Organization, Management, and Control Model

General Part

of

Mediberg S.r.l.

Calcinate, June 13, 2024

Glossary

- **Agent**: Collaborator of Mediberg S.r.l.; a natural or legal person linked to the company by an agency contract pursuant to Article 1742 and following of the Civil Code.
- **Register of pending charges for administrative offenses dependent on crime**: The set of data relating to judicial measures referring to entities with legal personality and to companies and associations, even without legal personality, to which administrative offenses dependent on crime have been contested pursuant to Legislative Decree 8 June 2001 n. 231.
- **Register of administrative sanctions dependent on crime**: The set of data relating to judicial measures that apply to entities with legal personality and to companies and associations, even without legal personality, pursuant to Legislative Decree 8 June 2001 n. 231. Article 80 of Legislative Decree n. 231/01 which provided for it has been repealed, but the related discipline can now be found in Articles 9 ff. of Presidential Decree 14 November 2002 n. 313 on the criminal record.
- **Top Executives**: Persons who perform representative, administrative, or managerial functions 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 same pursuant to Article 5, paragraph 1, letter a) of the Decree.
- **Risk Activities or Sensitive Activities (AS)**: Activities carried out by the company within which crimes referred to in Legislative Decree n. 231/2001 and any additions, as well as the transnational crimes indicated in Law 146 of 16 March 2006, as identified in the Special Part of the Model, can, in principle, be committed.
- **Public Supervisory Authorities**: By way of example but not limited to, the Public Supervisory Authorities are Consob, the Italian Stock Exchange, the Authority for Electricity and Gas, the Antitrust Authority, the Communications Authority, the Data Protection Authority.
- **Company**: Mediberg S.r.l.
- **C.C.**: Civil Code.
- **C.C.N.L.**: National Collective Labor Agreements stipulated by the most representative trade union associations for employees currently in force and applied by the company. In Mediberg S.r.l., the chemical-pharmaceutical industry contract is applied.
- **BoD**: Board of Directors.
- **C.P.**: Criminal Code.
- **Ethical Code**: Adopted by the company pursuant to Legislative Decree n. 231/01.
- **Responsibility**: Administrative responsibility to which the company may be subject in the event of the commission of one of the crimes provided for by

the Decree or by Law 146/06, responsibility which, if ascertained, entails the application of sanctions provided for by Legislative Decree n. 231/01.

- **Anonymous Report**: Any report in which the identity of the reporter is not disclosed nor traceable.
- **Malicious Report**: A report made solely to harm or otherwise prejudice a recipient of the Ethical Code and/or the Model.
- **Report**: Any information regarding alleged irregularities, violations, behaviors, and censurable facts, or any practice not compliant with what is established in the Ethical Code and/or the Model of Organization, Management, and Control, or any corporate news or event that may be relevant for the prevention or repression of illegal conduct.
- **SGQ**: Quality Management System.
- **SGA**: Environmental Management System.
- **Company**: Mediberg S.r.l.
- **Reporting Subjects**: Recipients of the Ethical Code and/or the Model, as well as any other subject that interacts with the company to make the report.
- **Reported Subjects**: Recipients of the Ethical Code and/or the Model who have committed alleged irregularities, violations, behaviors, and censurable facts, or any practice not compliant with what is established in the Ethical Code and/or the Model of Organization, Management, and Control.
- **Third Parties**: Counterparties of the company, whether natural or legal persons (such as suppliers, consultants, etc.), with whom the company engages in any form of contractually regulated collaboration intended to cooperate with the company in risk activities.
- **Subordinates**: Persons subjected to the direction or supervision of a Top Executive pursuant to Article 5, paragraph 1, letter b) of the Decree.
- **Stakeholders**: Natural or legal persons who have relationships with the company for any reason.
- **Statute**: Corporate Statute of the company.
- **U.O.**: Organizational Unit.

1 Legislative Decree 8 June 2001, No. 231

1.1 Administrative Responsibility of Entities

Legislative Decree 8 June 2001, No. 231 (hereinafter also referred to as the "Decree" or "Leg. Decree 231/01"), issued in execution of the Delegated Law referred to in Law No. 300/2000, introduced into our legal system the regime of "*Administrative Responsibility of legal persons, companies, and associations, even those without legal personality*."

The Decree, incorporating certain community and international measures (primarily the OECD Convention on combating international corruption), introduced an innovative sanctioning system for entities, establishing their responsibility for certain offenses committed in the interest or to the advantage of the entity by the following subjects:

a) persons holding functions of representation, administration, or management of the entity or one of its financially or functionally autonomous organizational units, as well as persons who, even de facto, manage or control the entity (so-called "Top Managers," Article 5, Paragraph 1, Letter a);

b) persons subject to the direction or supervision of one of the above-mentioned subjects (so-called "Subordinates," Article 5, Paragraph 1, Letter b).

However, the entity is not liable if the aforementioned subjects acted exclusively in their own interest or that of third parties (Article 5, Paragraph 2), or if the offense was committed by individuals other than those cited.

More precisely, for an entity to be held liable, the offense must be objectively attributable to it and therefore derive from an expression of will or, at the very least, from an "*organizational fault*" of the entity itself, understood as a deficiency or failure to adopt necessary precautions to prevent the commission of offenses.

Due to this direct imputability of the offense to the entity, Article 8 of the Decree stipulates that the entity is liable even if the individual who committed the act is not identified, not prosecutable, or if the offense is extinguished for reasons other than amnesty.
In any case, the Administrative Responsibility of the entity, if established, is in addition to the criminal liability of the individual who committed the offense and to the civil liability for damages.

This Administrative Responsibility of entities also applies to offenses committed abroad, provided that the state where the offense was committed does not proceed

against it (Article 4 of Leg. Decree 231/01).
Although the responsibility is defined as "*administrative*," it actually bears strong similarities to criminal responsibility since it arises from the commission of an offense and is established by the criminal judge with a sentence issued at the end of a criminal proceeding.

The Decree provides for the application of multiple sanctions against the Entity (Title I, Section II):

c) Monetary sanctions;

d) Prohibitive sanctions, such as prohibition from engaging in activity, suspension, or revocation of authorizations, licenses, or concessions, prohibition from contracting with Public Administration, exclusion from benefits, financing, contributions, and the possible revocation of those already granted, and finally the prohibition of advertising goods or services;

e) Confiscation of the price or profit of the offense;

f) Publication of the conviction sentence.

It should be noted that the types of offenses that may configure the Administrative Responsibility of the Company are only those expressly referred to by Leg. Decree 231/01 or by Law 146/06 and in the text of the Penal Code attached to the Model of Mediberg S.r.l.

Additionally, it is worth noting that certain types of offenses have been added after the entry into force of the Decree, in some cases through the inclusion of a new article in the Decree itself, in other cases through a reference to the rules established in Leg. Decree 231/01, as occurred with Law 146/06 relating to transnational crimes.
It is reasonable to assume that in the future the types of offenses relevant to the Decree will be further increased.

1.2 Actions Excluding Administrative Liability

Articles 6 and 7 of the Decree provide that, where one of the offenses referred to in the Decree is committed by a Senior Manager or a Subordinate in the interest or to the advantage of the legal entity, the entity can be exempt from liability if it has:

- adopted and effectively implemented internally an "Organizational, Management, and Control Model" suitable to prevent such offenses;

- appointed, within itself, a body endowed with autonomous powers of initiative and control tasked with overseeing the operation and compliance with the Model mentioned in the previous bullet point.

According to the provisions of Article 6, paragraph 2, of the Decree, this Model must specifically meet the following requirements:

1. Identify the activities within which offenses may be committed;
2. Provide specific protocols aimed at planning the formation and implementation of the entity's decisions concerning the offenses to be prevented;
3. Identify methods for managing financial resources suitable to prevent the commission of offenses;
4. Impose information obligations towards the body tasked with overseeing the operation and compliance with the Model;
5. Introduce a disciplinary system suitable to sanction non-compliance with the measures indicated in the Model.

Although Legislative Decree 231/01 emphasizes the "exempting" function of the Organizational, Management, and Control Model for the entity, the Model primarily has a "preventive" function concerning the offenses referred to in the Decree and, more generally, is aimed at ensuring that the entity's activity fully complies with a standard of "legality."

1.3 Actions Limiting Administrative Liability

Article 17 of the Decree provides forms of limitation of liability for the legal entity if the entity has:

1. fully compensated for the damage and eliminated the harmful or dangerous consequences of the offense or has otherwise taken action in this regard;
2. eliminated the organizational deficiencies that led to the offense through the adoption and implementation of a Model suitable for preventing offenses of the same kind as the one that occurred;
3. made available the profit gained from the commission of the offense.

If these conditions are met, before the declaration of the opening of the first instance trial, the entity will not be subjected to prohibitory sanctions in the event of a conviction, or the prohibitory precautionary measures applied during the investigation phase will be revoked pursuant to Article 50, paragraph 1, of the Decree.

Furthermore, Article 12 of the Decree provides for reductions in the financial penalty:

- by half, if: a) the perpetrator committed the offense primarily in their own interest or that of third parties, and the entity did not gain any advantage or gained only minimal advantage; b) the financial damage caused is particularly slight.
- by one-third to half if, before the declaration of the opening of the first instance trial, the entity: a) fully compensated for the damage and eliminated the harmful or dangerous consequences of the offense or has otherwise taken action in this regard; b) eliminated the organizational deficiencies that led to the offense through the adoption and implementation of a Model suitable for preventing offenses of the same kind as the one that occurred.
- by half to two-thirds, if both conditions outlined in points a) and b) of the previous bullet point are met.

1.4 Confindustria Guidelines

In compliance with Article 6, paragraph 3 of the Decree, Confindustria has issued its own "Guidelines for the construction of Organizational, Management, and Control Models pursuant to Legislative Decree 231/2001" (hereinafter also referred to as "Guidelines"). Consequently, the process of adapting for the definition and subsequent updates of Mediberg S.r.l.'s Model has been carried out taking into account the dictates not only of Legislative Decree 231/2001 but also of the Guidelines developed by Confindustria on the subject. The Guidelines provide methodological indications for the creation of an organizational model suitable for preventing the commission of the offenses provided for by the Decree and thus acting as an exemption from the liability and sanctions provided for by it. The fundamental phases identified by the Guidelines in the construction of the Models can be summarized as follows:

1. The first phase consists of risk identification, that is, the analysis of the business context to highlight where (in which area/sector of activity) and how adverse events for the objectives indicated by Legislative Decree 231/2001 can occur;
2. The second phase consists of designing the control system (so-called protocols for the planning and implementation of the entity's decisions), that is, the evaluation of the existing system within the entity and its possible adaptation, in terms of its ability to effectively counteract, that is, reduce to an acceptable level, the identified risks. The most relevant components of the control system, according to the Guidelines proposed by Confindustria, are:
3. The Code of Ethics concerning the considered offenses;

4. A sufficiently formalized and clear organizational system, especially regarding the allocation of responsibilities;
5. Manual and IT procedures (information systems) that regulate the performance of activities, providing appropriate control points; in this context, the control tool represented by the separation of tasks among those who perform crucial phases (activities) of a process at risk has particular preventive effectiveness;
6. Authorization and signature powers assigned consistently with the defined organizational and managerial responsibilities;
7. The management control system capable of providing timely reports of the existence and emergence of general and/or particular critical situations;
8. Communication to staff and their training.

According to Confindustria's Guidelines, the components described above must be organically integrated into a system architecture that respects a series of control principles, including:

1. Every operation, transaction, action must be: verifiable, documented, consistent, and appropriate: for every operation, there must be adequate documentation support that can be used at any time to carry out checks that attest to the characteristics and motivations of the operation and identify who authorized, performed, recorded, and verified the operation itself.
2. No one can independently manage an entire process: the system must ensure the application of the principle of separation of functions, whereby the authorization to carry out an operation must be the responsibility of a person different from the one who accounts for, operationally executes, or controls the operation.
3. Documentation of controls: the control system must document (possibly through the drafting of minutes) the performance of the controls, including supervision.

That said, these general indications required the Company to subsequently adapt them to take into account the characteristics and size of the Company, the geographical and economic market in which Mediberg S.r.l. operates, and, in particular, the specific risks identified by Mediberg S.r.l. in the mapping of the so-called Sensitive Activities.

2. Mediberg S.r.l.

2.1 Premise

Every entity that wishes to benefit from the exemption indicated in paragraph 1.2 of this document must have its own exclusive Model pursuant to Legislative Decree 231/2001. This implies that such a Model, to effectively address the needs arising from the entity's actual structure and organization, must be tailored to the specific reality of the company to which it necessarily refers.

Consequently, the Model must be aligned with the concrete business reality and draw upon the organization's experience. It must therefore result from a careful analysis of the business processes to determine the entity's exposure to the predicate offenses contemplated in the Decree.

Practically, the activity of identifying exposure to the aforementioned offenses, technically defined as the mapping of sensitive activities (those at risk of the commission of offenses) - present in the Special Part of the Model - must also involve a careful analysis of the specific peculiarities of the entity and its concrete operations.

Therefore, the following paragraphs will describe the corporate purpose, the governance model, and the organizational structure of Mediberg S.r.l., with particular reference to the activities it carries out and its internal organization.

2.2 Organizational Structure

Mediberg S.r.l.'s corporate purpose is the design, manufacture, and commercialization of medical devices.

The organizational structure relevant to the Organizational and Management Model is represented by two formalized tools designed to clarify the basic choices related to the assignment of roles and responsibilities:

a. the corporate organizational chart;
b. the job descriptions for each organizational position.

Both tools constitute the "Mediberg Organizational Manual."

a. The corporate organizational chart is the tool through which the work organization model is made explicit and formal. It provides a synthetic representation of the criteria for the division of labor, in terms of the "horizontal dimension" ("Who does what") and the "vertical dimension" or "hierarchical line" ("with what decision-

making responsibilities").
Mediberg S.r.l.'s organizational chart follows a functional model, which involves the creation of organizational units based on the breakdown of the main business processes (purchasing, production, sales, etc.). The updated version of the organizational chart is available in the dedicated company folder and can be accessed by all staff.

b. The job descriptions aim to succinctly represent the main work contents of each position, with particular emphasis on the assigned organizational and outcome responsibilities.
Mediberg S.r.l. has decided to describe the positions using a methodology that allows for a concise representation of all the key factors characterizing the spheres of responsibility entrusted.
To enhance employees' awareness of interdepartmental relationships and the Organizational and Management Model according to Legislative Decree 231/2001, it has been decided to reiterate two key aspects of organizational functioning within this tool:

- the main operational procedures in which the position is involved in carrying out the assigned responsibilities;
- the sensitive activities potentially connected to the work processes in which the position is involved.

Both the organizational chart and the job descriptions are defined, updated, and communicated by the company management, based on the organizational changes required by the company's evolution. The formalization and management of these tools are entrusted to the "Personnel Management."

In addition, the company:

- has defined a system of delegations and powers of attorney consistent with the responsibilities and roles characterizing the corporate structure;
- to foster greater participation in decision-making by the structure, has established a "Management Committee" composed of the company’s management, which has been assigned a series of powers formalized within a specific regulation.

3 Organizational and Management Model of Mediberg S.r.l.

3.1 Purpose of the Model

Mediberg S.r.l., sensitive to the need to ensure conditions of fairness and transparency in the conduct of business and corporate activities to protect its image, shareholders, and employees, has deemed it consistent with its corporate policies to implement the Model. This document, in addition to representing a potential exemption from liability, pursues the following fundamental objectives:

- Raise awareness among the Recipients of the Model to behave correctly and comply with internal and external regulations;
- Effectively prevent the commission of the offenses provided for by the Decree;
- Concrete implementation of the values declared in its Code of Ethics.

Consequently, from an organizational perspective, the Company believes that the adoption of the Model can also contribute to achieving the following results:

- Increase the effectiveness and efficiency of business operations in realizing the company's strategies. The Model establishes control mechanisms and behaviors that promote compliance with internal and external regulations;
- Improve competitiveness in the national and international market. The Model serves as a guarantee for the so-called "stakeholders" (all private and public, Italian and foreign individuals, groups, companies, institutions who have any type of contact with the company: suppliers, investors, employees, etc.) against the phenomenon of economic crime.
  By making the Company more ethical in the eyes of "third parties," the image of Mediberg S.r.l. is strengthened in public opinion, resulting in increased trust in business relationships between the company and investors, and between the company and customers (both potential and acquired);
- Improve the internal work environment. The Model promotes staff training and individual accountability. It enhances the contribution of human resources (employees and collaborators) in ensuring operational compliance with internal and external regulations and encourages behaviors based on principles such as honesty, professionalism, seriousness, and loyalty.

In conclusion, the Model allows the Company to both protect its social assets by avoiding the application of monetary and prohibitive sanctions, and to achieve a more organized management of the enterprise, oriented towards principles of sound administration, thus fostering the realization of economic development goals.

3.2 Methodology Followed for Drafting the Model

3.2.1 Premise

Article 6, paragraph 2, letter a) of the Decree indicates, as one of the requirements of the Model, the identification of the so-called "sensitive activities," i.e., those business activities where there is a potential risk of committing or, where provided, attempting to commit one of the offenses expressly referred to by the Decree itself or by Law 146/2006. Therefore, the operational reality of Mediberg S.r.l. was analyzed to identify the business sectors where the risk indicated in the previous paragraph resides, highlighting the most relevant moments and processes. Simultaneously, an investigation was conducted into the constituent elements of the predicate offenses in relation to the Company's activities to identify the concrete behaviors that, in the corporate context, could constitute criminal offenses.

3.2.2 Preparatory Phases for Constructing the Model

The activities aimed at adopting Mediberg's Model 231 can be divided into two different stages:

1. Initial development and adoption of Model 231;
2. Subsequent updates and revisions of Model 231.

In all cases, the activities carried out are structured in the following phases:

- **Phase 1**: Analysis of the organizational structure and activities managed by Mediberg.
- **Phase 2**: Mapping of activities at risk of committing offenses, i.e., all those business activities and processes that could potentially generate the commission of the offenses provided by the regulation.
- **Phase 3**: All activities identified as potentially at risk of offenses were analyzed to evaluate the presence of appropriate process controls capable of mitigating the identified risks (so-called gap analysis).
- **Phase 4**: Comparative analysis between existing controls overseeing the activities at risk of offenses and general control standards. From the results of the gap analysis, the relevant Action Plans were indicated.
- **Phase 5**: Definition of the Organizational Model 231, structured in all its components and operational rules, adapted to the corporate reality.

The versions of the Model resulting from the above activities have been adopted through a resolution by the Sole Director

3.3 Constitutive Elements and Adoption of the Model

Mediberg S.r.l.'s Model is composed of the following documents:

a) A general part: "General Model – GM";

b) A special part: "Special Model – SM";

c) The Code of Ethics;

d) Four Annexes:

- "Disciplinary System"
- Annex 1 – List of offenses and implementation methods
- Annex 2 – List of offenses under Legislative Decree 231/01 (updated to October 2023)
- The Whistleblowing Procedure and related annexes adopted by the Company pursuant to Legislative Decree 24/2023.

All the mentioned components (GM, SM, Annexes) are to be considered integral parts of the Company's Model. The General Model, Special Model, Code of Ethics, and Disciplinary System are approved by resolution of the Sole Director.

3.3.1 General Part

The GM is the document with which the Company outlines the principles of the Decree and presents the structure of the Model to the recipients of Mediberg S.r.l.

3.3.2 Special Part

The SM, as provided by Article 6, paragraph 2, letter a), of Legislative Decree no. 231/01, is divided into sections, one for each area of activity (or processes) of the Company at risk of committing the offenses contemplated by the decree itself, with particular regard to the possible implementation methods of criminal conduct and the corporate areas.

a) *Internal Regulations*

Over time, Mediberg S.r.l. has equipped itself with a set of corporate provisions suitable for providing those who operate on its behalf with both general and specific reference principles for regulating the activities carried out and which the operators are required to comply with.

These provisions are subject to continuous updates. The Company's internal regulations consist of:

- Statute;
- Organization Chart;
- Organizational Manual;
- ISO 9001, 14001, and 45001 Manuals with related procedures, forms, instruction notes, and operational instructions for Quality, Environmental, and Safety Management Systems;
- ISO 13485 Manual with related procedures, forms, instruction notes, and operational instructions for the Medical Devices Management System.

Regarding quality system documentation, the "PR 03 Documentation Management" procedure governs the issuance and updating of internal regulations, defining activities, methods, and responsibilities for their correct and efficient management.

b) Quality Management System and Medical Devices

Mediberg S.r.l. is certified for the Medical Devices and Quality Management System (QMS). The above certifications attest to the Company's compliance with the applicable requirements of UNI EN ISO 13485 and UNI EN ISO 9001, currently in the 2016 and 2015 editions, respectively. Through the application of the Management Systems, the organizational structure, capabilities, resources, synergies, activities, controls, and responsibilities have been defined to ensure product and service compliance with specified requirements for Medical Device safety and complete customer satisfaction. This system is described in the "ISO 13485 Manual" and the "ISO 9001 and 14001 Manual" and a series of procedures and technical instructions or work notes collected separately and in the documentation referenced.

In particular, the management systems implemented at Mediberg S.r.l. control work processes by assigning responsibilities, managing information flows, and maintaining relevant documentation, thereby serving as a general prevention protocol for the Company's Model. The Management Systems are subject to regular:

- Annual review by the Company's Top Management and the Quality Assurance Manager to ensure the adequacy and effectiveness of the systems, identify, and implement any necessary corrective and improvement actions. This review activity is expressly governed by the "PR 01 Review of Company Systems, Context Analysis, and Risk Assessment of Company Processes" procedure;
- Internal audits to verify the correct and effective application of the management systems and any corrective actions if found inadequate. The

QMS audit activity is expressly governed by the "PR 11 Audit Management" procedure.

c) *Environmental Management System (EMS)*

Mediberg S.r.l. obtained certification for the Environmental Management System (EMS) - ISO 14001 in 2017. The EMS certification attests to the Company's compliance with the applicable requirements of ISO 14001, currently in the 2015 edition. The Environmental Management System encompasses the organizational structure, capabilities, resources, synergies, activities, controls, and responsibilities aimed at ensuring compliance with specified environmental requirements. This system is described in the "ISO 9001 and 14001 Manual" and a series of procedures and technical instructions or work notes collected separately and referenced by the Manuals and procedures.

The EMS is subject to regular:

- Annual review by the Company's Top Management and the Quality and Environmental Assurance Manager to ensure the EMS's adequacy and effectiveness, identify, and implement any necessary corrective and preventive actions. This review activity is expressly governed by the "PR 01 Review of Company Systems, Context Analysis, and Risk Assessment of Company Processes" procedure;
- Internal environmental audits to verify the correct and effective application of the Environmental Management System and to adopt any corrective actions if found inadequate. The EMS audit activity is expressly governed by the "PR 11 Audit Management" procedure.

d) *Safety Management System*

Mediberg has implemented an Occupational Health and Safety Management System (OHSMS) integrated with the quality and environmental management systems and structured according to the guidelines of ISO 45001:2018, to implement what is established in the Integrated Quality, Safety, and Environment Policy, through the achievement of the objectives set by the organization through planning. The OHSMS certification according to the standard is a tool that allows managing safety-related issues within the company through a priori risk assessment and their reduction through preventive actions resulting from a continuous improvement plan.

The phases through which Mediberg's OHSMS is articulated are as follows:

- Initial situation assessment;
- Definition of an appropriate health and safety policy;

- Risk assessment;
- Planning and organization of the system;
- Intervention planning;
- Action sensitization;
- Monitoring;
- Review and improvement.

The OHSMS, an integral part of the company's general management system, is suitable for the activities carried out, as well as the nature and size of the risks present. For proper OHSMS implementation, an appropriate organizational structure has been defined, which, with reference to the company and safety organization charts, highlights the tasks and responsibilities attributed concerning safety with a cascading delegation system. The aim is to define tools for organizing an Occupational Health and Safety Management System, involving all company functions in adopting the same system. This is consistent with the goal of promoting and spreading a culture of safety and health protection within the company, increasing sensitivity towards risk perception, and ensuring the continuous monitoring of the system.

In line with the goal of involving all company functions in the OHSMS and continuously improving safety levels, the organization considers all company personnel, responsible for their role, as resources engaged in the system. Mediberg has also identified a company figure as the integrated system manager, capable of maintaining overall control of the entire system.

For proper OHSMS implementation, Mediberg conducted a preliminary analysis to identify hazards, evaluate the significance of associated risks, and identify possible outdated, surpassed, or adaptable practices/procedures to the system. The result of this analysis is contained in the Risk Assessment Document (DVR), which testifies to the Company's compliance with risk assessment legislation. The risk assessment is carried out and constantly updated by the Employer in concert with the Safety Manager and reworked as provided by Art 29, c 3 of Legislative Decree 81/2008 and subsequent amendments.

The documents prepared by Mediberg within the OHSMS, in addition to the DVR, are as follows:

- Integrated Management System Manual (UNI EN ISO 9001 – UNI ISO 45001 – UNI EN ISO 14001), which contains the Health and Safety Policy and describes the general organization of the Management Systems;
- Health and Safety Procedures: written provisions that formally define who, what, how, and when for an activity that requires control, directing specific

individuals towards precise tasks. They focus on the activity's how and are transversal to the organization;
- Health and Safety Operating Instructions, which detail the operations to be carried out and the means to be used for a specific activity in a specific area;
- Emergency Plan, which, as required by current legislation, identifies possible emergency situations, codifies actions to be taken, the equipment to be used, the people involved, responsibilities, and internal and external communication methods.

Mediberg has set objectives aligned with those defined within the Integrated Policy, achievable through specific improvement programs derived from the risk assessment process. The objectives are translated into activities and subjected to periodic monitoring and review. To better evaluate the effectiveness and achievement of the objectives, Mediberg has identified specific indicators that express and quantify each achieved objective.

The maintenance and continuous updating of the OHSMS are carried out through periodic audit activities, periodic review of reference legislation, and Management Review. The audits aim to:

- Verify the OHSMS's compliance with the reference standard;
- Ensure that activities with significant impacts on worker safety and health are conducted according to established methods;
- Ensure that the OHSMS is adequate for needs and operates in conformity with the Policy, objectives, and programs of the organization;
- Verify workers' knowledge, experience, awareness, and involvement within the OHSMS according to appropriate methods;
- Verify the implementation and effectiveness of corrective and preventive actions taken;
- Ensure the application and compliance with worker safety and health regulations;
- Identify areas for potential OHSMS improvement.

The purpose of the Management Review is to evaluate the system's suitability, adequacy, and effectiveness, verifying the achievement of the objectives for the examined period and identifying the elements necessary for defining improvement objectives and preventive actions. It is conducted annually and bi-monthly in a reduced form, addressing only short-term necessary topics, such as any organizational changes with immediate impacts and effects.

e) *Documentation Filing Criteria and Operation Traceability*

The creation of acts and informational/documentary sources used to support the activities carried out is always traceable, ensuring the transparency and accountability of the decisions made, and every corporate operation and/or transaction is authorized by the appropriate authorities. The documents concerning the activities are archived and stored by the responsible function. The operations conducted within Mediberg S.r.l. are regulated by mechanisms that allow for the identification of the activities performed, their authors, and the informational elements related to the decisions made.

3.3.3 Ethical Code

The Ethical Code is the document through which an entity sets forth the set of rights, duties, and responsibilities of the company towards all parties with whom it interacts to achieve its corporate purpose. Additionally, the Ethical Code aims to establish ethical standards and behavioral norms that the addressees of the Code must adhere to in their dealings with the entity for the purpose of preventing and addressing illicit conduct, not necessarily criminal offenses. The Ethical Code finds its rationale in Article 6, paragraph 2, letter b) of the Decree.

3.3.4 Disciplinary System

The establishment of an adequate Disciplinary System for violations of the conduct rules imposed by the Ethical Code and/or the General Model and the Preventive Protocols therein provided, is an essential requirement for effectively implementing the Model, as required by Articles 6, paragraph 2, and 7, fourth paragraph, of Legislative Decree no. 231 of 2001. The Disciplinary System safeguards the effectiveness of the control mechanism over compliance with the provisions contained in the Model and the Ethical Code.

3.3.5 Relationship between Model, Ethical Code, and Disciplinary System

Mediberg S.r.l.'s Ethical Code is the document adopted by the Company that expresses Mediberg S.r.l.'s ethical commitments, principles, and responsibilities in conducting business and corporate activities, and defines the behavioral guidelines to be followed by the addressees of this document.

The Ethical Code, consequently: g) identifies the principles to which Mediberg S.r.l., in its relations with stakeholders, recognizes a positive ethical value in order to guide its own and the addressees' activities towards a path of legality, efficiency, transparency, competence, integrity, and correctness; h) recommends, promotes, or prohibits certain behaviors that the addressees of the Ethical Code must adopt

towards Mediberg S.r.l., beyond and independently of what is provided for at the regulatory level.

Mediberg S.r.l.'s Model is the document adopted by the Company through which Mediberg S.r.l. has constructed a structured and systematic system of procedures as well as control activities, also to be carried out preventively (ex ante control), aimed at preventing the commission of various types of offenses contemplated by the Decree. It complies with the provisions contained in the Ethical Code, which constitutes an integral part as a prevention protocol.

From this perspective: i) the Ethical Code represents a tool adopted autonomously and is applicable on a general level by the Company to express principles of "business ethics" recognized as its own and to which it calls for compliance by all; j) the Model, while inspired by the principles of the Ethical Code, responds instead to specific provisions contained in the Decree, aimed at preventing the commission of particular types of offenses (for acts that, apparently committed to the advantage of the company, may entail administrative liability under the provisions of the same Decree) and apply to the subjects identified as addressees of the Model.

The Ethical Code complies with the principles indicated in the "Confindustria Guidelines for the construction of organizational, management and control models pursuant to Legislative Decree no. 231/2001."

The effectiveness of complying with the provisions contained in the Model and the Ethical Code is ensured by the provision of an adequate Disciplinary System. To this end, Mediberg S.r.l. has developed the Model by ensuring uniformity and consistency, in terms of sanctions, for violations of the provisions of the Model and the Ethical Code.

3.4 Model Addressees

The rules contained in the Model apply, within their respective competencies: a) to the corporate bodies; b) to those who perform, also de facto, functions of (i) representation, (ii) administration, (iii) management, or (iv) control of the Company itself or of its organizational unit that has financial and functional autonomy (persons in senior positions); c) to those who are subject to the direction and supervision of the above; d) to those who, although not belonging to the Company, act on its behalf or are linked to it through collaboration relationships.

Therefore, these rules are applicable—within their respective competencies and, of course, according to a principle of relevance and selective application—depending on the areas at risk involved from time to time, as well as the activities, functions, and corporate figures affected by specific risks. This includes shareholders, directors,

statutory auditors, and employees of the Company, as well as those who, although not belonging to the Company, act on its behalf or are linked to the Company through collaboration relationships.

Furthermore, negotiated instruments have been adopted to ensure that other parties (suppliers, consultants, partners, auditors, etc.), external to the Company but in relations with it, also respect the principles of the Decree and the Company's Organizational Model in this context.

In order to provide unity and efficiency to the corporate organizational system, Mediberg has adopted a "unitary" Organizational Model 231, which pertains to corporate bodies, persons in senior positions, and those subject to others' direction. Mediberg has entrusted the implementation and control of the Model itself to an internal body within the Company, specifically provided for this purpose, equipped with the necessary autonomy, independence, and professionalism, and which exercises its functions towards all addressees of the Model.

3.5 Dissemination and Communication of the Model

Regarding the dissemination of the Model, Mediberg S.r.l. publishes on the company website a statement declaring the voluntary compliance of the Company with the Decree, making available to anyone wishing to consult it a copy of the Code of Ethics.

Regarding communication with employees, the Company proceeds to make available to all new hires and current staff all the documentation comprising Model 231 (General Part, Special Part, Code of Ethics, and related attachments) within the "Personal Noticeboard" folder available online. The HR Director ensures specific organizational communications are forwarded in case of any updates.

Employees who do not have access to the documentation in the company directory can still consult it in paper format on the noticeboard.

The Regulations of the Supervisory Body (OdV) fall under the competence of the Supervisory Body and are communicated exclusively to the Sole Administrator.

3.6 Training for Senior Management and Subordinates

Following the adoption of the Model, training on the contents and updates of the MOG is implemented at the initiative of the Supervisory Body, which, in collaboration with the relevant functions, annually defines the training program, ensuring its relevance to the roles and responsibilities of the Recipients. Attendance at training courses is mandatory for the Recipients.

The training sessions include the following contents:

- a general part covering the regulatory framework (Legislative Decree 231/2001 and predicate offenses) and other aspects contained in the general part of the Model;
- a special part focusing on sensitive activities identified within mapped business processes and the key controls that the specified functions must ensure, as specified in the specific sections;
- description of the main contents of the Code of Ethics;
- illustration of the methods through which reports on violations of the Model and the Code of Ethics can be submitted in accordance with Legislative Decree 24/2023 and the related procedure adopted by the Company;
- assessment of the learning outcomes of the received training.

The training activities are delivered through classroom sessions, dedicated meetings, or by introducing specific modules within other training sessions, depending on the content and recipients of these sessions, with quizzes to assess learning outcomes.

The content of the training sessions is continuously updated in relation to any updates to the Model. The methods, timing, and participants are defined by the Company in accordance with the Supervisory Body's guidelines.

Participation in training sessions is mandatory. The Supervisory Body, also through designated company structures, collects and archives evidence/certificates regarding actual participation in these training sessions.

3.7 Model Update

In accordance with Article 6, paragraph 1, letter b) of the Decree, the Supervisory Body is tasked with ensuring the update of the Model.

To this end, the Supervisory Body, possibly with the support of the relevant company functions responsible for organizational changes and, where existing, dedicated to monitoring legislative and jurisprudential innovations, notifies the Sole Director of the need to proceed with updating the Model. It also provides indications regarding the methods for implementing the related interventions.

The Sole Director, after assessing the need for Model update signaled by the Supervisory Body, identifies the methods for revising the documentation and the company functions potentially involved in the project.

Factors necessitating adaptation and updating of the Model, exemplified but not exhaustive, include:

- issuance of a new regulatory provision integrating predicate offenses;
- modification or repeal of a current regulatory provision;
- issuance of a new jurisprudential provision affecting the Model adopted by Mediberg S.r.l.;
- changes in Mediberg S.r.l.'s corporate structure (e.g., acquisitions of new interests, sale of business units);
- modifications to Mediberg S.r.l.'s Organizational Manual;
- changes to Mediberg S.r.l.'s Organizational Chart;
- changes to the company regulations listed as preventive protocols in Mediberg S.r.l.'s Model;
- modifications to company information systems that could affect Mediberg S.r.l.'s risk profile;
- significant violations of Mediberg S.r.l.'s Model and/or outcomes of effectiveness checks on the same.

Approval of the Model update is promptly communicated to the Supervisory Body, which in turn oversees the correct implementation and dissemination of the updates made.

4 Supervisory Body of Mediberg S.r.l.

4.1 Introduction

The Decree, in Article 6, paragraph 1, letter b), stipulates that the task of overseeing the functioning and compliance of the Organizational Model, as well as ensuring its update, must be entrusted to a body with autonomous powers of initiative and control, known as the Supervisory Body (OdV).

The OdV must possess subjective requirements ensuring the autonomy, independence, and professionalism of the body itself in carrying out its activities. The characteristic of autonomy in initiative and control powers means that the Supervisory Body must be in a position of independence from those it supervises and have financial autonomy.

4.2 Composition, Appointment, and Requirements of the OdV

The Decree does not provide specific indications regarding the composition of the OdV. In the absence of such indications, Mediberg S.r.l. has opted for a solution that, considering the purposes pursued by the law, ensures the effectiveness of controls tailored to its size and organizational complexity.
Accordingly, the Supervisory Body of Mediberg S.r.l. is a collegiate body composed of three members with a mixed composition (internal and external to the Company), possessing proven specialized and professional expertise.

Among the main advantages resulting from this choice is the reinforcement of the authority of the Supervisory Body due to the presence of external members.

The Supervisory Body of Mediberg S.r.l. is identified by a determination of the Sole Director. Upon appointment of the OdV, the Sole Director determines the compensation to be attributed to the members of the OdV. The compensation cannot be modified during the term of office.

As required by the Decree, the OdV operates with autonomy, independence, professionalism, integrity, and continuity of action. To meet the requirements of:

- integrity, autonomy, and independence, understood as authority and autonomy of judgment and initiative and control powers, specific integrity and eligibility requirements have been established;
- availability of autonomous resources;
- absence of subordination constraints in inspection activities and other assigned functions;
- professionalism, understood as a set of skills suitable for the purpose, significant expertise and experience in legal, economic, organizational, entrepreneurial, and control fields are required;
- continuity of action, understood as planned and non-occasional activities organized directly and independently within the Company, recourse to company or external structures identified from time to time has been provided.

In line with the above requirements, the Company assures the OdV:

- that the revocation of the appointment can only occur for just cause (for example, serious and proven reasons of incompatibility questioning autonomy and independence, serious negligence in carrying out the duties associated with the appointment, involvement in a criminal process, violation of confidentiality obligations imposed on the OdV);
- adequate informational, inspection, and reporting powers and, based on a specific budget provision, the necessary financial resources;
- adequate company support in carrying out the activities and the possibility to resort to external consultants and independent advisors if necessary.

The Sole Director evaluates, prior to the appointment of OdV members and subsequently at appropriate intervals, the existence of subjective requirements of professionalism and integrity in the members of the OdV. Failure to meet these requirements results in removal from office.

The term of office for a member of the Supervisory Body is set at three years and may be renewed by resolution of the Sole Director; notwithstanding cases of automatic removal, a member of the OdV can only be revoked by the Sole Director for just cause.

4.2.1 Resignation and Replacement

OdV members have the option to resign from their position at any time. In such cases, they must notify the Sole Director via registered letter with acknowledgment of receipt, stating the reasons for their resignation. The resignation takes effect from the date of appointment of the new member.

In case of expiration of the OdV's mandate or resignation, death, or removal of a member of the OdV, the Sole Director appoints a new OdV or new member accordingly.

If a single member is replaced, the newly appointed member's term expires along with the other members of the OdV. In case of cessation of the President or from the position of President, the function is temporarily assumed by the oldest member until the Supervisory Body resolves to appoint a new President.

The Sole Director promptly arranges for the replacement of a member of the OdV who has ceased, after verifying the existence of the required professionalism, integrity, and independence requirements.

4.3 Role of the Supervisory Body (OdV)

The main functions of the Supervisory Body are as follows:

- Supervision over the effective implementation of the Model, through the development and implementation of a monitoring and control program/plan;
- Oversight of the adequacy of the Model, i.e., its effectiveness in preventing Offenses;
- Monitoring the ongoing maintenance of the Model's effectiveness;
- Promotion of updates to the Model, where necessary.

Specifically, the Supervisory Body has the following powers:

- Verify, across the entire company, that risks of committing relevant offenses under the Decree are identified, mapped, and monitored, urging their continuous updating;
- Assess the adequacy of the protocols adopted for the prevention and repression of illicit behaviors within the identified sensitive activities;

- Prompt the establishment or modification of prevention protocols in case of deficiencies, inadequacies, or changes in the internal organization and/or company activities;
- Gather, process, and store relevant information regarding compliance with the Model, as well as update the list of information that must be compulsorily transmitted to the OdV;
- Request differentiated training activities to sensitize and educate Senior Management and Subordinates, as recipients of the Model, on:
    - Legislation and its evolution regarding Corporate Liability under Legislative Decree 231/01;
    - The Organizational and Management Model and the Code of Ethics adopted by the Company;
    - Adopted prevention protocols.
- Promote and monitor initiatives aimed at communicating and disseminating the Model and Code of Ethics to all parties obliged to comply with their provisions;
- Provide clarifications and instructions for compliance with the Model;
- Report semi-annually to the Sole Director on the status of implementation and effectiveness of the Organizational Model;
- Evaluate and propose to the Sole Director changes and/or updates to be made to the Model.

In compliance with current privacy regulations, the OdV has access to all company documentation that it deems relevant to fulfilling its duties. Additionally, the OdV may gather any information deemed useful for supervision from anyone operating on behalf of Mediberg S.r.l.

The operational rules of the Supervisory Body are provided in its own Regulations, which are an integral part of the Model but are drafted and approved by the Body itself.

4.4 Information Obligations towards the Supervisory Body

4.4.1 Periodic Information Flows

In compliance with Article 6, paragraph 2, letter d) of the Decree, Mediberg S.r.l. imposes on its Organizational Units an obligation to provide information to the Supervisory Body (OdV) regarding compliance with the Model's prescriptions and prevention protocols. This enables the OdV to effectively monitor the functioning and compliance of the Model.

Failure by company representatives to fulfill these information obligations constitutes a Model violation, leading to the application of sanctions under the disciplinary system.

It is the responsibility of the Supervisory Body to identify the list of information that must be compulsorily transmitted to it, and to determine the relevant Organizational Units responsible for sending the information flows.

4.4.2 Reporting

With Legislative Decree No. 24 of March 10, 2023, the legislature amended the provisions concerning the protection of persons reporting violations of Union law and national legislation, in implementation of EU Directive 2019/1937. This legislative change involved the repeal of paragraphs 2-ter and 2-quater of Article 6 of Legislative Decree 231/01, and amended paragraph 2-bis, requiring that Model 231 include "internal reporting channels, prohibition of retaliation, and disciplinary system" concerning reporting matters.

As a result, the Company has implemented a specific procedure establishing an internal channel for collecting reports, ensuring confidentiality for the reporter in compliance with the new legislation and ANAC Guidelines.

Mediberg S.R.L., being a private entity with an average workforce exceeding 50 in 2022, has adopted an Organizational Model under Legislative Decree 231/01. According to Legislative Decree 24/2023, for companies meeting these criteria, reported violations must pertain to:

- Relevant unlawful conduct under Legislative Decree No. 231/2001, violations of organizational and management models provided in Legislative Decree No. 231/2001, including the Code of Ethics, exclusively using the internal channel established by the Company;
- Offenses falling within the scope of Union or national acts listed in the annex to Legislative Decree 24/2023 (public procurement, prevention of money laundering and terrorism financing, product safety and compliance, consumer protection, privacy and personal data protection, network and information system security, etc.);
- Acts or omissions constituting fraud (or other illegal activity) detrimental to the financial interests of the European Union;
- Acts or behaviors undermining the purpose or objectives of Union acts in the aforementioned sectors.

Subjectively, the procedure applies to employees, subcontractors, freelancers, consultants, volunteers, trainees, and shareholders providing services to the Company.

The Company has entrusted the handling of reports to one of the members of its collegial Supervisory Body.

Mediberg has identified two possible forms for making reports: (a) Dedicated "Whistleblower Software" platform. (b) Oral form - meeting request: The reporter can request an in-person meeting through the channel mentioned in point (a).

The procedure specifically addresses:

- Commitments to communicate with the reporter,
- Treatment of anonymous reports,
- Cases of conflict of interest,
- Methods for handling confidentiality,
- Methods for managing personal data protection,
- Conducting investigations,
- Managing investigation outcomes,
- Potential imposition of sanctions,
- Training,
- Publicizing the procedure,
- Document retention.

The Company is committed to ensuring adequate protection for reporters and all involved parties by prohibiting retaliatory or discriminatory acts, whether direct or indirect, related to the reports (Reporting Management Procedure and attachments).

4.5 Information Obligations of the Supervisory Body

The Supervisory Body (OdV) reports on the outcomes of its activities, the functioning, and compliance of the Model with a dedicated semi-annual report to the Sole Director.

The OdV can be consulted at any time by the Sole Director; likewise, the OdV can request its own hearing with the Sole Director, specifying the topics to be discussed and the reasons for the request.