

KEDRION

B I O P H A R M A

Kedrion S.p.A.

Organisation, Management and Control Model
(adopted pursuant to Legislative Decree No. 231/2001)

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Introduction

Foreword

This document is an update of the Organisation, Management, and Control Model already adopted by Kedrion S.p.A. (hereinafter also “Kedrion” or the “Company”) pursuant to Legislative Decree No. 231 of 8 June 2001 (hereinafter also “L.D. 231/2001” or the “Decree”).

By adopting and implementing this Model, the Company pursues the following objectives:

- comply with the statutory regulations on the administrative liability of entities, by checking and enhancing the protective measures already adopted to prevent the unlawful conducts relevant for the purposes of L.D. 231/2001;
- inform the Recipients (as defined below) of the relevance of L.D. 231/2001 with respect to:
 - the subject matter and scope of application of the above statutory regulation;
 - the sanctions which may be applied to the Company and to the author of the unlawful conduct in the event of perpetration of the offences and administrative wrongful acts punishable under L.D. 231/2001
 - the need to strictly comply with the provisions contained in the Model, which violation entails the adoption of disciplinary and/or contractual measures;
- in general, undertake the necessary courses of action, by adopting suitable measures, in order to prevent the commission of unlawful acts in the performance of company business.

Structure of the Document

The Organisation, Management, and Control Model includes:

- a General Part, which describes the contents of the Decree, provides a synthetic overview of the corporate governance, and organisation and management models of the Company, the function and general operating principles of the Model, and the mechanisms to concretely implement the Model;
- Special Parts, which describe, for each corporate area exposed to the risk of perpetration of “231 offences”, the relevant types of crimes and the principles of conduct to be complied with. Each Special Part includes a list of Corporate Procedures applicable, which contain the control measures the Recipients must comply with to ensure the prevention of 231 offences.

The Model also includes the following documents (hereinafter collectively referred to as “Annexes”), which constitute an integral part of the Model:

- List of Crimes (Annex 1);
- Code of Ethics (Annex 2);
- Surveillance Body Bylaws (Annex 3);
- Flow of Information to the Surveillance Body and notification of violations (SB) (Annex 4);
- Complementary disciplinary system adopted pursuant to Legislative Decree 231/2001 (Annex 5).
- 231 Risk analysis and controls (Annex 6).

Recipients

The rules and provisions contained in the Model and its Annexes apply to and must be complied with by the Company's employees, by individuals who discharge, including de facto, the Company's management, administrative, directive, or control tasks, by members of staff, and those who, though not being part of the Company, operate based on mandates they received from the Company.

With respect to collaborators, consultants (including those who operate in name and on behalf of the Company in liaising with public officers, judicial authorities, etc, or in the business areas deemed at risk), suppliers, other partners, and other contractual counterparties in general, Kedrion requires their compliance with the provisions detailed in the Decree and with the ethical principles adopted by the Company, by entering into specific contractual provisions to ensure their commitment to comply with the provisions under Legislative Decree 231/2001, and with the ethical principles and guidelines adopted by the Company.

General Part

1. Legislative Decree No. 231/2001

1.1 The framework governing the administrative liability upon legal persons

Legislative Decree 231/2001, issued in implementation of the delegation to the Government under Article 11 of Law No. 300 of 29 September 2000, governs the **“liability of legal persons for administrative offences arising from crimes”**.

This statutory provision applies to legal persons and companies and associations including without legal personality.

Legislative Decree No. 231/2001 was drawn up on the basis of a few **international and EU conventions ratified by Italy** which impose to provide forms of liability of collective bodies for certain types of crimes, including:

- Brussels Convention of 26 July 1995 on the protection of the European Communities' financial interests;
- Convention of 26 May 1997 on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union;
- OECD Convention of 17 December 1997 on Combating Bribery of Foreign Public Officials in International Business Transactions

Under the legal framework introduced by Legislative Decree 231/2001, an entity (hereinafter also referred to as “company”) may be deemed **“liable” for certain crimes committed or attempted, in the interest or to the advantage of the company**, by

- **Senior Executives**, or in other words, individuals who hold positions of representation, administration, or direction of a company, a company’s organisational unit with financial and functional autonomy, and individuals who perform, including de facto, the management and control of such companies or units;
- **Individuals subject to the management or supervision** of senior executives.

As to the notion of **“interest”**, it arises every time an unlawful act is carried out with the exclusive intent of obtaining a benefit for the company, irrespective of the circumstances in which such objective is obtained.

Likewise, the liability which is upon the company every time the author of the unlawful act, though not acting for the purpose of gaining a benefit for the company, has nonetheless attracted an **“advantage”** to said company, either financial or other.

The **administrative liability of companies is independent from the criminal liability of the natural person** committing the criminal offence, and it complements the latter.

1.2 Types of crimes provided under the Decree

The Decree concerns exclusively **certain particular types of criminal offences**, expressly detailed in the Decree.

Such types of crimes may be grouped, for the sake of convenience, in the following categories:

- crimes against the Public Administration (Articles 24 and 25 Legislative Decree 231/2001);
- IT-related felonies and unlawful processing of data (Article 24-*bis* Legislative Decree 231/2001);
- felonies committed by criminal organisations (Article 24-*ter* Legislative Decree 231/2001);
- crimes concerning the forgery of money, money values having legal tender or revenue stamps and instruments or identification signs (Article 25-*bis* Legislative Decree 231/2001);

- felonies against industry and commerce (Article 25-*bis*.1 Legislative Decree 231/2001);
- corporate offences (Article 25-*ter* Legislative Decree 231/2001)¹;
- felonies committed for purposes of terrorism or felonies designed to subvert democracy (Article 25-*quater* Legislative Decree 231/2001);
- mutilation of women’s genitals (Article 25-*quater*.1 Legislative Decree 231/2001);
- felonies against individual’s freedoms (Article 25-*quinquies* Legislative Decree 231/2001);
- offences of abuse of privileged information and market manipulation (Article 25-*sexies* Legislative Decree 231/2001; Articles 187-*bis*, 187-*ter*, 187-*quinquies* T.U.F.);
- manslaughter or serious bodily harm committed with breach of laws governing the safeguarding of workplace health and safety (Article 25-*septies* Legislative Decree 231/2001);
- handling stolen goods, laundering and use of money, assets or benefits whose origin is illegal, and self-laundering (Article 25-*octies* Legislative Decree 231/2001);
- felonies regarding breach of copyright (Article 25-*novies* Legislative Decree 231/2001);
- inducements not to make statements or to make false statements to the courts) (Article 25-*decies* Legislative Decree 231/2001);
- environmental crimes (Article 25-*undecies* Legislative Decree 231/2001);
- transnational crimes (Article 10 Law No. 146/2006);
- employment of third-country nationals without regular stay permit (Article 25-*duodecies* Legislative Decree 231/2001).
- racism and xenofoby crimes (art. 25-*terdecies* D.Lgs. 231/2001) .
- fraud in sports competitions, gaming improper exercise or wagering and gambling exercised by means of equipment prohibited (Art. 25 quaterdecies Legislative Decree no. 231/2001);
- tax offenses (Article 25-*quinquiesdecies* of Legislative Decree 231/2001);
- smuggling (Article 25-*sexiesdecies* of Legislative Decree 231/2001).

For a detailed description of the crimes provided under the Decree, as amended and supplemented, please see Annex 1.

1.3 Crimes committed abroad

Legislative Decree 231/2001 contains a provision, inspired on the principle of universal jurisdiction, based on which **an entity may be held liable in Italy for crimes committed abroad** (Article 4 Legislative Decree 231/2001).

The Illustrative Report to Legislative Decree 231/2001 highlights the need to provide a sanctions system applicable to frequently occurring crimes, including for the purpose of preventing easy elusions of the entire legal framework against such crimes.

The **assumptions underlying the administrative liability of bodies for crimes committed abroad** are:

¹ Including also the crime of “Bribery among private individuals”.

- 1) the crime must be committed abroad by an individual functionally connected to the body, as per Article 5, paragraph 1, of Legislative Decree 231/2001;
- 2) the body must have their main headquarters within the territory of the State of Italy;
- 3) the body may be held liable only in the cases and under the condition provided under Articles 7, 8, 9, 10 of the Criminal Code (where the law provides that the culprit – a natural person – is punished on request by the Minister of Justice, then action is taken against the body only if the request is formulated also against the body).
- 4) the application of Articles 7-10 of the Criminal Code must be coordinated with the provisions for the crimes detailed under Legislative Decree 231/2001, therefore – in line also with the principle of legality as per Article 2 of Legislative Decree 231/2001 – the crimes listed under Articles 7-10 of the Criminal Code, a company may be held liable only for the crimes for which it is held liable under *ad hoc* provisions of law.
- 5) in the presence of the cases and condition detailed under the above articles of the Criminal Code, the company is not object to a legal action brought by the State where the unlawful act was committed.

1.4 Penalties

In the cases where a company may be held liable under the Decree, in consequence of the commission or attempted commission of the above-mentioned crimes, **the company may be subject to the following penalties:**

- Fines, calculated through a system based on rates, which number and amount are determined by the judge, within the limitation of law.
- Disqualification measures, which may consist of:
 - disqualification from exercising the activity;
 - suspension or cancellation of authorisations, licences or concessions serving to commit the unlawful act;
 - prohibition on entering into contracts with the public administration;
 - exclusion from benefits, loans, contributions or subsidies and possible cancellation of those already granted;
 - prohibition on publicising goods or services;
- seizure of the sum paid for or the profit gained from the crime;
- publication of the decision on one or more newspapers.

1.5 The exonerating condition: organisation, management, and control models

Legislative Decree 231/2001 expressly provides, in Articles 6 and 7, that **a body shall be exempt from administrative liability** for the crimes committed to the its advantage and/or interest where the Body has adopted effective and efficient Organisation, Management, and Control Models suitable to prevent the crimes envisioned in Legislative Decree 231/2001.

The simple adoption of the Model by a Body's management is not, however, sufficient to determine the Body's exonerated from administrative liability, as the Model must also be deemed to be effective and efficient.

A Body may be exonerated from administrative liability when:

- 1) the “senior executive organ” **adopted and efficiently enacted**, “organisational and management models” which are capable of preventing offences of the type occurring;
- 2) the task of **overseeing such operations, compliance with the models** and the updating of the same has been delegated to an **organisation** within the body vested with powers to act on its own initiative and conduct monitoring;
- 3) the persons **committed the offence by fraudulently circumventing** the organisational and management models;
- 4) **there has been no omission or insufficient oversight on the part of the organisation** referred to in subparagraph b) point (2) above.”

In the event the model is deemed to be suitable, and there has been no omission or insufficient oversight on the part of the organisation mentioned above, the Body may be held exempted from liability as the persons who have committed the crime have done so by fraudulently circumventing said model, and thus the measures of prevention and control enacted.

In particular, with regards to what is set forth in the art. 6, subsection 2, 231 Decree, **a Model must meet the following requirements:**

- identify the activities in relation to which offences may be committed (so-called “mapping” of activities at risk);
- provide for specific direct protocols and schedule training and implementation of decisions by the body regarding offences to be prevented;
- identify procedures for managing financial resources which are fit to prevent the commission of offences;
- provide for obligations to disclose information to the organisation tasked with overseeing the working of and compliance with the models;
- introduce a new disciplinary system to punish noncompliance with the measures set out in the model.

More recently the 179/2017 law has integrated the regulation in reference to art. 6, 231/1 Decree by adding a new subsection, 2 bis, on the basis of such subsection , the Model must also foresee:

- a) one or more communication tools at disposal of people as mentioned in the art. 5 , subsection 1, lett. a) and b) for submitting notifications, by defending the company’s integrity, well detailed illegal action notifications, relevant to the 231/01 legislative Decree and based on detailed and consistent facts and evidences, or violations of the Organization, Management and Control Model of the company, which they may have found out in accordance with their function and activities; such communication tools guarantee the privacy of who may advise of a notification in the whole process of his/her communication;
- b) At least an alternative communication tool suitable for guaranteeing, by means of IT systems, the privacy of the person who may advise a notification;
- c) The ban of any retaliation actions rather than discrimination ones , both direct and indirect , towards the person who might advise of a notification, due to reasons linked to the notification in a direct or indirect ways.
- d) Sanctions both towards the person who violates the guarantee measures of who advise of a notification as well as towards the individual who may advise of a notification, while committing serious fraud or crime, since such notification has been proved as not well founded.

1.6 Codes of Conduct drawn up by the associations representing the bodies

Article 6, paragraph 3, del Legislative Decree 231/2001 provides that “the organisational and management models may be adopted, by guaranteeing that the requirements set out in paragraph 2 are met, on the basis of codes of conduct drawn up by the associations representing the bodies, notified to the Ministry of Justice which, in concert with the competent ministries, may, within thirty days, draw up observations on the suitability of models designed to prevent offences” This Model was drawn up in keeping with the instructions contained in the guidelines drawn up (and updated in 2004) by Confindustria, and approved by the Ministry of Justice, and in line with the indication provided by Farmindustria.

2. The Organisation, Management, and Control Model adopted by Kedrion S.p.A.

2.1 Kedrion S.p.A.'s field of activity

Kedrion is an international company that collects and fractionates blood plasma to produce and distribute plasma-derived therapeutic products for use in treating serious diseases, disorders and conditions such as haemophilia and immune system deficiencies.

Kedrion was established in Italy in 2001, but the roots of the companies from which it was born stretch back several decades in the production of blood and plasma derived products. A primarily family-owned business, it places a high value not only on the welfare of those who benefit from its products but also on the people and communities where it operates.

Kedrion Biopharma has a long history of collaboration with the Italian National Health System, and partners the country in its move toward self-sufficiency in plasma-derived products.

At the same time, the company brought this experience and the dedication to that goal to potential partners around the world. In recent years Kedrion has expanded its operations into the United States , Germany and Hungary as well. It now has a market presence in about 100 countries, in Asia, Europe, and North and South America. In addition, it has acquired collection and production capacity as well as the rights to significant products for treating haemophilia and preventing Rh sensitization, a condition which can lead to Haemolytic Disease of the Foetus and the Newborn (HDFN).

Kedrion looks forward to continued expansion and the wider sharing of its experience, know-how and technology to foster self-sufficiency of plasma-derived products in healthcare systems and communities around the world and to bring healthier and less restricted lives to people suffering from rare disorders.

Kedrion produces wealth for investors, employees and for the local community, consistently with its own vision and values: responsibility, transparency, confidence in and respect for people.

Kedrion's activities include:

- **Production and distribution:** Kedrion collects and fractionates blood plasma to produce plasma-derived therapeutic products and virus-inactivated plasma. These products are also distributed by Kedrion.
- **Contract manufacturing:** in collaboration with the National Health Services, Kedrion receives plasma from Regions and transforms it into the therapeutic products which are then redistributed to the Regions to meet local therapeutic needs (as part of a project to reach national self-sufficiency in the availability of plasma-derived products, produced with plasma from Italian donors).
- **Technology transfer:** Kedrion transfers its expertise and technology to produce (specific products or full product lines) and establish or renovate production lines or fractionation services. The services offered to clients may include plant design and construction, support for authorisation and start-up, personnel training, etc.

2.2 Vision, Mission, and Ethical Values of Kedrion S.p.A.

Everyone has the right to life, liberty and security of person.

Sometimes, natural, accidental or social causes obstruct the natural right to life, liberty and personal security. Because of the special nature of its products, Kedrion supports people, communities and institutions in reducing or removing those obstacles that prevent people enjoying such rights.

Kedrion helps turn the natural rights (life, liberty, security) into the social right to live in the best possible conditions. For this reason, it collects and converts, makes active and usable that vital energy that is generated and regenerated, preserved and carried through blood; so that it can be transferred from one human being to the next, and anyone can enjoy one's fundamental rights.

Kedrion contributes to the production and distribution of human plasma-derived medicinal products used to treat and prevent rare and debilitating diseases and disorders. Kedrion works to maintain excellent industry standards and aspires to ongoing improvement, in order to retain a leading position in Italy and to increase its share of the international market. It works to strengthen its role as the accredited partner of the medical, scientific and institutional communities.

Kedrion's ambition is to enhance its worldwide role as a strategic partner of the national health systems of those countries which aim to become self-sufficient in the availability of plasma-derived products, also via technology transfer. Kedrion produces wealth for investors, employees and for the local community, consistently with its own vision and values: responsibility, transparency, confidence in and respect for people.

Kedrion is committed to:

- Making social responsibility the guiding value underlying the Company's actions;
- Ensuring transparent and comprehensive information in its relationship with stakeholders;
- Making sure the trust given to, and within the company, is constantly strengthened by competent, honest, and conscious actions.
- Demonstrating care and respect towards people, by a continuous emphasis to the safety and quality of its products and services.

2.3 Corporate structure and governance of Kedrion S.p.A.

Kedrion S.p.A. has adopted a traditional management system, structured around the following bodies:

- **Board of Directors** (hereinafter also "BoD"): the Company's bylaws entrust the management of the Company to a number of directors between nine and eleven. Currently the board of directors includes eleven members. Within the BoD, the following offices are appointed: Chairman, Deputy Chairman, and Chief Executive Officer.
- **Board of Auditors and statutory auditor**: the Company's bylaws require the presence of a board of directors with five standing members and three alternative members. The statutory auditing is carried out by an auditing firm.

The Company has implemented a **specific system to authorise expenditures** and a **signature powers system**, under which only the individuals formally granted specific powers may take any commitment towards third parties in name or on behalf of the Company.

On this regard, in general, the Company acknowledges the following guidelines respecting its authorisation system:

- **Powers regarding "single deals"** are granted through *ad hoc* instruments, conferred through notarised powers of attorney, or other forms of delegation of power with respect to the scope thereof;

- **“Permanent representation” powers** are granted through notarised powers of attorney registered with specific reference to the exercise of permanent responsibilities within the Company’s organisation. Such powers of attorney are conferred exclusively with respect to the performance of organisational roles entailing representative needs. The conferral of such powers is thus determined by keeping into account the organisational responsibilities formally attributed to the structure headed by the individual with power of attorney, and the actual need for said individual to be granted representative powers towards third parties.

2.4 Adoption of the Organisation, Management and Control Model

The Board of Directors of Kedrion S.p.A., being aware of the importance of guaranteeing conditions of correctness and transparency in carrying out its business activities and corporate activities, has decided to implement the Organisation, Management, and Control Model in line with the Decree, approving its Model.

This decision was taken with the conviction that the adoption of the Organisation, Management, and Control Model – though the Decree indicates the adoption thereof as optional and not mandatory – may constitute a valid tool to raise awareness among the individuals who act in name and on behalf of the Company, prompting them to act, in the performance of their activities, with honesty and transparency, so as to prevent the risk of commission of any offence, particularly the offences contemplated in the Decree.

On this regard, the Company stresses its non-tolerance to any unlawful conduct of any kind, irrespective of the purposes thereof, as such conducts – even where they may seem to bring some form of benefit to Company – are nonetheless contrary to its ethical principles, by which the Company intends to abide as it carries out its corporate mission.

The Model was drawn up and later updated, keeping into account, in addition to the provisions of the Decree and the government’s report attached thereto, also the guidelines issued by Confindustria, and Farindustria’s Code of Professional Practice (updated in 2014).

The Model constitutes an “instrument issued by the senior executive organ”, pursuant to Article 6, paragraph 1, letter a) of Legislative Decree n. 231/2001. Therefore, any modification and addition to the Organisation, Management, and Control Model are a prerogative of the Board of Directors of Kedrion S.p.A.

2.5 Structure of the Organisation, Management, and Control Model

This Organisation, Management, and Control Model is constituted by a General Part and single Special Parts, each drawn up with respect to sensitive activities, relevant under Legislative Decree 231.

Before drawing up and updating of the Model, the Company carried out a corporate risk assessment in connection with a review of the main internal management processes in the “sensitive” areas. Each Special Part is aimed at regulating the conducts of the Recipients in the areas deemed to be potentially at risk, with respect to the various types of criminal offences relevant under Legislative Decree 231/2001.

Each Special Part thus includes the description of the areas and processes exposed to the risk of commission of 231 Crimes, detailing the types of crimes that potentially apply. In addition, for each area are listed the specific principles and rules of conduct the Recipients must abide by.

The Company's Organisation, Management, and Control Model and the documents and provision of law that are a part thereof must be constantly be kept updated by the Board of Directors, in close cooperation with the Surveillance Body.

The General Part and the Special Parts of the Model shall be constantly monitored, adjusted, and reviewed by the Surveillance Body, following any changes in the legal framework that may be introduced from time to time, and any organisational changes deriving from any strategic modifications decided by the senior executive body.

3. The Code of Ethics

Kedrion has adopted a Code of Ethics to highlight the **fundamental ethical values** it aspires to and which all employees and external collaborators (consultants, agents, providers of services) abide by in the performance of the tasks and roles they have been assigned. **The Principles contained in the Code of Ethics apply to all employees, administrators, corporate bodies, and external collaborators.**

Given the range of social – economic interests and sectors in which the Company operates, combined with its organisational procedures, everyone must strive to ensure that the activities of the Company are carried out in strict observation of current legislation, in a framework of fair competition, with honesty, integrity, correctness and good faith, in respect of the legitimate interests of clients, employees, commercial and financial partners and Communities in which the Company is actively present.

It is necessary therefore that all those who work for Kedrion or act in the pursuit of its objectives are reminded of the importance of upholding these Principles when carrying out their own individual roles, responsibilities, duties and tasks.

The conviction that one is acting for the good of Kedrion in no way justifies their behaviour which is in contrast with these Principles.

Adherence to the rules set out in the Code of Ethics is an integral part of the contractual obligations of all the employees and external collaborators of the Company, pursuant to and for all purposes of law.

As such, the Code of Ethics is handed to all the employees and collaborators, and signed in acceptance thereof. The Code of Ethics is attached to this Model (Annex 2).

4. Mapping of Risk Areas

4.1 Foreword

Article 6, paragraph 2, letter a) of Legislative Decree 231/2001 expressly provides that the organisation and management models must “**identify the activities in relation to which offences may be committed**”. For this reason, Kedrion analysed the company’s activities, the decision-making and implementing processes within each corporate area, and the internal control systems, to locate the **areas that are most “susceptible” to the risk of commission of the crimes provided under Legislative Decree 231/2001**.

Such analysis was carried out also through the assistance of external consultants, by examining company documentation (activity carried out, key processes, organizational charts, powers of attorney, organisational provisions, etc.), and by interviewing the individuals in charge of the various corporate structures. The process of analysis and the drawing up of the Model was developed in various phases and in a way such as to enable the tracing of the activity carried out.

The Company:

- 1) **Identified the corporate activities** in relation to which Administrative Crimes and Wrongful Acts may be committed;
- 2) **Identified the persons and corporate functions** involved in the performance of such activities;
- 3) **Analysed the potential risks**, as well as the potential and possible manners in which the wrongful acts may be committed;
- 4) **Defined**, and, where needed, adjusted **the internal controls system**.

4.2 List of the processes / corporate areas at risk

Following the above analysis, the following areas susceptible to risk were identified:

- Management, coordination and performance of the business activity of which the BoD is in charge;
- Administration, Finance, and Company Secretarial services
- Human Resources
- Sales and Marketing
- Procurement
- Gifts and Entertainment Expenses
- Legal and Privacy Management
- Social Responsibility (Ethics Officer)
- Logistics
- *Information technology*
- Insider Information
- Production and Quality Control
- *Product development*
- Relationship with the Public Administration and Certification Bodies
- Health and Safety in the Workplace
- Environmental protection
- Management of tax obligations and relations with competent public authority

4.3 List of applicable crimes

Regarding the areas identified, and their potential risk profile, Kedrion decided to **regulate their processes with respect to the following specific types of Crimes and Offences** provided under the Decree:

- Crimes against the Public Administration - Articles 24 and 25 Legislative Decree 231/2001
- IT-related felonies and unlawful processing of data - Article 24-*bis* Legislative Decree 231/2001
- Felonies committed by criminal organisations - Article 24-*ter* Legislative Decree 231/2001)
- Transnational crimes - Article 10 Law No. 146/2006
- Crimes concerning the forgery of money, money values having legal tender or revenue stamps and instruments or identification signs - Article 25-*bis* Legislative Decree 231/2001
- Felonies against industry and commerce - Article 25-*bis*.1 Legislative Decree 231/2001
- Corporate offences - Article 25-*ter* Legislative Decree 231/2001
- Felonies committed for purposes of terrorism or felonies designed to subvert democracy - Article 25-*quater* Legislative Decree 231/2001
- Felonies against individual's freedoms - Article 25-*quinquies* Legislative Decree 231/2001
- Offences of abuse of privileged information and market manipulation - Article 25-*sexies* Legislative Decree 231/2001; Articles 187-*bis*, 187-*ter*, 187-*quinquies* T.U.F.
- Manslaughter or serious bodily harm committed with breach of laws governing the safeguarding of workplace health and safety - Article 25-*septies* Legislative Decree 231/2001
- Handling stolen goods, laundering and use of money, assets or benefits whose origin is illegal, and self-laundering - Article 25-*octies* Legislative Decree 231/2001
- Felonies regarding breach of copyright - Article 25-*novies* Legislative Decree 231/2001
- Inducements not to make statements or to make false statements to the courts - Article 25-*decies* Legislative Decree 231/2001
- Environmental crimes - Article 25-*undecies* Legislative Decree 231/2001
- Employment of third-country nationals without regular stay permit - Article 25-*duodecies* Legislative Decree 231/2001
- Tax offenses (Article 25-*quinquiesdecies* of Legislative Decree 231/2001)
- Contraband (Article 25-*sexiesdecies* of Legislative Decree 231/2001)

5. Surveillance Body

Article 6 of Legislative Decree 231/2001 provides that the Company may be exonerated from any liability deriving from the commission of the crimes therein indicated where the senior executive organ has, among others, delegated the task of **overseeing the operation and compliance with the Model** and of **seeing to updating of the same to an organisation within the company vested with powers to act on its own initiative and conduct monitoring**;

The delegation of such tasks to the Surveillance Body is an **indispensable requirement to be exonerated from liability**, whether the crime is committed by the so-called “senior officers” (expressly contemplated in Article 6), or by the persons subject to the direction of others (as per Article 7).

Article 7, paragraph 4, stresses the fact that the effective implementation of the Model requires, in addition to the creation of a disciplinary system (see Chapter 7), also the periodic monitoring thereof by the body entrusted with such duties.

5.1 Establishment of the Surveillance Body

The Board of Directors of Kedrion S.p.A., implementing the provisions of the Decree, created the Surveillance and Monitoring Body (hereinafter, also referred to as the “SB”), entrusted with the task of monitoring the operation of and compliance with the Model, and to see to its updating. The Surveillance Body of Kedrion S.p.A. is thus in charge of the oversight and control activities provided in the Model.

The appointment of the SB, and its removal (for just cause) are within the sphere of competence of the Board of Directors. The SB reports directly to the Board of Directors.

Furthermore, by approving the Model, the Board of Directors of the Company regulates the primary interest elements concerning the Surveillance Body, including:

- the number of members and the composition of the SB;
- the process of appointment and the duration of the office;
- the causes of ineligibility and dismissal of the SB and its single members;
- the causes and the process to revoke the appointment of the SB and its single members;
- the duties and powers of the SB;
- the resources assigned to the SB;
- the flows of information (from the SB to the corporate bodies and resources, and towards the SB)
- the principles of ethics that regulate the activity of the SB;
- the sphere of accountability of the members of the SB.

According to the provisions of Legislative Decree 231/2001 (Articles 6 and 7) and the instructions contained in the accompanying Report to Legislative Decree 231/2001, the SB must have the following characteristics:

1) **Autonomy and independence**

The requirements of autonomy and independence are fundamental for the SB not to be directly involved in the management activities that are subject to the SB’s surveillance.

Such requirements may be obtained by granting the SB the highest possible degree of hierarchical independence, and by requiring the SB to report directly to the Senior Executive Organ, or in other words, to the Board of Directors.

2) Professionalism

The members of the SB must have the technical-professional competences suitable for the tasks it is called to perform. Such characteristics, together with independence, ensure objectivity of judgment.

3) Ongoing action

The SB must:

- be constantly engaged in overseeing the Model through the necessary investigation powers;
- be an “internal” structure, so as to ensure continuity of the oversight activity;
- see to the implementation of the Model and ensure its constant updating;
- never carry out operating tasks which may condition the overall vision of the corporate activities that the SB is required to maintain.

5.2 Appointment and Composition of the Surveillance Body

The Board of Directors of the Company appointed the SB as indicated in the Decree, in compliance with the provisions contained in Confindustria’s Guidelines. In particular, as resolved by the Board of Directors, the SB, established within the Company, is a **multi-member body**, held to report to the Company’s top management.

The composition of the Surveillance Body and the identification of the knowledge and expertise required of such body are within the scope of competence of the Board of Directors, who appoints and revokes the appointment of the Surveillance Body by resolution.

In compliance with the provisions of the Decree and the above Guidelines, the SB of the Company meets the following requirements:

- **Autonomy and independence:** the SB must be ensured full autonomy, including financial, from the members of the top management, being established as a structure placed at the top of the corporate hierarchy, unconnected and autonomous from the other bodies and functions of the company. The Surveillance Body, furthermore, reports directly to the senior executive organ. For the purpose of ensuring the autonomy and independence of the SB, its members may be either internal or external, who are not linked to the Company’s senior executive organ under any hierarchical subordination. In the event of a multi-member body, upon their appointment, the Chairman of the SB must not be affiliated in any way whatsoever to the company under any employment agreement or subordination of any kind, or hold any executive offices within the company. The Surveillance Body is provided the financial and logistic means to ensure its ordinary operation.
- **professionalism:** intended as a set of tools and skills required to carry out the activity assigned, including with respect to inspections or consulting competence;
- **ongoing action:** in order to ensure an effective and constant implementation of the Model, the structure of the SB is exclusively dedicated to the oversight activities on a full-time basis;
- **respectability and absence of conflicts of interest:** intended as defined under the Law with reference to directors and members of the Board of Auditors.

The members of the Surveillance Body are in office for a term of three years and may be re-elected. Their replacement prior to the expiry of their term of office may only occur for just cause or justified reason, such as, by way of example,

- 1) voluntary renunciation by the member of the SB;
- 2) supervening incapacity to perform the duties assigned due to natural causes;
- 3) loss of the requirement of respectability;
- 4) non-attendance of two or more meetings, including non-consecutive, without a justified reason within a period of 12 months;
- 5) failure, on the part of the member of the SB, to inform the Board of Directors of the grounds for dismissal from office as detailed under Paragraph 3.3 below;
- 6) occurrence of one of the causes for suspension or revocation as per paragraph 3.3. below.

The Board of Directors establishes, for the entire duration of the term of office, the annual remuneration payable to the members of the Surveillance Body.

5.3 Causes of (in)eligibility, discharge, suspension, and revocation of the members of the Surveillance Body

The members of the Surveillance Body must meet the **respectability requirements** provided under Article 109 of Legislative Decree No. 385 of 1 September 1993. In particular, appointment to the Surveillance Body is barred to any of the persons in the conditions provided under Article 2382 of the Civil Code.

Appointment to the Surveillance Body is also barred to any person who has been sentenced, with a judgment that has become final and enforceable, including when issued under Articles 444 et. seq. of the Code of Criminal Procedure, and including if their sentence has been conditionally suspended, without prejudice to the effects of rehabilitation:

- to incarceration for a term of no less than a year for one of the crimes provided under Royal Decree No. 267 of 16 March 1942;
- to a custodial sentence for a term of no less than a year for one of the crimes provided under the laws regulating the banking, financial, securities, and insurance activities, and under the laws respecting markets and transferable securities and payment instruments;
- to incarceration for a term of no less than a year for a crime against the public administration, against public trust, against property, and against public economy, and for a fiscal crime;
- for any crime committed with intent, to a custodial sentence for a time of no less than two years;
- for any of the crimes provided under Title XI of Book V of the Civil Code, as re-worded into Legislative Decree No. 61/2002;
- for a crime which results and has resulted in the sentence of a punishment leading to disqualification, even temporary, from public offices, or temporary disqualification from the managerial posts with corporations and businesses;
- for one or more crimes including those expressly provided for in Legislative Decree 231/2001, including those entailing lesser penalties than those indicated in the points above;
- persons who have held the position of members of the Surveillance Body within companies against which have been applied the penalties detailed under Article 9 of Legislative Decree 231/2001;

- persons against whom has been applied one of the preventive measures provided under Article 10, paragraph 3 of Law No. 575 of 31 May 1965, as replaced by Article 3 of Law Mo. 55 of 19 March 1990, as amended;
- persons against whom have been applied the accessory administrative penalties provided under Article 187-*quater* of Legislative Decree No. 58/1998.

The **candidates** to the office of member of the Surveillance Body must submit a **personal sworn declaration in lieu of affidavit** that they are under any of the condition listed above from point 1 to 10, expressly undertaking to communicate any variation to the content of such declaration.

The members of the Surveillance Body **are dismissed from office** as of the moment when they are in the following conditions after their appointment:

- a) in one of the situations contemplated in Article 2399 of the Civil Code;
- b) they have been convicted by final judgment (including also a conviction pronounced under the terms of Article 444 of the Code of Criminal Procedure) for one of the crimes indicated under points 1, 2, 3, 4, 5, 6, and 7 of the conditions for ineligibility indicated above;
- c) in a situation where, after their appointment, a candidate is found to have held the office of member of the Surveillance Body within a company against which have been applied the penalties provided under Article 9 of Legislative Decree No. 231/2001 on account of administrative offences committed during their term of office.

The following constitute **causes of suspension or revocation** from the office of member of the Surveillance Body:

- a) conviction by a sentence subject to appeal for one of the crimes listed under points from 1 to 7 of the condition for ineligibility indicated above;
- b) application, on request of the parties, of one of the penalties listed under points from 1 to 7 of the condition for ineligibility indicated above;
- c) application of a pre-trial detention measure;
- d) provisional application of one of the pre-trial detention measures provided under Article 10, paragraph 3, of Law No. 575 of 31 May 1965, as replaced by Article 3 of Law Mo. 55 of 19 March 1990, as amended;
- e) where the Board of Directors has ascertained that such member of the SB performed the tasks assigned as per paragraph 7.1 above with negligence, incompetence or serious misconduct, and particularly, where they were found to have detected and consequently disregarded violations of the Model, or, in more serious cases, where they were found to have committed criminal offences.

In case of a Surveillance Body formed by one internal member (an employee or executive officer of the Company), the revocation is applicable also in case of termination of their work agreement with the company.

5.4 Duties and Powers

The Surveillance Body defines and performs the activities within its sphere of competence in line with the principle of collegiality, when a multi-member body, and is vested, as provided under Article 6, paragraph 1, letter b), of Legislative Decree 231/2001, “with powers to act on its own initiative and conduct monitoring”.

In compliance with the provisions of Article 6, paragraph 1 of the Decree, the Company's SB is assigned the task of overseeing the operation and compliance with the Organisation, Management and Control Model, and seeing to the updating thereof.

In general, the SB is assigned the following tasks:

1) **Oversight and Monitoring of the Model**, meaning:

- ensuring the fitness of the Model, or in other words, its suitability to prevent the occurrence of unlawful conducts, and to call attention to the commission thereof;
- ensuring that the Model is effective, or in other words, that there is a correspondence between actual conducts and the conducts formally envisioned in the Model;
- monitoring corporate activities by conducting periodic checks and follow-ups.

2) **Updating of the Model**, or, in other words, seeing to the updating of the Model by offering the Board of Directors, where necessary, proposals on the updating thereof, in order to improve the suitability and effectiveness thereof, including in consideration of any intervening provisions of law and/or variations in the corporate structure or the corporate business and/or when detecting significant violation of the Model.

3) **Information and Training on the Model**, meaning:

- Promoting and monitoring the initiatives aimed at advancing the diffusion of the Model with all the persons held to comply with the provisions thereof;
- Promoting and monitoring the initiatives, including training courses and communications, aimed at furthering an adequate knowledge of the Model by all the Recipients;
- Provide responses, with the appropriate speed, including by drafting memoranda, to the requests for clarifications and/or for advice submitted by the corporate functions or single resources, or by the company's administrative or control bodies, when connected and/or linked to the Model.

4) **Management of the flows of information to and from the SB**, or in other words,

- Ensuring the correct performance, by the interested persons, of all the reporting tasks concerning the compliance with the Model;
- Examining and assessing all the information and/or reports received and connected with the compliance with the Model, including also with respect to any violation thereof;
- Informing the competent bodies, as detailed below, on the activities carried out, the results obtained, and the planned activities;
- Reporting to the competent bodies, for the adoption of opportune measures, any violation of the Model and the names of the authors thereof, submitting proposals on the penalties deemed most opportune for each case;
- In the event of inspections by institutional bodies, including the Public Authorities, provide all the necessary information and assistance to such inspection bodies.

To perform the tasks assigned, the **SB is vested with the necessary powers to ensure timely and effective oversight** over the operation of and compliance with the Model.

The SB shall have the authority, including through the resources at its disposal, (by way of example):

- To carry out, including unannounced, any audit and inspection deemed opportune for the purpose of the correct performance of the duties assigned;
- To be granted free access to all the functions, archives, and documents of the Company, without requiring a prior consent or without the need of any authorisation, in order to obtain every piece of information, datum, or document deemed necessary;
- To require all the employees and collaborators to provide additional information on aspects connected with the application of the Model, and information concerning the performance of the company's activities;
- To use the assistance, under the SB's supervision and responsibility, of all the structures of the Company, or of external consultants;
- To have at its disposal, for any requirement necessary for the correct performance of its tasks, all the financial resources allocated by the Board of Directors.

5.5 Checks to verify the effective and constant updating of the Model, and Action Plan

In coordination with the heads of the Functions interested from time to time, the SB must periodically check that the Model is effective and suitable to prevent the commission of the unlawful acts detailed in the Special Parts. In particular, the SB shall carry out:

- 1) **Review of single instruments.** To this end, the SB shall periodically check the instruments and agreements relating to the processes at risk, in the manners established by the SB;
- 2) **Review of protocols.** To this end, the SB shall periodically carry out checks on the effectiveness and implementation of the protocols provide in this Model;
- 3) **Assessment of the degree of knowledge of the Model,** including by analysing the requests for clarifications or the reports received;
- 4) **Periodic updating of Risk Assessment activities,** aimed at reviewing the map of the activities potentially at risk, and particularly the presence of changes within the organisation or business of Kedrion S.p.A., or in case of additions to or amendments of the Decree.

For the purposes of a planned exercise of the oversight powers of which it is vested, every six months the SB submits to the Board of Directors an **Action Plan for the following six months**, detailing the activities to be carried out and the areas to be subject to checks and audits. The Surveillance body may in any case carry out, within the scope of sensitive corporate activities, and whenever it deems it necessary in order to perform the duties assigned, unscheduled checks, not included in the Action Plan (so called "surprise checks").

In implementing the Action Plan, the SB adopts procedures useful to carry out its assigned supervisory and monitoring duties, which shall be communicated to the functions interested, and may establish work groups on specific topics. In special circumstances (such as detection of prior violations or a high turnover), the SB shall apply systematic procedures to research and identify the risks being analysed.

Following the checks carried out, the SB may report its observations and/or suggestions to the Functions interested from time to time.

The activity carried out by the SB must be documented, including in summary form. The relating documentation must be kept by the SB, so as to ensure the confidentiality thereof, in compliance with the laws regulating the protection of personal data.

On account of the checks performed, of intervening modifications in the legal framework applicable, and the possible arising of new processes at risk, the SB submits the amendments and updates to the Model deemed most opportune to the competent bodies.

5.6 Regulation of the Surveillance Body

As an integration of the provisions included in this Model, the SB also has an internal regulation (Annex 3) to regulate the material aspects and manners in which to perform its duties, including also respecting the SB/s organisational and operating system.

The regulation provides guidelines on the following areas:

- The type of monitoring and oversight activities carried out by the SB;
- The type of activities connected with the updating of the Model;
- The activities connected with the performance of the information and training activities aimed at the Model's recipients;
- The management of the information flows to and from the SB;
- The operation and internal organisation of the SB (e.g., call and decision of the Body, meeting records, etc.)

5.7 Information obligations towards the SB

The system to convey information to the SB is aimed at **making the information necessary to prevent the crimes defined in the Decree available to the Surveillance Body, within reasonable time-frames**. Said information system consists in identifying rules to generate, access, and report information functional to the effective monitoring of the sensitive activities identified in the Model.

All the Recipients of this Model have the **obligation to promptly report to the SB** the following information (where present):

- 1) the commission or attempted commission of unlawful acts under Legislative Decree 231/2001;
- 2) violations of the rules of conduct and operation set forth in the Model, which may come, either directly or indirectly, to the attention of the Recipients;
- 3) in any case, any act, fact, event, or omission detected or observed in the exercise of the responsibilities and tasks assigned, relevant to the provisions of Legislative Decree 231/2001.
- 4) observations on the suitability of the system, highlighting the shortcomings detected;
- 5) any exception to ordinary conduct or any unusual event, indicating the reasons for such divergence, and relating the alternative course of action followed.

In order to regulate and detail the reporting of flows of information to the SB, a specific procedure was set up (Flows of Information and notification of violations to the SB - Annex 4)

The above procedure reinforces the contents of the Code of Ethics, particularly with respect to the processes through which the Recipients of the Model send their reports, and how the Company manages such report through the SB.

5.8 Processing of Reports

The Surveillance Body **carries out the required investigations** in order to ascertain the validity and accuracy of the reports received, confirming the existence of clues that unambiguously corroborate the non-compliance, on the part of the persons reported, with the procedures contained in the Model or the rules of conduct expressed in the Code of Ethics, or the holding of conducts liable to produce, including potentially, one of the crimes detailed under Legislative Decree 231/2001.

In conducting the investigation, the Surveillance Body may hear, if required, the author of the report and/or the author of the alleged violation rather than fulfilling any other kind of investigation, which is deemed as necessary in order to verify the trustworthiness of the notification.

Should the SB decide not to act on the report, it must detail in writing the reasons that prompted the decision to file the case.

Any report on violations of the Organisation, Management, and Control Model, or in any way deriving from conducts not in line with the rules of conduct adopted by the Company, are filed, by the Surveillance Body, in a dedicated archive, accessible exclusively to the Surveillance Body.

When the SB has ascertained the commission of violations, it identifies the measures that should be adopted, in compliance with the process to notify violations, and issue disciplinary measures, provided in the disciplinary system. To this end, the Surveillance Body is not vested with coercive powers, but it rather coordinates its action with the company's top management.

The head of Human Resources must keep the Surveillance Body informed, on a monthly basis, of the number of disciplinary procedures open with respect to violation reports, of the disciplinary measures adopted, and of the disciplinary procedures having been closed, indicating, in the latter case, the reasons why the case was closed.

The **personal data** acquired by the Surveillance Body, by the head of Human Resources, by the Legal Offices, or by any of the functions interested from time to time, including **sensitive or legal data, shall be processed** in line with the laws and regulation for the protection of private information.

5.9 Reporting by the Surveillance Body to the corporate bodies

The SB **reports directly to the Board of Directors** with respect to issues relating to the Model.

The SB **informs, including in writing, the Board of Directors on the application and the effectiveness of the Model at least on six-monthly basis** (detailing the checks carried out and the results thereof, and the updating of the processes at risk), or may submit reports at different times with respect to specific or significant circumstances.

The SB may be called by the Board of Directors to report on its activity, and may request to confer with the Board of Directors. The SB may also request to be heard by the Board of Directors any time it may deem it opportune to promptly report on violations of the Model or call attention to critical aspects concerning the operation of the Model.

The SB is in responsible for providing clarifications on matters of interpretation or questions concerning the Model.

6. Drawing up and distribution of the Model

The effective implementation of this Model relies on its **adequate distribution and** on the **knowledge of its contents** on the part of the Company's employees and interested third parties.

To this end, in collaboration with the competent corporate functions, the Surveillance Body designs **information and training programs**, providing a more or less detailed study of the Model in accordance with the Recipients' level of involvement in the activities at risk.

In general, the Surveillance Body:

- defines the contents of the **periodic communications** to be transmitted to the corporate bodies and employees, to provide them the necessary awareness and basic knowledge of the Decree;
- promotes **training courses** on Legislative Decree No. 231/2001;
- in collaboration with the function entrusted with updating the **corporate website**, designs and updates the company's intranet section dedicated to Legislative Decree No. 231/2001;
- promotes appropriate **actions suitable to advance the knowledge and understanding** of the Model;
- draws up the **organisational documents** containing instructions, clarifications or updates with respect to the operation of the Model.

6.1 Communication to the members of the corporate bodies

The Organization, Management, and Control Model is **formally sent to each member of the corporate bodies**, who signs a **declaration acknowledging to have read and to subscribe** to the Model, which is then filed by the Surveillance Body.

6.2 Initial communication to the employees

The adoption of this Model and its subsequent updates are communicated **to all the employed members of staff and to the members of the senior executive organ** working for the Company at the time the Model is adopted or when the Model is updated, and to all the heads of the areas at risk.

Every time the Model is **modified or updated**, the Surveillance Body shall send all the Recipients, or only the recipients directly involved with the updates, **information detailing the modifications made** and their impact over the company's operations. The process of such information and the level of detail thereof shall be specified by the Surveillance Body with respect to the type and scope of the modifications.

Newly hired members of staff and members of the senior executive organ receive communication on the adoption of the Model. By signing a dedicated form, the newly hired members of staff undertake to comply with the principles, rules, and procedures contained in the Model in the performance of their tasks within the areas with relevance to Legislative Decree 231/2001 and in any other activity that may be carried out in the interest or to the advantage of the Company.

6.3 Training

The **training activities aimed at promoting the knowledge of the legal framework** provided under Legislative Decree No. 231/2001 is differentiated, in terms of contents and method, according to the position held by the Recipients, the level of risk of the areas in which they operate, and according to whether or not they act as representatives of the Company.

The SB is in charge of designing and periodically submitting to the Board of Directors a Training Plan, detailing the contents of the training courses, the course method (on-line or classroom based), how often they will be offered, and the method for checking the recipients' attendance. Attendance to courses shall be mandatory for recipients, and non-attendance without a justified reason may be deemed by the SB as a violation of the Model.

Newly hired members of staff operating in the areas with at-risk activities, shall be offered targeted training courses (on-line or classroom based).

6.4 Other forms of communication to the staff

The full text of the Model is made available to all the members of staff in a dedicated section of the **Company's Intranet**.

The General Part of the Model is published on the Company's **Website**.

6.5 Information to consultants, suppliers and collaborators

The Company promotes the knowledge of and compliance with the Model including among its financial and commercial partners, consultants, collaborators of all types, clients, and suppliers.

These recipients shall be therefore provided specific **information on the principles, policies, and procedures adopted by the Company based on this Model**, and the texts of the contractual provision which, in line with said principles, policies, and procedures, shall be adopted by the Company, and whose acceptance is required of all such recipients.

7. Disciplinary System

In line with the provisions of Article 6, paragraph 2, letter e) and of Article 7, paragraph 4, letter b) of Legislative Decree 231/2001, the Company adopted a specific disciplinary system (Complementary Disciplinary System under Legislative Decree 231/2001 – Annex 5) suitable to **punish the conducts that violate the provisions contained in the Model.**

The disciplinary system is aimed at punishing the **non-compliance with the principles and obligations of conduct and the protocols provided in the Model**, and, pursuant to Article 2106 of the Civil Code, **it incorporates, for any matter not expressly provided and limited to the cases contemplated therein, the National Collective Bargaining Agreements (CCNL)** applicable to each category of staff employed by the Company.

The disciplinary system **is eminently internal to the Company**, and it may not be deemed to replace, but rather to add to the provision of law and regulations applicable, and it is complimentary to the other intra-company policies, including disciplinary regulations.

The violations to the Model punishable under the disciplinary system are those perpetrated by persons in “senior executive” positions, by persons subject to the direction and oversight of others, and by those who act in name and/or on behalf of the Company.

Disciplinary processes are brought, and the punishments provided in the disciplinary system are applied irrespective of any other proceedings being brought and/or of any outcome of other proceedings respecting the same conducts having relevance for the purpose of this disciplinary system.

7.1 Scope of application

This Disciplinary System applies to Directors, Auditors, members of staff of the auditing firm, members of the Surveillance Body, members of the “senior executive” body, and any other person holding a “senior executive” office, employees, and third-parties who have contractual relations and/or have entered into professional collaboration agreements with the Company.

All the Recipients must be informed as to the existence and contents of this Model. The Personnel Office shall be in charge, in collaboration with the Surveillance Body, to see to the distribution of the Model to such Recipients. The Company shall bring the Disciplinary System to the attention of all the members of staff holding Senior Executive, Executive, and Office and Manual Worker positions, and of all the recipients listed above, by posting a copy of thereof in the Company’s noticeboards, in a location accessible to all, and by publishing it on the Company’s Intranet.

A copy of this Disciplinary System shall be handed to newly hired employees together with their work agreement. The Code of Ethics shall also be handed to all newly hired members of staff. The members of staff receiving such copy shall sign a receipt.

When an updated version of the Model is implemented, the members of staff are fully informed of such modifications through a service order, together with the Disciplinary System and the Code of Ethics, sent electronically to all members of staff, with the specification that the Disciplinary System shall be applicable alongside with the disciplinary system provided in the sector-specific national collective bargaining agreement.

Under the combined provisions of Articles 5, letter b) and 7 of the Decree, punishments may be applied against the person carrying out any unlawful act deriving from:

- 1) **Non-compliance with the provisions** of the Model;
- 2) **Lack of evidence, or false evidence of the activities carried out** with respect to the process for documenting and for keeping and monitoring actions, such as to prevent the transparency and verifiability of such actions;
- 3) **Lack of training and/or failure to provide updates and/or omitted communication** to the members of staff operating in the areas at risk, with respect to the processes interested by the Model;
- 4) **Violation and/or avoidance of the monitoring system** perpetrated by removing, destroying, or altering documentation, or by preventing the bodies appointed, including the Surveillance and Monitoring Body, to monitor or access information or documentation.
- 5) **violation of the measures created to guarantee the privacy of the person who does a warning**
- 6) The act by committing serious fraud or crime of doing warnings then proved as not well founded. (art. 6 subsection 2-bis, lett. d). 231/01 Legislative Decree

7.2 General Criteria for the application of disciplinary measures

For each single case, the type and scope of specific penalties shall be applied proportionally to the seriousness of the violations, and in any case, in consideration of the following elements:

- a) subjective element of conduct, whether negligent or wilful conduct (whether the conduct was carried out with intent or whether it was due to negligence, recklessness or incompetence – with respect also to the degree of predictability of the event);
- b) relevance of the obligations violated and level of hierarchical and/or technical responsibilities;
- c) presence of aggravating or mitigating circumstances, with respect to professional skills, prior working experience, and the circumstances in which the act was perpetrated;
- d) overall conduct of the worker, with particular attention to whether or not the worker has been subject to disciplinary proceedings in the past;
- e) whether or not the person who perpetrated the unlawful act shared responsibility with others who have played a role in such violation;
- f) conducts that may compromise, including potentially, the effectiveness of the Model.

The application of disciplinary measures, irrespective of whether or not criminal proceedings are brought, and/or irrespective of the results of such criminal proceedings, must be, as far as possible, inspired on the principle of timeliness and speed of action.

7.3 Disciplinary Measures Applicable

The Disciplinary System does not replace the disciplinary measures envisioned in the National Collective Bargaining Agreements, but it is directed exclusively to denouncing and punishing only **conducts not in line with the provisions of the Organisation, Management, and Control Model established pursuant to Legislative Decree 231/2001** and violations to the Company's operating procedures perpetrated by the above-identified individuals.

The disciplinary measures applicable in case of violations to the rules provided in the Model, listed in ascending order, according to their degree of seriousness,

- a) disciplinary measures **not entailing termination**:

- verbal reprimand or warning;
- written reprimand or warning;
- in case of repeated violation within one year of the written reprimand, or in case of a more serious violation of one or more of the rules provided in the Model, the worker incurs in a pecuniary penalty, consisting in a deduction from their wage, not exceeding an amount corresponding to three working hours;
- suspension from working duties without pay for a duration equivalent to the duration provided in the applicable national collective bargaining agreements;

b) disciplinary measures entailing **termination**:

- disciplinary dismissal on the grounds of serious breach of the contractual obligations undertaken by the worker;
- disciplinary dismissal on the grounds of a violation which seriousness is such as to prevent the continuation of employment including on a temporary basis.

7.4 Disciplinary Measures based on Category

The Disciplinary System differentiates the measures applicable based on the position held within the Company and on the responsibilities assigned, as outlined below.

Measures applicable to Directors, Auditors, members of the Surveillance Body, and of the auditing firm:

- written warning;
- formal warning and invitation to comply with the Model;
- removal from office.

Measures applicable to “senior executive” officers and other “executive” officers

- verbal warning;
- written warning;
- penalty fee up to the maximum sum provided in the National Collective Bargaining Agreement applicable;
- suspension from work duties without pay, up to the maximum duration provided under the applicable National Collective Bargaining Agreement;
- dismissal for justified subjective reasons, with notice;
- dismissal for just cause without notice.

Please note that for the individuals employed by the Company in an “executive” office, the following also constitute serious breaches of the provision of the Model for the purposes of determining a disciplinary measure applicable:

- noncompliance with the obligation to manage or supervise subordinate workers, concerning the correct and effective application of the Model;
- noncompliance with the obligation to manage or supervise other workers who, though not subordinate to the Company (including, by way of example, consultants, external collaborators, etc), are still subject to the management and supervision of the “senior executive” officer under Article 5 paragraph 1 letter b) of Legislative Decree 231/01.

Disciplinary measures against non-senior executive members of staff:

- verbal warning

- written warning or application of a penalty fee not exceeding a sum payable for three ordinary working hours , in case of repeated breach of the conducts referred to in the point above;
- penalty fee up to the maximum measure applicable under the National Collective Bargaining Agreement, or suspension from work duties without pay up to the maximum measure applicable under the National Collective Bargaining Agreement of reference, in case of repeated breach of the conducts referred to in the point above;
- dismissal, with or without notice;
- dismissal for just cause.

Penalties applicable to third party recipients:

- formal notice and invitation to comply with the Model;
- termination of the agreement in place with the Company (using the express termination clause contained in the agreement).

The Company reserves the right to claim compensation for the damages suffered in consequence of such conducts, including also any damages suffered by the Company as a consequence of the application, as decided by a court of law, of the measures provided under Legislative Decree No. 231/2001 against the Company.

7.5 Process to Ascertain Penalties

As to the process to ascertain the perpetration of violations, we must keep the same distinction already clarified in the foreword, between the persons employed by the Company under a work agreement, the other categories of parties that may be subject to penalties.

Among the former, the disciplinary procedure shall strictly be compliant with the process regulated under the “Workers’ Statute of Rights” (Law No. 300 of 1970) and under the applicable National Collective Bargaining Agreement adopted. To this end, with respect to the violation of the rules contained in the Model, the powers already conferred to the senior executive body and the head of the personnel office, within the limits of the respective spheres of competence, shall not be affected.

However, the Surveillance Body’s necessary involvement in the process to ascertain the perpetration of violations of the Model, and to determine the disciplinary measures or penalties applicable thereto, shall in any case be ensured. Therefore, no disciplinary procedure or disciplinary measure concerning the above violations may be filed without previously informing and obtaining the opinion of the Surveillance Body, including when the request to open such disciplinary process originates within the Surveillance Body.

8. Updating and Amending the Model

Legislative Decree 231/2001 expressly provides the **requirement to update the Organisation, Management and Control Model for the purpose of fine-tuning the contents thereof** to the specific needs of the Company and its operations. Any amendments to and/or updates of the Model shall be carried out essentially upon:

- **changes to the applicable legal framework;**
- **violations of the Model and/or negative results of the audits on its effectiveness** (which may be surmised also based on the experience of other companies);
- **changes to the Company’s organisational structure**, including deriving from extraordinary finance operations, or from changes in the business strategy upon entering new fields of activity

The Board of Directors passes resolutions on the updating of the Model and its amendments based on the changes and/or additions that may be deemed necessary.

Any events that would require amendments or updates of the Model must be reported in writing by the SB to the Board of Directors, so that the latter may pass the necessary resolutions within its sphere of competence.

The SB is kept informed on the updates and implementation of any new regulations or company policies, and has the right to express its opinion on the proposed changes.

Any substantive modification, concerning, by way of example, the introduction of new Special Parts or new protocols in corporate areas at risk, requires the previous approval of the Board of Directors of Kedrion S.p.A. Any non-substantive changes, including formal changes such as the aligning of protocols with new organisational provisions, may be made directly by the Chief Executive Officer, and ratified by the Board of Directors.

The Surveillance Body has the duty of “seeing to the updating” of the Model, or submitting invitations to make such updates, but shall not be in charge of the direct implementation thereof.

Proposals to modify, make additions to, or eliminate any of the procedures referred to in the Model and the procedures which, though not expressly mentioned, regulate the processes pertaining to the areas at risk (so-called Special Parts), must be submitted, by the competent Functions, to the scrutiny of the Surveillance Body.