev.</b>	<b>Subject</b>	<b>Date</b>
0	First issue	2015
1	Adjustment on whistleblowing and new indictable offences (environmental offences, bribery among private individuals, employment of third-party nationals whose stay is illegal ...)	2019
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## GENERAL PART

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## 1 1 THE ADMINISTRATIVE RESPONSIBILITY OF THE ORGANIZATIONS

### 1.1 REGULATORY FRAMEWORK

Decree no. 231 of 8th June 2001, *regulating the administrative liability of legal entities, companies and associations, including those without legal capacity, and article 11 of Decree no. 300 of 29th September 2000*, introduced into the Italian legal system a particular regime of administrative liability of entities (partnerships and capital companies *in primis*).

This is a regime of administrative liability in addition to the liability of the individual who has committed certain unlawful acts and which aims to involve, in punishing them, the Entities in whose interest or advantage the offences in question were committed.

This regime extends the punishment of the criminal offences identified in the Decree to Entities that have benefited or in whose interest the offences in question were committed and brings Italian legislation on the liability of legal entities into line with international conventions already signed by Italy, in particular the Brussels Convention of 26th July 1995 on the protection of the financial interests of the European Community, the Brussels Convention of 26th May 1997 on combating bribery of public officials of both the European Community and the Member States and the OECD Convention of 17th December 1997 on combating bribery of foreign public officials in economic and international transactions.

The innovative scope of Decree no. 231/2001 is represented by the provision for the administrative liability of the legal entity in relation to the commission of an offence by an employee or a director. With the entry into force of this Decree, companies can no longer say that they are extraneous to the direct consequences of crimes committed by an individual in the interest or to the advantage of said companies. The system of sanctions provided for by Decree no. 231/2001 is particularly severe; in fact, in addition to financial penalties, there are those of suspension and partial or total disqualification of business activities that may have permanent effects for the recipient companies.

As regards the offences referred to above, the following types are currently involved:

- a) offences against the Public Administration;
- b) computer crimes;
- c) organized crime offences;
- d) crimes against public trust;
- e) crimes against industry and trade;
- f) corporate offences;

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- g) terrorist offences;
- h) female genital mutilation;
- i) crimes against the person;
- j) market abuse;
- k) occupational health and safety offences;
- l) crimes of receiving stolen goods, money laundering, use of money, goods or benefits of illegal origin, self- laundering;
- m) copyright infringement offences;
- n) incitement to make false statements to the judicial authorities;
- o) environmental crime;
- p) offences connected with the employment of non-EU workers not in compliance with the residence permit;
- q) offences relating to racism and xenophobia;
- r) sports fraud.
- s) fiscal crimes.
- t) smuggling

## 1.2 EXEMPTIONS FROM ADMINISTRATIVE LIABILITY

Article 6 of the Decree establishes that the company is not punishable from an administrative point of view if it proves that the Management Body has adopted and effectively implemented, prior to the commission of the offence, "*Organizational and management models capable of preventing offences of the type that occurred*".

The same rule also provides for the establishment of an internal control body within the entity - the Supervisory Body - with the task of supervising the functioning, effectiveness and compliance with the aforesaid models, as well as requesting that they be updated.

These models of organization, management and control, pursuant to Article 6, paragraphs 2 and 3, of Decree no. 231/2001, must meet the following requirements:

- identify the activities for which the offences provided for in the Decree may be committed.
- establish specific protocols aimed at planning the formation and implementation of the company's decisions in relation to the crimes to be prevented;
- identify ways of managing financial resources capable of preventing such offences being

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committed;

- establish information obligations towards the Supervisory body, responsible for supervising the functioning and compliance with the Models;
- introduce a disciplinary system capable of sanctioning non-compliance with the measures indicated in the Organizational Model.

Where the offence is committed by persons who hold positions of representation, administration or management of the entity or one of its organizational units with financial and functional autonomy, as well as persons who exercise, even *de facto*, the management and control of the entity, the entity is not liable if it proves that:

- the management body has adopted and effectively implemented, prior to the offence being committed, a Model suitable for preventing offences of the type that has occurred;
- the task of supervising the functioning and observance of the Model and ensuring that it is updated, has been entrusted to a body of the entity with autonomous powers of initiative and control (the Supervisory Body);
- the individuals have committed the offence by fraudulently evading the Model;
- there was no omitted or insufficient supervision by the Supervisory Body with regard to compliance with the Model.

If, on the other hand, the offence is committed by persons subject to the management or supervision of one of the persons indicated above, the entity is liable if the commission of the offence was made possible by failure to comply with the obligations of management and supervision.

Administrative liability is excluded if, before the offence was committed, the company adopted and effectively implemented a Model capable of preventing offences of the type that has occurred.

The Model must provide for appropriate measures to ensure that activities are carried out in compliance with the law, and to discover and promptly eliminate risky situations.

### 1.3 EFFECTIVE IMPLEMENTATION OF THE MODEL

The effective implementation of the Model entails:

- a regular review and possible modification of the above when significant violations of the prescriptions are discovered or when there are changes in the organization or in the activity;
- a disciplinary system capable of sanctioning non-compliance with the measures indicated in the Model.

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#### 1.4 TYPOLOGY OF SANCTIONS TO BE APPLIED TO THE ENTITY ACCORDING TO DECREE NO. 231/2001

The Decree sets out the types of sanctions for administrative offences with a criminal dimension.

The applicable sanctions are:

- a) financial penalties;
- b) disqualification sanctions;
- c) confiscation;
- d) publication of the judgment.

The disqualification sanctions are:

- disqualification;
- suspension or revocation of authorisations, licences or concessions that were functional to the offence being committed;
- prohibition on contracting with the Public Administration, except to obtain the services of a public service;
- exclusion from relief, funding, grants and subsidies, as well as the revocation of any grants already made;
- prohibition on advertising goods or services.

Without prejudice to the possible reduction of the pecuniary sanctions referred to in article 12 (cases of reduction of financial penalties) and article 26 (offences in question), no liability arises for the Entities if they have prevented the action being committed or the event taking place.

#### 1.5 THE SITUATION OF GALENTIS S.R.L. AND THE OBJECTIVES THAT THE COMPANY INTENDS TO PURSUE

Galentis S.r.l. is active in the research, production and trade, in Italy and abroad, of raw materials and semi-finished products for the pharmaceutical industry, as well as, in general, chemical, organic and inorganic products, which can be used in various applications.

Galentis S.r.l.'s production takes place by multi-stage chemical synthesis. The processes are discontinuous (batch-based) and are conducted both in dedicated and non-dedicated reactors. The production is characterized as a fine chemical activity, with relatively limited quantities of final products (about 200 tons/year). The production process consists of a sequence of synthesis steps with the isolation of intermediate substances.

The Galentis S.r.l. plant, consisting of two buildings, is located in the second industrial area of the Municipality of Marcon. The total area of 8,000 square meters is located east of Via delle Industrie n. 11.

The company was founded as Galentis S.p.A. - Following the merger by incorporation in 1999 with GRB S.r.l., Galentis S.p.A. acquired authorisation from the Ministry of Health for the

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production of pharmacologically active principles obtained by chemical synthesis and concentrated on the fine chemicals and A.P.I. market. (Active Pharmaceutical Ingredients).

In 2001 Galentis S.p.A. was authorized by the Ministry of Health to produce active ingredients belonging to class B 3.2. qualified as steroid hormones and synthetic analogues.

In December 2007 the company New G. S.r.l. incorporated Galentis S.p.A. and changed its name to Galentis S.r.l.

In February 2012 Galentis S.r.l. was incorporated by Specialty Coating Systems SCS Inc. and transformed into Galentis S.r.l. as sole shareholder subject to the management and control of SCS. The business of the new owner includes both the production of machinery for the manufacture of coatings for medical, pharmaceutical and industrial products in general, and the direct production of such coatings, therefore SCS decided to change the core business of Galentis, directing it to the production of the basic substances for the creation of the aforementioned coatings and since 2014 the production of Pharmaceutical Active Ingredients has been definitively discontinued.

The administration of Galentis S.r.l. is headed by a Board of Directors composed of four directors. The Board of Directors has appointed a Chief Executive Officer with broad powers of representation and administration. The Chief Executive Officer is required, among other things, to comply with all of the employer's statutory obligations with regard to occupational safety and environmental protection. The Chief Executive Officer has access to the funds with individual signatures for all transactions with a value of less than 100,000 euros; transactions with a value greater than this amount require the joint signature of the Chairman of the Board of Directors and the Chief Executive Officer. For transactions with a value between 25,000 euros and 99,999 euros, the Chief Executive Officer must be authorized in advance by the Chairman of the Board of Directors or another Director by written communication.

Galentis S.r.l.'s quality control system was certified according to the UNI ISO 9001:2008 standard in May 2015 and, in May 2018, the company was upgraded to the new ISO 9001:2015 standard. In addition, in June 2021, the Company obtained certification in accordance with the UNI CEI EN ISO 13485:2016 standard on quality management systems for medical devices.

Galentis S.r.l. also operates in accordance with Good Manufacturing Practises (GMP) or Norme di Buona Fabbricazione (NBF) guidelines. GMPs describe the methods, equipment, means and management of production to ensure the appropriate quality standards. GMPs require: the documentation of every aspect of the process and every operation through appropriate records; the use of trained personnel; active cleaning and sanitizing; regular checks on the proper functioning of tools and machinery; process validation; and complaint handling.

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In compliance with Good Manufacturing Practices Galentis S.r.l. has appointed a Quality Assurance Manager, with the task of ensuring the documentation, control and efficiency of the quality system. The main activities of the Quality Assurance Manager, in particular in the companies of the pharmaceutical sector, consist in verifying that: medicines are designed and developed in accordance with Good Manufacturing Practices and Good Laboratory Practices; management responsibilities and production and control operations are clearly specified; the medicinal products are not sold or supplied to third parties, before a qualified person has certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorisation and any other regulations relating to the production, control and approval of medicinal products; there is an internal inspection and quality control procedure to assess the effectiveness and applicability of the quality system; all operations are documented and traceable in relation to each production batch.

The Quality Assurance Manager is independent from Production, has no other roles or duties outside of the establishment, implementation, maintenance, updating and review of the quality management system and has no formal delegation of functions.

Galentis S.r.l., given that it already has a quality, safety and environmental management system consisting of multiple procedures and operating instructions, in the spring of 2015 it set itself the objective of adopting the Organizational Model provided for by Decree no. 231/2001, in order to strengthen the measures necessary to protect legality, to prevent certain crimes from being committed by its directors and employees and to avoid the application of fines and disqualifications provided for by the aforementioned Decree.

The Organizational Model therefore integrates the organizational and control tools already operational in Galentis S.r.l., such as:

The Ethical Code;

company procedures and organizational charts;

the risk analysis carried out through the examination of documents and interviews with department heads;

the system of controls which provides for the distinction between auditor and audited and the traceability of operations;

the continuous training and education provided to employees.

The general update of its Organisational Model provided for by Legislative Decree no. 231/2001 in the spring of 2019, in view of the legislative changes made to the list of

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indictable offences provided for by Decree no. 231/2001, the indications given by the Supervisory Board and the changes to its organizational and management structure

In the summer of 2021, the Company set out to proceed with a further update of the Organisational Model, given the introduction of a number of tax and smuggling offences among the indictable offences covered by administrative liability under Legislative Decree no. 231/2001.

## 1.6 EXEMPTION OF THE ENTITY FROM LIABILITY

In summary, the Decree stipulates that the company shall not be liable for offences:

- in the event that top management and/or their subordinates have acted exclusively in their own interest or that of third parties and in the event that the Company proves that it has adopted and effectively implemented organizational and management models capable of preventing offences;
- if the task of supervising the functioning and observance of the organizational models has been entrusted to a Body of the entity with autonomous powers of initiative and control: the so-called Supervisory Body;
- if the persons have committed the offence by fraudulently evading the organizational and management models.

## 1.7 WHISTLEBLOWING PROVISIONS

Decree no. 231/2001 contains provisions aimed at protecting employees or collaborators who report offences in the private sector. In particular, Article 6, paragraph 2.2 (introduced by Article 2 of Law no. 179/2017 "Protection of the employee or collaborator who reports offences in the private sector"), requires the Organisation and Management Model to provide for:

- one or more channels that allow the persons indicated in Article 5, paragraph 1, letters a) and b), of the Decree, to submit, in order to protect the integrity of the company, detailed reports of unlawful conduct, based on precise factual elements, or of violations of the Organization and Management Model of the entity, of which they have become aware due to the functions performed; these channels must guarantee the confidentiality of the identity of the whistleblower in the activities of managing the report;

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- at least one alternative reporting channel suitable to guarantee, by computerized means, the confidentiality of the whistleblower's identity;
- the prohibition of any act of retaliation or discrimination, direct or indirect, against the whistleblower for reasons related, directly or indirectly, to the report;
- sanctions against those who violate the protection measures of the whistleblower, as well as those who make intentional or grossly negligent reports that prove to be unfounded.

By "*whistleblower*" reference is therefore made to the employee or collaborator who - in the representation, administration or management of the entity or one of its organizational units, or being subject to the management or supervision of such top management - presents detailed reports of illegal conduct or violations of the Organisation and Management Model, of which he or she has become aware in the performance of his or her duties.

The same paragraph 2-2 has introduced a series of guarantees with regard to people who report crimes or irregularities of which they have become aware in the context of an employment or collaboration relationship:

- **confidentiality obligations on the identity of the Whistleblower:** the identity of the whistleblower is protected in all contexts following the report, except in cases where liability for slander and defamation under the provisions of the Italian Criminal Code or Article 2043 of the Italian Civil Code and in cases where anonymity is not enforceable by law (for the purposes of example without being exhaustive: criminal, tax or administrative investigations, inspections of supervisory bodies);
- **prohibition of discrimination against the Whistleblower:** No form of retaliation or discriminatory measures, whether direct or indirect, affecting working conditions is allowed or tolerated against the whistleblower for reasons directly or indirectly related to the report. It is understood that the Company may take the most appropriate disciplinary and/or legal measures to protect its rights, assets and image, against anyone who, in bad faith, has made false, unfounded or opportunistic reports and/or for the sole purpose of slandering, defaming or prejudicing the whistleblown person or other persons mentioned in the report. Any hypothesis of improper use or intentional misuse of the institution subject to this particular procedure is also a source of liability, in disciplinary proceedings and in other competent offices;
- **protection of the Whistleblown Person:** the subject of a report of internal irregularities must be informed by the supervisory board as soon as possible after the recording of the data concerning him/her. In particular, the whistleblown person must be informed about:

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(i) the facts for which he or she is accused; (ii) the office or services that may receive the report within the Company or in other entities or companies of the group to which the Company belongs and (iii) the exercise of his or her rights of access and rectification of the data.

## 1.8 THE OFFENCES IN QUESTION

Section III of Chapter I of Decree no. 231/2001 (Articles 24-26) lists the offences that may give rise to the company's liability.

### A) OFFENCES AGAINST THE PUBLIC ADMINISTRATION (ART. 24 AND 25 DECREE N. 231/2001)

- Article 314 of the Italian Criminal Code (embezzlement);
- Article 316-2 of the Italian Criminal Code (embezzlement to the detriment of the State);
- Article 316-3 of the Italian Criminal Code (undue receipt of payments to the detriment of the State);
- Article 317 of the Italian Criminal Code (extortion committed by a public official);
- Article 318 of the Italian Criminal Code (bribery for the exercise of a power);
- Article 319 of the Italian Criminal Code (bribery for an act contrary to official duties);
- Article 319-2 of the Italian Criminal Code (aggravating circumstances: when the Entity has made a significant profit from the offence);
- Article 319-3, of the Italian Criminal Code (bribery in judicial acts);
- Article 319-4 of the Italian Criminal Code (undue induction to give or promise benefits);
- Article 320 of the Italian Criminal Code (bribery of a person in charge of a public service);
- Article 321 of the Italian Criminal Code (punishment for the corruptor);
- Article 322 of the Italian Criminal Code (incitement to corruption);
- Article 322-2 of the Italian Criminal Code (embezzlement, extortion, bribery and incitement to corruption of members of the bodies of the European Communities and officials of the European Communities and Foreign States);
- Article 323 of the Italian Criminal Code (abuse of position);
- Article 346-2 of the Italian Criminal Code (trafficking in illicit influences);

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- Article 640, paragraph 2, no. 1 of the Italian Criminal Code (fraud against the State or other public body);
- Article 640-2 of the Italian Criminal Code (aggravated fraud to obtain public funds);
- Article 640-3 of the Italian Criminal Code (computer fraud to the detriment of the State or other public body);
- Article 356 of the Italian Criminal Code (fraud in public supply);
- Article 2 of Law No. 898/1986F (fraud against the European Agricultural Fund).

#### **B) COMPUTER CRIMES (ART. 24-2 DECREE N. 231/2001)**

- Article 491-2 of the Italian Criminal Code (falsehoods in a public computer document or with documentary evidence);
- Article 615-3 of the Italian Criminal Code (unauthorised access to a computer or telematic system);
- Article 615-4 of the Italian Civil Code (unauthorized possession and dissemination of access codes to computer or telematic systems);
- Article 615-5 of the Italian Criminal Code (dissemination of equipment, devices or computer programs aimed at damaging or interrupting a computer or telematic system);
- art. 617-4 of the Italian Criminal Code (unlawful interception, impediment or interruption of computer or telematic communications);
- Article 617-5 of the Italian Criminal Code (installation of equipment designed to intercept, prevent or interrupt computer or telematic communications);
- Article 635-2 of the Italian Criminal Code (damage to information, data and computer programs);
- Article 635-ter of the Italian Criminal Code (damage to information, data and computer programs used by the State or other public body or in any case of public utility);
- Article 635-4 of the Italian Criminal Code (damage to computer and telematic systems);
- Article 635-5 of the Italian Criminal Code (damage to computer or telematic systems of public utility);
- Article 640-5 of the Italian Criminal Code (computer fraud of the digital signature verifier);
- Article 1, paragraph 11, Decree-Law No. 105/2019 (violation of the rules on the National Cyber Security Perimeter).

#### **C) ORGANIZED CRIME OFFENCES (ART. 24-3 DECREE N. 231/2001)**

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- Article 416 of the Italian Criminal Code (criminal conspiracy);
- Article 416-2 of the Italian Criminal Code (mafia-type crime);
- Article 416-3 of the Italian Criminal Code (political-mafia electoral exchange);
- Article 630 of the Italian Criminal Code (kidnapping for extortion);
- Article 74 DPR 9/10/1990, no. 309 (association aimed at illicit traffic of narcotic or psychotropic substances);
- Article 407, paragraph 2, letter a), no. 5 of the Italian Criminal Code (illegal manufacture, introduction into the State, sale, transfer, possession and carrying in a public place or place open to the public of weapons of war or war-type weapons or parts of them, explosives, clandestine weapons as well as several common firing weapons).

**D) FORGERY OF MONEY, PUBLIC CREDIT CARDS, DUTY STAMPS, AND INSTRUMENTS OR MEANS OF IDENTIFICATION (ARTICLE 25-2 OF DECREE NO. 231/2001)**

- Article 453 of the Italian Criminal Code (counterfeiting of money, spending and introduction into the State with the agreement of counterfeit money);
- Article 454 of the Italian Criminal Code (alteration of money);
- Article 455 of the Italian Criminal Code (spending and introduction into the State of counterfeit money, without agreement);
- Article 457 of the Italian Criminal Code (spending of counterfeit money received in good faith);
- Article 459 of the Italian Criminal Code (falsification of revenue stamps, introduction into the State, purchase, possession or circulation of forged duty stamps);
- Article 460 of the Italian Criminal Code (counterfeiting of watermarked paper used for the production of public credit cards or revenue stamps);
- Article 461 of the Italian Civil Code (manufacture or possession of watermarks or instruments for the counterfeiting of money, revenue stamps and watermarked paper);
- Article 464 of the Italian Civil Code (use of counterfeit or altered revenue stamps);
- Article 473 of the Italian Criminal Code (counterfeiting, alteration or use of trademarks or distinctive signs or of patents, models and designs);
- Article 474 of the Italian Criminal Code (introduction into the State and trade of products with false signs).

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#### **E) CRIMES AGAINST INDUSTRY AND TRADE (ART. 25-2.1 DECREE NO. 231/2001)**

- Article 513 of the Italian Criminal Code (disturbed freedom of industry and trade);
- Article 513-2 of the Italian Criminal Code (illegal competition with threat of violence);
- Article 514 of the Italian Criminal Code (fraud against national industries);
- Article 515 of the Italian Criminal Code (fraud in the exercise of trade);
- Article 516 of the Italian Criminal Code (sale of non-genuine food substances as genuine);
- Article 517 of the Italian Criminal Code (sale of industrial products with false signage);
- Article 517-3 of the Italian Criminal Code (Manufacture and trade of goods made by usurping industrial property rights);
- Article 517-4 of the Italian Criminal Code (counterfeiting of geographical indications or designations of origin of agri-food products).

#### **F) CORPORATE OFFENCES (ART. 25-3 DECREE N. 231/2001)**

- Article 2621 of the Italian Civil Code (false corporate communications);
- Article 2622 of the Italian Civil Code (false corporate communications to the detriment of shareholders and creditors);
- Article 2623 of the Italian Civil Code (false statement);
- Article 2624 of the Italian Civil Code (falsehoods in the reports or communications of the independent auditors);
- Article 2625, paragraph 2 of the Italian Civil Code. (prevented checks from being conducted);
- Article 2626 of the Italian Civil Code (undue return of capital);
- Article 2627 of the Italian Civil Code (illegal distribution of profits and reserves);
- Article 2628 of the Italian Civil Code (unlawful transactions on shares or quotas of the parent company);
- Article 2629 of the Italian Civil Code (transactions to the detriment of creditors);
- Article 2629-2 of the Italian Civil Code (failure to disclose a conflict of interest);
- Article 2632 of the Italian Civil Code (fictitious formation of capital);
- Article 2633 of the Italian Civil Code (undue distribution of company assets by liquidators);

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- Article 2635 of the Italian Civil Code (bribery among private individuals);
- Article 2635-2 of the Italian Civil Code (incitement to corruption among private individuals);
- Article 2636 of the Italian Civil Code (unlawful influence over the shareholders' meeting);
- Article 2637 of the Italian Civil Code (stock manipulation);
- Article 2638 of the Italian Civil Code (obstruction of the exercise of the functions of public supervisory authorities).

#### **G) TERRORIST OFFENCES (ART. 25-QUARTER DECREE NO. 231/2001)**

- - Article 270 of the Italian Criminal Code (subversive associations);
- - Article 270-2 of the Italian Criminal Code and Special Laws (associations for the purposes of terrorism and subversion of the democratic order);
- - Article 270-3 of the Italian Criminal Code (assistance to members)
- - Article 270-4 of the Italian Criminal Code (recruitment for the purposes of terrorism, including international terrorism);
- - Article 270-5 of the Italian Criminal Code (training for terrorist activities, including international terrorism);
- - Article 270-6 of the Italian Criminal Code (conduct for the purposes of terrorism);
- - Article 280 of the Italian Criminal Code (attack for the purposes of terrorism or subversion);
- - Article 280-2 of the Italian Criminal Code (act of terrorism with deadly or explosive devices);
- - Article 289-2 of the Italian Criminal Code (kidnapping for the purpose of terrorism or subversion);
- - Article 2 of the New York Convention of 9/12/1999.

#### **H) FEMALE GENITAL MUTILATION (ART. 25-4.1 DECREE NO. 231/2001)**

- Article 583-2 of the Italian Criminal Code (female genital mutilation practices).

#### **I) CRIMES AGAINST THE PERSON (ART. 25-5 DECREE NO. 231/2001)**

- Article 600 of the Italian Criminal Code (enslavement);
- Article 600-2 of the Italian Criminal Code (child prostitution);
- Article 600-3 of the Italian Criminal Code (child pornography);
- Article 600-4 of the Italian Criminal Code (possession of child pornographic material);

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- Article 600-4.1 of the Italian Criminal Code (virtual child pornography);
- Article 600-5 of the Italian Criminal Code (tourist initiatives aimed at the exploitation and prostitution of minors);
- Article 601 of the Italian Criminal Code (trafficking in persons);
- Article 602 of the Italian Criminal Code (purchase and transfer of slaves);
- Article 603-2 of the Italian Criminal Code (illegal intermediation and exploitation of labour);
- Article 609-11 of the Italian Criminal Code (solicitation of minors).

#### **L) MARKET ABUSE (ART. 25-6 DECREE NO. 231/2001)**

- - Article 184 of Decree 58/1998 (abuse of privileged information);
- - Article 185 of Decree 58/1998 (market manipulation).

#### **M) MANSLAUGHTER AND NEGLIGENT INJURY IN VIOLATION OF OCCUPATIONAL HEALTH AND SAFETY REGULATIONS (ART. 25-7 DECREE NO. 231/2001)**

- Article 589 Italian Civil Code (manslaughter);
- Article 590, paragraph 3, Italian Criminal Code (negligent injury).

#### **N) CRIMES OF RECEIVING STOLEN GOODS, MONEY LAUNDERING, USE OF MONEY, GOODS OR BENEFITS OF ILLEGAL ORIGIN, SELF-LAUNDERING; (ART. 25-8 DECREE NO. 231/2001)**

- Article 648 of the Italian Criminal Code (receiving stolen goods);
- Article 648-2 of the Italian Criminal Code (money laundering);
- Article 648-3 of the Italian Criminal Code (use of money, goods or utilities of illegal origin).
- Article 648-3.1 (self-laundering).

#### **O) COPYRIGHT INFRINGEMENT OFFENCES (ART. 25-9 DECREE NO. 231/2001)**

- Article 171(1)(a) of Law No 633/1941 (making available to the public, in a system of telematic networks, by means of connections of any kind, of a protected intellectual work or part thereof);
- Article 171, paragraph 3 of Law no. 633/1941 (offences referred to in the previous point committed on the works of others not intended for publication, if honour or reputation is offended);

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- Article 171-2, paragraph 1, Law no. 633/1941 (unlawful duplication, for profit, of computer programs or for the same purposes import, distribution, sale, possession for commercial or business purposes or lease of programs contained in media not marked by the Italian Society of Authors and Publishers (Società Italiana degli Autori ed Editori, SIAE); preparation of means to remove or circumvent the protection devices of computer programs);
- Article 171-3 of Law no. 633/1941 (unlawful duplication, reproduction, transmission or dissemination in public with any procedure, in whole or in part, of intellectual property intended for the television, cinema, sale or rental of records, tapes or similar media or any other media containing phonograms or videos of musical, cinematographic or audio-visual equivalent works or sequences of moving images; literary, dramatic, scientific or educational, musical or musical drama or multimedia works, whether or not included in collective or composite works or databases; unauthorised reproduction, duplication, transmission or dissemination, sale or trade, transfer for any reason whatsoever, or unauthorised import of more than fifty copies or copies of works protected by copyright and related rights; placing in a computer network system, by means of connections of any kind, of an intellectual work protected by copyright, or part thereof);
- Article 171-7 of Law no. 633/1941 (failure to communicate to the SIAE the identification data of the supports not subject to the mark or false declaration);
- Article 171-8, Law no. 633/1941 (fraudulent production, sale, import, promotion, installation, modification, use for public and private use of equipment or parts of equipment for the decoding of audio-visual transmissions with conditional access made over the air, via satellite, cable, in both analogical and digital form).

**P) INCITEMENT NOT TO MAKE STATEMENTS OR TO MAKE FALSE STATEMENTS TO THE JUDICIAL AUTHORITIES (ARTICLE 25-10 OF LEGISLATIVE DECREE NO. 231/2001)**

- Article 377-2 of the Italian Criminal Code (incitement not to make statements or to make false statements to the Judicial Authorities).

**Q) ENVIRONMENTAL CRIME (ARTICLE 25-10 DECREE 231/2001)**

- Article 452-2 of the Italian Criminal Code (environmental pollution);
- Article 452-4 of the Italian Criminal Code (environmental disaster);
- Article 452-5 of the Italian Criminal Code (negligent crimes against the environment);

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- Article 452-6 of the Italian Criminal Code (traffic and abandonment of highly radioactive material);
- Article 452-8 of the Italian Criminal Code (conspiracy to commit environmental crimes);
- Article 452-14 of the Italian Criminal Code (Organizing activities for the illegal trafficking of waste);
- Article 727-2 of the Italian Criminal Code (killing, destruction, capture, collection or possession of specimens of protected wild animal or plant species);
- Article 733-2 of the Italian Criminal Code (damage to habitats within a protected site);
- Article 137 of Decree no. 152/2006 (environmental crimes related to the unauthorized discharge of industrial waste water);
- Article 256, paragraph 1, letters a) and b), 3, 5, 4 and 6 of Legislative Decree no. 152/2006 (unauthorized waste management activities);
- Article 257, paragraphs 1 and 2, Decree 152/2006 (site remediation);
- Article 258, paragraph 4, 2nd period, Decree no. 152/2006 (violation of the obligations to communicate and keep mandatory registers and forms);
- Article 259, paragraph 1, Decree no. 152/2006 (illegal trafficking of waste);
- Article 260-2 of Decree no. 152/2006 (computerized control system for waste traceability);
- Article 279, paragraph 5, Decree no. 152/2006 (violation of emission limit values);
- Article 1 and 2 of Law no. 150/1992 (unauthorized trafficking of specimens and safety of specimens);
- Article 3-2 of Law no. 150/1992 (falsification of certificates);
- Article 3(6) of Law no. 549/1993 (infringement of the provisions on the cessation of the use of harmful substances);
- Articles 8 and 9 of Decree no. 202/2007 (intentional and negligent pollution by the master or crew of a ship).

#### **R) EMPLOYMENT OF NATIONALS WITHOUT RESIDENCE (ARTICLE 25-12 DECREE N. 231/2001)**

- Article 22, paragraph 12-2, lett. a) Decree no. 286/1998 (use of workers without a residence permit);

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- Article 12, paragraph 3, 3-bis, 3-ter, 5 of Decree no. 286/1998 (provisions against illegal immigration).

#### **S) RACISM AND XENOPHOBIA (ARTICLE 25-13 DECREE N. 231/2001)**

- Article 3, paragraph 3.2 of Law No 645/1975 (racial discrimination).

#### **T) SPORTS FRAUD (ART. 25-14 DECREE N. 231/2001)**

- Article 1 of Law no. 401/1989 (fraud in sporting competitions);
- Article 4 of Law no. 401/1989 (abuse of gambling or betting activities).

#### **U) FISCAL CRIMES (ARTICLE 25-QUINQUESDECIES OF LEGISLATIVE DECREE NO. 231/2001)**

- Article 2(1) and (2-bis) of Legislative Decree no. 72/2000 (fraudulent declaration through the use of invoices or other documents for non-existent transactions);
- Article 3 of Legislative Decree no. Lgs. no. 74/2000 (fraudulent declaration by means of fraudulent misrepresentation);
- Article 4 of Legislative Decree no. 74/2000 (false declaration);
- Article 5 of Legislative Decree No 74/2000 (failure to make a declaration);
- Article 8(1) and (2-bis) of Legislative Decree No 74/2000 (issue of invoices or other documents for non-existent transactions);
- Article 10 of Legislative Decree 74/2000 (concealment or destruction of accounting documents);
- art. 10 quarter Lgs. Decree 74/2000 (undue compensation)
- Article 11 of Legislative Decree No 74/2000 (fraudulent evasion of tax payments).

#### **V) SMUGGLING (ARTICLE 25-SEXIESDECIES OF LEGISLATIVE DECREE NO. 231/2001)**

- Smuggling in the movement of goods across land borders and customs areas (Article 282 of Presidential Decree no. 73/1943);

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- Smuggling in the movement of goods across border lakes (Article 283 Presidential Decree no. 73/1943);
- Smuggling in the maritime movement of goods (Article 284 Presidential Decree No. 73/1943);
- Smuggling in the movement of goods by air (Article 285 of Presidential Decree No 73/1943);
- Smuggling in non-customs areas (Article 286 of Presidential Decree no. 73/1943);
- Smuggling for undue use of goods imported with customs facilities (Article 287 of Presidential Decree No. 73/1943);
- Smuggling in customs warehouses (Article 288 of Presidential Decree no. 73/1943);
- Smuggling in cabotage and traffic (Article 289 of Presidential Decree No. 73/1943);
- Smuggling in the export of goods eligible for restitution of duty (Article 290 Presidential Decree 73/1943);
- Smuggling on temporary import or export (Article 291 of Presidential Decree no. 73/1943);
- Smuggling of foreign manufactured tobacco (Article 291-bis of Presidential Decree 73/1943);
- Aggravating circumstances of the crime of smuggling of foreign processed tobacco (Article 291-ter of Presidential Decree no. 73/1943);
- Criminal association for the purpose of smuggling foreign manufactured tobacco (Article 291-quater of Presidential Decree No 73/1943);
- Other cases of smuggling (Article 292 of Presidential Decree no. 73/1943);
- Aggravating circumstances of the aforementioned offences (Article 295, paragraphs 2 and 3, Presidential Decree no. 73/1943).

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## 2 THE MODEL

### 2.1 THE CREATION AND THE UPDATING OF THE MODEL

The drafting of the Model was preceded by a series of preliminary activities divided into different phases, aimed at the in-depth study of Galentis S.r.l., in order to achieve a system of prevention and management of crime risks in line with the provisions of Decree 231/2001.

These activities have involved, in addition to the analysis of corporate documents (articles of association, Chamber of Commerce registration, manuals, procedures, organization charts, etc.), the implementation of interviews and conversations with top management, with the aim of identifying and recording contacts, behaviours and processes that could give rise to the commission of one or more of the offences.

The updates of the Model have included a thorough review of the risk analysis of the risks of the offences being committed within the company, preceded by an examination of the company documents amended in the medium term and the conduct of interviews and conversations with the various company departments, in order to verify the conformity of the provisions of the Model with the current organizational structure and the legislative changes that have taken place.

### 2.2 THE MODEL FUNCTION

The adoption and effective implementation of the Model, including the supervisory activity carried out by the Supervisory Body, enable the Company to reduce the risk of commission of offences and to benefit from the exemption provided for by the Decree.

One of the aims of the Organizational Model is to develop awareness and sensitivity in people who work on behalf or in the interest of the Company that they may commit - in the event of conduct that does not comply with the law and company procedures - offences liable to criminal consequences not only for themselves, but also for Galentis S.r.l.

Additionally, with the implementation of the Model and its control, it is intended to effectively censure any unlawful conduct, through the activity of the Supervisory Body and the imposition of disciplinary or contractual sanctions.

### 2.3 THE ADOPTION OF THE MODEL AND SUBSEQUENT AMENDMENTS

Galentis S.r.l. has chosen to proceed with the adoption of the Organizational Model, whose approval, integration and revision are the responsibility of the Board of Directors.

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## 2.4 MODEL COMPOSITION

The Organizational Model is composed of:

- 1) General Part
- 2) Analysis of the risks of the offences in question being committed
- 3) Special Part
- 4) Ethical Code

Annex A: Company organisation chart;

Annex B: Whistleblowing Procedure.

The following also forms an integral part of the Model, of which they must be considered organic annexes in the most up-to-date version:

- the general and specific functional organisation charts for safety at work and environmental protection;
- the certified management systems of the Company;
- company procedures, operating instructions, service orders.

## 3 THE SUPERVISORY BODY (ORGANISMO DI VIGILANZA, ODV)

### 3.1 THE SUPERVISORY BODY OF GALENTIS

The Supervisory Body (O.d.V.) is entrusted with the task of supervising the operation of and compliance with the Organisational Model.

The main requirements of the Supervisory Board, as proposed in the Guidelines for the preparation of Organizational and Management Models issued by Confindustria, are:

- autonomy and independence;
- professionalism;
- continuity of action.

Decree no. 231/2001 does not provide specific information on the composition of the Supervisory Body. In the absence of indications, the Company has opted for a collective composition of its Supervisory Board, appointing three members selected on the basis of their professional skills and integrity.

The members of the Supervisory Board must not have incurred:

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- convictions, even if not final, and also pursuant to Article 444 of the Italian Criminal Code, for the intentional crimes referred to in Decree no. 231/2001 or for other intentional crimes in any case affecting professional morality;
- judgements, even if not final, of a sentence which includes disqualification, even temporary, from public office, i.e. temporary disqualification from the management offices of legal persons and companies.

If any of the above reasons for ineligibility should arise against an appointed person, the latter shall automatically forfeit the office.

The Supervisory Body may avail itself - under its direct supervision and responsibility - of the collaboration of all the functions and structures of Galentis S.r.l. or external consultants, making use of their respective skills and professionalism in carrying out the tasks entrusted to it. This power enables the Supervisory Body to ensure a high level of professionalism and the necessary continuity of action.

To this end, each year the Board of Directors assigns an expense budget to the Supervisory Board, taking into account the latter's requests, which must be formally submitted to the Board.

The allocation of the budget allows the Supervisory Body to operate autonomously and with the appropriate instruments for the effective performance of the task assigned to it by this Model, in accordance with the provisions of Decree no. 231/2001.

In order to guarantee the necessary stability for the members of the Supervisory Board, the revocation of the powers of the Supervisory Board and the attribution of such powers to another person may only take place for just cause by a specific resolution of the Board of Directors.

### **3.2 FUNCTIONS AND POWERS OF THE SUPERVISORY BODY**

The activities carried out by the Supervisory Body cannot be reviewed by any other body or structure of Galentis S.r.l., without prejudice, however, to the fact that the Board of Directors is in any case called upon to supervise the adequacy of its work, since the Administrative Body has ultimate responsibility for the functioning of the Model.

The Supervisory Body is granted the powers of initiative and control necessary to ensure effective and efficient supervision of the functioning and compliance with the Model in accordance with the provisions of Article 6 of Decree 231/2001.

Therefore, this Body is entrusted with the task of generally supervising:

1. The effectiveness of the Model and its adequacy with respect to the need to prevent the commission of the crimes for which Decree no. 231/01 applies;

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2. compliance with the provisions of the Model by the recipients;
3. the updating of the Model in the event that there is a need to adapt it in relation to changed company or regulatory conditions.

In particular, the Supervisory Body is entrusted with the following tasks and powers in order to carry out and exercise its functions:

- a) to carry out targeted checks on specific activities that are at risk, with free access to the relevant data;
- b) to promote the updating of risk mapping in the event of significant organizational changes or the extension of the type of crimes taken into consideration by Decree 231/2001;
- c) to monitor the information/training initiatives, aimed at disseminating knowledge and understanding of the Model within the company, promoted by the competent function;
- d) to collect and manage the information necessary to provide a constantly updated picture of the implementation of the Model, together with reports of suspected violations of the Decree and the Model, including those drawn up pursuant to Law No. 179/2017 (*whistleblowing*);
- e) to express, on the basis of the results of the audit and control activities, a periodic assessment of the adequacy of the Model to prevent the commission of offences;
- f) to report to the Chairman of the Board of Directors or the CEO any breaches of protocols or shortcomings found during the checks carried out, so that the latter may take the necessary sanctions or compliance measures involving, where necessary, the Board of Directors;
- g) detect any behavioural deviations that may emerge from the analysis of information flows and from the reports to which the persons in charge of the various Functions are required to report;
- h) to supervise the effective and correct application of the disciplinary sanctions provided for in cases of violation of the Model.

The Supervisory Board is obliged to maintain confidentiality with regard to all information of which it is aware as a result of the performance of its duties.

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### 3.3 INFORMATION OBLIGATIONS OF THE SUPERVISORY BODY - INFORMATION FLOWS AND WHISTLEBLOWING

The Supervisory Body must be promptly informed of any acts, behaviours or events that may lead to a violation of the Model or that in any case are relevant for the purposes of Decree no. 231/2001.

The obligations to provide information on any conduct contrary to the provisions contained in the Model are part of the broader duty of diligence and duty of loyalty of the employee pursuant to articles 2104 and 2105 of the Italian Civil Code.

The following general requirements apply in this respect:

- Report must be sent to the supervisory body concerning:
  - a. the committing - or reasonable suspicion of committing, of the offences referred to in Decree no. 231/2001;
  - b. the violation of rules for the protection of health and safety at work and the environment, even if they do not constitute the offences in question;
  - c. conduct that may lead to a violation of the Model;
  - d. an employee who intends to report a violation (or presumed violation) of the Model and who for this purpose may contact his or her direct superior or, if the report is unsuccessful or the employee feels uncomfortable in addressing his or her direct superior to make the report, to report directly to the Supervisory Body. Pursuant to Article 6, paragraph 2-2, of Decree 231/2001, reports must concern unlawful conduct or violations of Model 231 based on precise and consistent facts. Any documentation on the facts reported, as well as the results of any investigations already carried out in this regard, must also be sent to the Supervisory Board for the assessments for which it is responsible;
  - e. the Supervisory Body, and the persons designated to support it who, in order to ensure confidentiality about the identity of the Whistleblower, undertake to maintain the strictest confidentiality on reports and not to disclose any information they have learned in the performance of their duties. Anyone who receives a report that has passed outside the channels provided for, shall promptly forward it in original to the Supervisory Body, using the appropriate channels and criteria of maximum confidentiality appropriate to protect the integrity of the whistleblower, the whistleblown persons and the effectiveness of the investigations.

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- f. the Supervisory Board which evaluates the reports received and consequent initiatives at its reasonable discretion and responsibility, possibly consulting the author of the report and/or the person responsible for the alleged violation, drawing up a report of the meeting and giving written reasons for any decisions to proceed or not to proceed with an internal investigation.
- g. Whistleblowers acting in good faith, to be protected against any form of retaliation, discrimination or penalisation and in any case the confidentiality of their identity is guaranteed, without prejudice to legal obligations and the protection of the rights of Galentis S.r.l. or of persons accused wrongly or in bad faith.

In addition to the above reports, information must be sent to the Supervisory Body concerning:

- the measures adopted by Judicial Police Bodies, or by any other Authority, from which it can be inferred that investigations are being carried out, even against unknown persons, for the crimes covered by Decree no. 231/2001 that may involve the Company;
- the requests for legal assistance made by directors or employees in the event of the initiation of legal proceedings against them and in relation to the offences referred to in Decree no. 231/2001;
- information relating to disciplinary proceedings carried out and any sanctions imposed, or measures for the archiving of such proceedings, together with the relevant motives;
- organizational and corporate changes.
- changes relating to top positions (legal representatives, managers, function delegates, special attorneys), to the perimeter of their decision-making powers and their spending capacities
- changes relating to persons holding one of the functions provided for by Legislative Decree no. 81/2008 (Employer, Head of Prevention and Protection Service, Workers' Safety Representative, Competent Doctor, any delegate for work safety);
- the issue, renewal, suspension or non-renewal of management system certifications;
- the issue, renewal or non-renewal, warnings, suspensions or revocations of any authorisation/permit essential for the exercise of the activity;
- notifications to the Company of acts of introduction of civil suits of significant importance;

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- notifications to the Company or to its directors and managers of acts issued by the Prefecture, the Police Headquarters, National Anti-Corruption Authority or other national Guarantee Authorities.

With regard to the information that must be transmitted without delay to the Supervisory Body, reference should be made to what is described in detail in the Special Part of the Model, without prejudice to the possibility for the Supervisory Body to stipulate further information obligations in its Regulations.

All reports and communications addressed to the Supervisory Body may be forwarded through the following channels, either by post or by email:

**Organismo di Vigilanza di Galentis S.r.l.**

**Via delle Industrie n. 11**

**30020 - Marcon (Ve)**

**Italy**

or: [odv@galentis.it](mailto:odv@galentis.it)

All information, disclosures and reports are kept by the Supervisory Board in a special confidential archive (computer or paper).

**3.4 REPORTING BY THE SUPERVISORY BODY TO THE CORPORATE BODIES**

The Supervisory Body reports on the effectiveness and compliance with the Model, the emergence of any critical aspects and the need for modification. To this end, the Supervisory Board prepares:

- on a half-yearly basis, an information report on the activities carried out, to be submitted to the Board of Directors, through the CEO;
- immediately upon the occurrence of ascertained violations of the Model, with alleged commission of offences, a communication to be submitted to the Chairman of the Board of Directors and the Chief Executive Officer.

Regular meetings with one or more members of the Board of Directors must also be documented. The Supervisory Board takes care of filing the relevant documents.

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#### **4 DISSEMINATION OF THE MODEL**

The Company is committed to promoting the disclosure of the Model to its employees, with a degree of depth that varies according to position and role.

The principles and contents of the Model are also disclosed through training courses.

The structure of the training courses is defined by the Company in agreement with the Supervisory Body. Targeted training and information initiatives may also take place at a distance and through the use of IT resources (e.g. e-learning).

The Company undertakes to disclose the model also to those with whom it has business relations. The commitment to respect the principles of the Model by third parties having contractual relations with the Company - from the approval of this Model - shall be provided for by a specific contractual clause.

#### **5 DISCIPLINARY SYSTEM**

##### **5.1 FUNCTION OF THE DISCIPLINARY SYSTEM**

The definition of a system of sanctions (commensurate with the violation and with a deterrent effect) applicable in the event of violation of the rules set out in the Model makes the supervisory action of the Supervisory Body efficient and practicable and aims to ensure the effectiveness of the Model.

The preparation of a disciplinary system constitutes, pursuant to Article 6, paragraph 1, letter e) of Decree 231/2001, an essential requirement of the Model.

The application of the disciplinary system and related sanctions is independent of the course and outcome of any criminal proceedings initiated by the Judicial Authorities in the event that the conduct to be censured also constitutes a relevant offence according to the Decree.

##### **5.2 MEASURES TAKEN AGAINST EMPLOYEES**

Without prejudice to the obligations of the Company, arising from the Workers' Statute (Law no. 300 of 30<sup>th</sup> May 1970, the following conduct is punishable:

- a) violation of laws provided for or referred to by Decree no. 231/2001;
- b) violation of procedures provided for or referred to in the Model (e.g. failure to comply with prescribed procedures, omission of communications to the Supervisory Board regarding required information, omission of checks, etc.);

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- c) adoption, in the performance of activities connected with Sensitive Processes, of conduct that does not comply with the prescriptions of this Model or the procedures referred to therein and unequivocally aimed at committing one or more Offences;
- d) adoption, in the performance of activities connected to the Sensitive Processes, of conducts clearly in violation of the prescriptions of this Model or of the procedures referred to therein, such as to determine the concrete application against the Company of the sanctions provided for by the Decree.

The penalties and any claim for damages will be commensurate with the level of responsibility and autonomy of the employee, the possible existence of previous disciplinary precedents against him/her, the intentionality of his/her conduct and the seriousness of his/her conduct, meaning the level of risk to which the Company can reasonably be deemed to have been exposed to - in accordance with Decree no. 231/2001 - as a result of the censured conduct.

The Chief Executive Officer is responsible for the concrete application of disciplinary measures. The sanctions that can be imposed on employees - in compliance with the procedures provided for by Article 7 of Law no. 300 of 30 May 1970 (Workers' Statute) and any special applicable regulations - are those provided for by the sanction's apparatus of the National collective labour agreement (Contratto collettivo nazionale di lavoro, CCNL).

The Chief Executive Officer is responsible for investigating violations, handling disciplinary proceedings, and imposing sanctions.

### **5.3 MEASURES AGAINST DIRECTORS**

In the event of violation of the Model by one or more members of the Board of Directors, the Supervisory Board shall inform the entire Board of Directors, which shall take the appropriate measures, including, for example, convening the Shareholders' Meeting in order to adopt the most appropriate measures, including suspension or revocation of the office of director. In the event of violation of the Model by all members of the Board of Directors, the Supervisory Board shall inform the shareholders of Galentis S.r.l.

### **5.4 MEASURES AGAINST CONSULTANTS AND PARTNERS**

Any violation of the Model by Consultants or Partners is sanctioned in accordance with the provisions of the contractual clauses.

This is without prejudice to any claim for compensation if such conduct results in concrete damage to the Company, as in the case of the application by the Judge of the measures provided for by Decree no. 231/2001.