

**BRAINLAB ITALIA S.R.L.**

**ORGANIZATIONAL  
MANAGEMENT AND CONTROL MODEL  
PURSUANT TO LEGISLATIVE DECREE 231/01**

CONTENTS

CLAUSE	PAGE
<b>A. PREMISE</b>	<b>2</b>
<b>A.1. Legislative Decree 231/2001 and the Administrative Liability for Legal Persons resulting from a crime</b>	<b>2</b>
<i>A.1.1. FRAMEWORK</i>	<i>2</i>
<i>A.1.2. CRIMES CONTEMPLATED BY THE DECREE</i>	<i>3</i>
<i>A.1.3. NO CORPORATE LIABILITY FOR THE COMPANY</i>	<i>7</i>
<b>A.2. Objectives of the MODEL</b>	<b>8</b>
<b>A.3. Activities carried out for the adoption of the MODEL</b>	<b>10</b>
<i>A.3.1. MAPPING - INTRODUCTION</i>	<i>10</i>
<i>A.3.2 MAPPING STAGES - ANALYSIS OF GENERAL OVERVIEW</i>	<i>12</i>
<i>A.3.3 MAPPING STAGES - ANALYSIS OF COMPANY POLICIES</i>	<i>12</i>
<b>B. GENERAL SECTION</b>	<b>16</b>
<b>B.1. Business and Description of Company</b>	<b>16</b>
<i>B.1.1. COMPANY SNAPSHOT</i>	<i>16</i>
<i>B.1.2. COMPANY BUSINESS</i>	<i>16</i>
<b>B.2. Governance, Organization Structure, Internal Audit and Risk Management System</b>	<b>17</b>
<i>B.2.1. CORPORATE GOVERNANCE</i>	<i>17</i>
<i>B.2.2. CORPORATE GOVERNANCE</i>	<i>17</i>
<i>B.2.3. INTERNAL AUDIT AND RISK MANAGEMENT SYSTEM (SB)</i>	<i>18</i>
<i>B.2.4. THE SANCTIONS SYSTEM</i>	<i>20</i>
<b>B.3 TRAINING AND INFORMATION</b>	<b>20</b>
<b>C. SPECIAL SECTION - PROTOCOLS</b>	<b>22</b>
<b>C.1. GENERAL CRIME PREVENTION PRINCIPLES</b>	<b>22</b>

**PREMISE**

Brainlab Italia S.r.l. (hereinafter the “**Company**”) including with respect to the Assobimedita guidelines, has prepared and revised this organizational, management and control model (the “**MODEL**”), which is composed of the following sections:

**Premise**, which summarizes the applicable legislative framework and the purpose of this MODEL, along with the procedure for adopting, amending, and/or updating the MODEL.

**General**

Description of Company

Applicable external references

The Company’s governance and internal audit systems

The supervisory body pursuant to Legislative Decree 231/01

The disciplinary and sanctions system

**Special section**, which sets out the risk activities/operations and provides a breakdown of the parts that compose the audit system, which oversees the commission of crimes as well as the procedures concerning aforementioned risk activities/operations.

As it is structured, the MODEL also includes **APPENDICES**, which form an integral and essential part hereof.

which sets out the at-risk activities/operations and provides a breakdown of the audit systems and its components, which is overseen by the Crimes Committee as well as other procedures concerning said at-risk activities/operations.

## **A. PREMISE**

### **A.1. Legislative Decree 231/2001 and the Administrative Liability for Legal Persons resulting from a crime**

#### **A.1.1. FRAMEWORK**

##### **COMPANY'S LIABILITY**

Legislative Decree 231/2001 (the "**Decree**") introduced direct liability for companies (and in general for Institutions) into Italian law for crimes committed by individuals with representative powers, in administrative and management positions, known as upper management, or by individuals subject to the management or supervision of the former positions.

The liability of a Company is separate and not connected with the actions of the perpetrator of the crime. In particular, a Company is liable with its assets, even if:

- the perpetrator has not been identified;
- the perpetrator may not be ascribed the crime;
- the crime is no longer punishable for reasons other than amnesty (e.g. statute of limitations, death of perpetrator prior to being charged, etc.).

The criminal judge is in charge of proceedings against individuals charged with the crime but also proceedings against the Company that gained a benefit from said crime or in whose interest it was committed.

An essential condition for a Company being held liable for a crime is that it was committed in its interest or to its advantage.

The Company is therefore liable if the perpetrator committed the crime pursuing his/her own interest or that of the Company, and if the conduct was in any case to the advantage of the Company.

In the latter case, even if an advantage was gained, the Company is not liable if the perpetrator committed the crime in his/her own interest or the interest of someone other than the Company.

Furthermore, an institution may be held liable in Italy for crimes committed abroad if the country where the conduct was committed does not take action against such crime autonomously.

##### **APPLICABLE SANCTIONS**

In the event of a manager of a Company committing any crime that is subject to the legal provisions contemplated hereunder, the Company would be subject to pecuniary sanctions and disqualification, in addition to confiscation and the publication of the sentence.

Pecuniary sanctions are applied using a quota, the amount of which is determined by the judge using specific parameters including the seriousness of the crime and the extent of the Company's liability.

The disqualification sanctions include:

- disqualification from running a business;
- suspension or revocation of authorizations, licenses or grants relating to the crime committed;

## Organizational, management, and control model Legislative Decree 231/2001

- prohibition from entering into contract with the public administration, unless for receiving public services;
- prohibition from obtaining credit, loans, contributions or funding and the revocation of those already granted;
- prohibition from advertising goods and/or services.

If the Company is deemed to be significantly liable and there is the risk that the crime will be repeated, the Public Prosecutor may request for the sanctions to be applied by the judge in the interim.

The parameters applied by the judge for such preventive sanctions include the interim seizure of assets subject to confiscation and preventive attachment if there is a risk of loss of guarantees for State credits (legal expenses, pecuniary sanctions).

### **A.1.2. CRIMES CONTEMPLATED BY THE DECREE**

The Company may be held liable only for the crimes expressly referred to in Legislative Decree 231/2001 if committed, as said, in its interest or to its advantage.

A list of the crimes subject to the application of Legislative Decree 231/01 has been broadened with the insertion of a number of different types of crimes. To date, the crimes to be taken into consideration when drafting an organizational model include the following, as specified in Chapter I, Section III of Legislative Decree 231/01:

- **art. 24** *“Undue receipt of payments, fraud against the State or a public institution or for obtaining public funds and computer fraud to the damage of the State or a public institution”*  
  
(this entails misappropriation to the damage of the State, undue receipt of payments to the damage of the State, fraud with public institutions, aggravated fraud to receive public funds, computer fraud);
- **art. 24-bis** *“Computer crimes and unlawful data processing”*  
  
(this includes the actions contemplated in articles 615-ter, 617-quater, 617-quinquies, 635-bis, 635-ter, 635-quater and 635-quinquies 491-bis, and 640-quinquies of the Criminal Code);
- **art. 24-ter** *“Organized crime”*  
  
(this includes the crimes provided for by articles 416 (vi), 416-bis, 416-ter and 630 of the Criminal Code, crimes committed using the conditions described in article 416-bis or in order to assist the business of the associations identified in article);
- **art. 25** *“Bribery, unduly offering or promising something of value and corruption”*  
  
(this includes the actions described in articles 317, 318, 319, 319-bis, 319-ter, 319-quater, 320, 321, 322 e 322-bis of the Criminal Code, including therein bribery in legal proceedings, the inducement of corruption, and the corruption of public officials in the European Community or foreign countries);
- **art. 25-bis** *“Counterfeiting money, credit cards, stamps or other distinctive instruments or signs”*  
  
(this includes forging money, spending, and introducing counterfeit money into the State acting in concert; spending forged money that was received in good faith; the forgery of

## Organizational, management, and control model Legislative Decree 231/2001

stamps, introducing into the State, buying, keeping or circulating counterfeit stamps; Counterfeiting watermarked paper used for forging credit cards or stamps; Manufacturing or keeping watermarks or tools used for forging money, stamps or watermarked paper; the use of counterfeited or altered stamps);

- **25-bis. 1.** *“Crimes against industry and trade”*

(these include the crimes provided for by articles 513, 513-bis, 515, 516, 517, 517-ter e 517-quater of the *Criminal Code*);

- **art 25-ter** *“Corporate crimes”*

(these are almost all the crimes contemplated by applicable special laws, if committed in the interest of the Company, by directors, general directors or receivers or individuals under their supervision, if it would not have been committed if they had supervised properly in accordance with their obligations deriving from their office: articles 2621 and 2621-bis of the Civil Code, (false statements) art. 2622 (i) and (iii) of the Civil Code (false statements by listed companies); art 2623 (i) and (ii) of the Civil Code (false statements in a prospectus); art 2625 (ii) Civil Code (obstructing audit); art 2632 Civil Code (fictitious capital); art. 2626 Civil Code (undue reimbursement of contributions); art. 2627 Civil Code (unlawful distribution of profits and reserves); art. 2628 Civil Code (unlawful transactions on shares or quota or in the controlling Company); art. 2629 Civil Code (transactions prejudicing creditors); art. 2633 Civil Code (unlawful distribution of Company assets by receivers); art. 2636 Civil Code (undue influence over meetings); art. 2637 Civil Code (market manipulation) and art. 2629-bis Civil Code (failure to declare conflict of interest); art. 2638 (i) and (ii) Civil Code (obstaculating public supervisory authorities));

- **art. 25-quater** *“Terrorist crimes or crimes against democracy”*

(these include *“terrorist crimes or crimes against democracy provided for by the Criminal Code and special laws”* and it is worth mentioning the crime described in article 270-bis of the Criminal Code *“Association for the purpose of terrorism and against democracy”* and reference to the crimes that are subject to the New York Convention, which punishes the direct and indirect intentional provision of funds to persons intending to commit terrorist acts);

- **art. 25-quater. 1.** *“Female genital mutilation”*

(this includes the crimes recently introduced by article 583-bis of the Criminal Code);

- **art. 25-quinquies** *“Crimes against individuals”*

(these include the crimes provided for by Section I of Chapter III of Title XII of Book II of the Criminal Code. The crimes provided for by: art. 600 Criminal Code *“Leading or keeping in slavery and servitude”*; art. 600-bis Criminal Code - Prostitution of minors; art. 600-ter Criminal Code - Child Pornography; art. 600-quinquies - Tourism aimed at child pornography; art. 601 Criminal Code - Human trafficking; art. 602 Criminal Code - Purchasing and selling slaves);

- **art. 25-sexies** *“Market abuse”*

(this entails the abuse of privileged information and market manipulation provided for by Part V, Title I-bis, Chapter II of the Consolidated Act provided for by Legislative Decree 58 - 24 February 1998);

## Organizational, management, and control model Legislative Decree 231/2001

- **art. 25-septies** *“Manslaughter and serious or very serious personal injury committed in breach of occupational health and safety regulations”*

(these include the crimes introduced by Legislative Decree 123/2007, which entail the application of Legislative Decree 321/01 including to the offenses detailed in articles 589 Criminal Code - Manslaughter, and 590 (iii) Criminal Code - aggravated personal injury - committed in breach of occupational health and safety regulations, and article 300 of Legislative Decree 81 - 9 April 2008);

- **art. 25-octies** *“Stolen goods, laundering of money, goods or other assets from an illegal source, and self-laundering”* (these include **the** crimes provided for by articles 648, 648-bis, 648-ter and 648-ter. 1 of the Criminal Code);

- **art. 25-novies** *“Copyright offenses”*

(these include the crimes provided for by articles 171 (i)(a-bis) and 171-bis (iii), 171-ter, 171-septies and 171-octies of Law 633 - 22 April 1941);

- **art. 25-decies** *“Incitement not to make statements or to make false statements to the judicial authorities”*

(these include the crimes provided for by article 377-bis of the Criminal Code);

- **art. 25-undecies** *“Environmental offenses”*

On August 1, 2011, Legislative Decree 121/11 was published in the Official Journal issue 177 which with article 25-undecies, introduced the environmental offenses in the “catalog” of crimes provided for by Legislative Decree 231/01 relating to the administrative liability of Institutions and Companies.

The Decree, which was adopted in the implementation of Law 96 - 4 June 2010, and Directive 2008/99/EC on criminal provisions safeguarding the environment, and Directive 2009/123/EC relating to pollution caused by ships, came into force on 16 August 2011.

Law 68 - 22 May 2015 introduced new environmental offenses into the Criminal Code, many of which are referred to in article 25-undecies of Decree 231/2001, amended by Law 68 of 2015.

(these include the crimes provided for:

- by the new articles 727-bis (murder, destruction capturing, extraction or possession of protected animals or wild plants) and 733-bis of the Criminal Code (Destruction of or damage to protected habitats), and the new Title VI-bis of the Criminal Code, “Crimes against the environment”;
- in the “Environment Code” (Legislative Decree 152/06) for waste water, industrial waste, the management, transportation, disposal, and trafficking of waste, land restoration, and carrying out of dangerous activities;
- by Law 150/92 with respect to the marketing of animals risking extinction, the murder of abandoned animals, damaging national archaeological, historical, or art sites, and the defacement of natural heritage;
- by law 549/93 which governs protection of the ozone by criminal law;
- by Legislative Decree 202/07, which punishes negligent and willful water pollution by vessels);

## Organizational, management, and control model Legislative Decree 231/2001

- **art. 25-duodecies** *“Employment of citizens of third party countries lacking immigration authorization” (art. 22 (xii-bis) of Legislative Decree 286 - 25 July 1998, introduced by Legislative Decree 109 - 16 July 2012);*
- **art. 26** “Attempted crimes”  
  
(these include the crimes detailed above but “attempted”);
- **transnational crimes** (the Parliament ratified the UN Convention against Transnational Crime with Law 146 - 16.03.2006. The term “transnational crime” means a crime punishable with at least 4 years’ imprisonment where there is the involvement of organized crime which is a) committed in more than one State; b) or is committed on one State but the substantial part of the preparation, planning, management or control of the crime occurred in another State; c) or was committed in one State but involved a criminal organization engaging in criminal activity in more than one State; d) or was committed on one State but its effects were substantially felt in another State).

**A.1.3. NO CORPORATE LIABILITY FOR THE COMPANY**

According to article 6 of the Decree, a Company may be exempt from corporate liability.

The Company will not be held liable if in the event of a crime, it may demonstrate that:

- (a) the management body had adopted and in effect implemented a MODEL that was suitable for preventing that type of crime from being committed;
- (b) the task of supervising the functioning and the compliance with the MODEL, as well as the necessary revisions, was allocated to a specific Supervisory Body, which had the autonomous power to take action and check compliance;
- (c) the individuals committed the crime by fraudulently not complying with the MODEL;
- (d) there was no omission or failing in terms of supervisory activity by the Supervisory Body.

Moreover, the law sets out the requirements with respect to the effective implementation of the MODEL:

- periodic checks and making changes when a material breach is discovered of the provisions, or when there is a change in the organization or the business;
- the creation of a disciplinary system that suitably sanctions the failure to comply with the provisions of the MODEL.

Article 6 (iii) of the Decree provides that models may be adopted on the basis of a code of conduct that is drafted by an institution's sector associations.

According to said provision, all the main sector associations have approved and published their own respective codes of conduct.

In particular, in November 2013, Assobiomedica (associated with Confindustria) issued their revised version of their "Guidelines relating to the preparation of organization, management, and control models", which are an important source with respect to the interpretation and the suitability of the MODEL.

The MODEL of the Company was drafted in December 2013 and revised in April 2016, taking into consideration the Assobiomedica Guidelines, which substantially reflect those issued by Confindustria and approved by the Ministry of Justice.

## A.2. Objectives of the MODEL

Although adopting the MODEL is not compulsory under the Decree, the Company deemed that it was consistent with its Company policies:

1. to set up an audit system that is aimed at ruling out conduct that could trigger the corporate liability of the Company pursuant to the Decree;
2. to adopt all the undertakings expressly provided for by article 6 of the Decree, in order to rule out the Company's corporate liability;
3. to improve efficacy and transparency in managing the Company's business.

The adoption of the MODEL, described in this document, was therefore aimed at (i) promptly identifying areas of the business where in theory criminal activity could be committed; (ii) creating an audit system that is aimed at mitigating the risk of crimes being committed.

In that respect, note that:

- Back in 2012, the Brainlab Group approved a **Code of Conduct**, which the Company adopted on 1 December 2012, directly informing the management bodies and the employees of its existence and requested compliance with the principles set out therein, both with respect to their relationship with the Company and with third parties. The version in Italian is attached in Appendix III and its circulation internally in the Company, which in the past involved having each employee sign it by way of confirmation, is currently included in the Learning Management System.
- Upon adopting the MODEL on 9 December 2013, the Company planned a series of checks aimed at preventing crimes from being committed which is based on the following principles:
  - o the existence of a set of clear internal rules to allocate liability, the Company's hierarchy, a description of allocated tasks, and the checks to be carried out. The objective is to (i) transparently define everyone's tasks and responsibilities in terms of decision-making; (ii) allow for the traceability and the monitoring of said processes in sensitive business; (iii) inform the perpetrator of the risk of a crime being committed which is breaks the law and is not consistent with the principles or the interests of the Company;
  - o the proper keeping of documents and the traceability of relevant transactions (e.g. transport orders and documentation, the traceability of financial transactions, traceability of accounts, etc.) so that all operations, transactions, and actions may be checked;
  - o the formal separation of roles and signatory powers for relevant operations, in order to avoid one individual having full management over an entire process;
  - o compliance with the Code of Conduct as an essential part of the MODEL;
  - o periodic reporting obligations relating to information concerning individual Company positions to the Supervisory Body in order to ensure a management and control system that promptly flags any potential issue be it in general or a specific situation;
  - o the possibility for employees to flag any anomaly by directly informing the group's audit functions, without having to involve their direct managers;
  - o the obligation to document checks carried out (including by producing minutes).

## **Organizational, management, and control model Legislative Decree 231/2001**

Moreover, in accordance with the provisions of the Decree, the Company appointed a Supervisory Body on December 9, 2013, which met the requirements concerning independence, autonomy, professional capacity, and continuity of action, whose purpose is to monitor the correct application of the MODEL by monitoring activities and the flow of information from sensitive areas.

The said body and higher management were allocated specific tasks and powers to ensure the effective monitoring of the application and the suitability of the MODEL, including for determination exemption.

There is also a disciplinary system that applies in the event of a breach of the MODEL and the Code of Conduct where all levels of the Company are made aware and trained on the procedure and the application of the rules governing conduct.

The drafting and the revision of the MODEL have entailed respectively the operational process described in the section below.

### **A.3. Activities carried out for the adoption of the MODEL**

#### ***A.3.1. MAPPING - INTRODUCTION***

The Methodology applied when preparing the MODEL was mainly aimed at identifying “sensitive” or “at risk” areas - namely, the processes and the business activities where there could be a risk of any of the crimes expressly referred to in the Decree being committed. Those provisions take into account legal provisions, according to which risk areas should be identified from an organizational and audit perspective of Company events, together with a legal analysis of the situation.

From this point of view, the Company in this current stage of checking and revising the MODEL, but also in the prior stage of adopting the high number of laws and the group's Company procedures which form the base for the MODEL that was approved, has launched an action plan aimed at defining, drafting and revising the MODEL, which, according to the Company's effective operations and the terms on how the crimes may be committed, can achieve its purpose efficiently and effectively.

For the purpose of implementing the above, it was necessary to conduct interviews and draw up comparisons with the managers of the Company's business areas and also with individual workers.

#### **QUANTITATIVE INDICATORS**

The procedures for identifying, assessing, and managing risks are the basis for this MODEL, as they are necessary to improve the Company's organization, in order to avoid any situation subject to criminal legal provisions.

First, with the aim of providing a definition of risk for the purpose of this, it is possible to identify it as the potential discrepancy with expected results as a result of events whose occurrence was not known, internally or externally from the Company's organization.

The occurrence of such events may vary broadly depending on the degree of sensitivity of the key variables of the organizational model and the level of risk factors.

The variables fall into three categories:

- Structural variables, which define the characteristics of the participants in the management of business transactions (management, clients, suppliers) and how they are connected (the type of hierarchy and the type of market relationships).
- Content variables, which qualify the goods and the services being exchanged and define the characteristics of the infrastructure and the mechanisms governing how such services are exchanged.
- Governance variables, which set out the Company's governance bodies and the terms on which they act, the decision making process, and the legal forms adopted for organizing the business.

That definition introduces the concept of risk exposure: a business is exposed to the risk of a crime being committed when the potential change in any one of the organization's variables could trigger, within a certain time frame, a variation in expected behaviors. The breadth of the definition defines the extent of the Company's risk exposure.

In essence, a clear definition suggests that the concept of risk is strictly connected with the characteristics of the organizational model chosen by the Company and can be assessed by evaluating the expected impact on the lawful conduct of the people carrying out the Company's business.

Risk management entails a procedure of identifying and evaluating several risks to which a Company is exposed, in order to decide on the strategy to adopt to face said risks, after having adequately evaluated the costs and benefits.

One of the most efficient and common tools when managing risk is mapping risks, which in our case will mean mapping out the crimes that could be committed whilst the business is carried out.

Mapping the risks will in particular regard **the participation in tenders and all relationships with the Public Administration.**

A risk assessment will be conducted taking into equal consideration the impact on the expected behaviors and the issue of the probability of that particular crime or series of crimes being committed within a set period of time. The start point for creating a map of the relevant risks is identifying the subject matter of the analysis (a business unit, a procedure, a single business activity, etc.) and the timeframe within which the risks are assessed.

In this case, the subjective probability becomes particularly relevant, which means the degree of likelihood we give to the probability of a certain event actually occurring. Although the degree of likelihood is obtained using a qualitative approach, it is possible to use a quantitative approach, increasing the likelihood of a certain crime being committed in a certain situation, giving a value from 0 to 0.5, as follows:

<b>Range</b>	<b>Estimate</b>
None	0
Very low	0.01
Low	0.1~0.2
Medium	0.2~0.3
High	0.3~0.4
Very high	0.4~0.5

An important step in mapping sensitive areas is the **gap analysis**: this is an assessment which starting from the gaps identified in the audit system and the procedures applied by the Company, is aimed at starting to indicate a prevention system which in theory, is able to eliminate or to mitigate the risk of crimes flagged in each area.

***A.3.2 MAPPING STAGES - ANALYSIS OF GENERAL OVERVIEW***

An analysis was conducted of applicable legislation to gauge the level of awareness of personnel with respect to the laws and their impact on the Company's operations.

The Company's audit framework was then analyzed along with the main organizational aspects by examining the following elements:

- The Company's by-laws;
- The Company's organization structure;
- The activities, the positions, and the responsibilities of all the main roles;
- The terms for granting mandates and powers;
- The terms for creating and circulating internal rules;
- The subsequent traceability and the verifiability of the procedures relying on adequate supporting documentation and information.

***A.3.3 MAPPING STAGES - ANALYSIS OF COMPANY POLICIES***

After finishing that analysis, an analysis was conducted on the Company's operations by examining its internal policies and rules in force from time to time, in order to identify the main areas of business and identify who is responsible for the control procedures and the mechanisms in place.

The Brainlab Group is part of a comprehensive European multinational which implements the highest professional standards and applies different Company policies and procedures to its members.

Note that, according to the organization of the group, and further to the Decree coming into force, the Company has adopted all the Brainlab Group's internal rules and Company procedures from time to time, as confirmed by several e-mails demonstrating the circulation to the Company's personnel or members of upper management, as attached in the Appendix. The MODEL, the Code of Conduct, and the main procedures are available at any time on the Company intranet at <http://intranet.brainlab.net/Company/SitePages/PoliciesGuidelines.aspx>.

For the purpose of keeping the MODEL updated, including the addition of new potential crimes, the Company recently carried out an in-depth analysis of the Company's existing operations and procedures safeguarding the risk areas, including by obtaining professional support from external advisors, the results of which contributed to the preparation of this revised MODEL.

The analysis was focused on the sensitive areas of the crimes provided for by articles 24 and 25 of the Decree (known as crimes against Public Administration), with particular emphasis on article 25.

Periodically revising the risk assessment for crimes, given the expanding legislation and the specific business as well as the development of the Company's own organization and internal checks, the Company has identified (see **Appendix I** of the MODEL) the following sensitive areas:

1. Participation in public tenders and connected relationships with Public Administration (authorizing and control institutions)

For a description of the Sensitive Areas and the risk of the crimes that could potentially be committed, please see **Appendix II** of the MODEL (DESCRIPTION OF THE CRIMES RELEVANT FOR Brainlab ITALIA SRL).

***Company tools underlying the MODEL***

The Company has dedicated and continues to dedicate the utmost attention to creating a key sole definition of the structure, the operating procedures, the regulations and the audit systems needed to ensure the efficient, effective and transparent management of activities and the allocation of responsibility.

In view of applicable legislation, the Company has implemented a number of rules, which are aimed at:

- (a) organizing the system of powers and delegated tasks;
- (b) governing and creating procedures for the activities carried out within the Company;
- (c) managing relations with the various functions comprising the internal audit system;
- (d) regulating information flows between the various Company departments, which form the basis of the MODEL according to the DECREE and are determined and constantly monitored in order to comply with the laws and regulations applicable to the Company.

That set of internal rules is also an efficient tool for the prevention of unlawful behavior in general, including the conduct identified by law with respect to the “corporate liability of institutions”.

The monitoring of risks resulting from the DECREE is therefore ensured with this MODEL and the set of rules described in the paragraph below, the procedures, the operating procedures, the audit systems (see below) and the system of powers and delegated tasks (see below) which form an essential and substantial part.

***Regulatory framework for Brainlab Italia S.r.l.***

The internal regulatory framework is aimed at achieving the compliance of the operations and in general the Company’s business, with all applicable laws and regulations; the compliance of the Company strategies and having efficient and effective Company policies; protecting the value of its assets and safeguarding against losses; the reliability and the integrity of the accounts and management information.

The COMPANY’s internal rules comprise:

- (a) The Code of Conduct which sets out the values and the general principles of conduct which the Company is built on.
- (b) The procedures, operating policies and other internal rules which form a base that defines - with respect to the activities at risk of CRIMES - the process, the general principles of conduct and the audit system (the “**PROCEDURES**”).
- (c) The system of **powers** and delegated tasks, which are the basis of the Company’s governance system.

The above-mentioned set of rules provide for organization solutions which:

- (i) ensure the separation of tasks by correctly distributing responsibility and setting adequate authorization levels, in order to avoid any overlapping in roles or the allocation of power which allocate critical actions to the one person (the “Segregation of Roles”);
- (ii) identify a clear and formal allocation of powers and responsibilities, with an express indication of the limits in their exercise;

## Organizational, management, and control model Legislative Decree 231/2001

- (iii) provide for the traceability of actions, operations and transactions via sufficient supporting documentation and information;
- (iv) define decision making procedures connected with set objective criteria;
- (v) govern the traceability of audit and supervision activities carried out in relation to the Company transactions;
- (vi) ensure there are reliable information systems and suitable reporting procedures on different managerial levels who have been allocated audit tasks;
- (vii) guarantee that any anomalies encountered in the Company's roles, internal audit roles or other audit positions are timely flagged to the appropriate levels in the Company and managed promptly.

### ***Internal procedures***

As mentioned above, in addition to the aforementioned Code of Conduct, the set of rules regulating the Company also includes the PROCEDURES, which in the majority of cases, comprise the internal rules and policies adopted at group level to guarantee compliance with the core values of the MODEL and the Code of Conduct. All the PROCEDURES (with a relevant list) relating to the risk areas identified within the Company are set out under APPENDIX VII (PROCEDURES for the Brainlab GROUP).

Given the importance they have with respect to the Company structure, below are set out the PROCEDURES which are an essential and substantial part of the MODEL:

- (a) Internal procedures for the negotiation, execution, and performance of contracts with public subjects - Relations with public administration (authorizing and audit institutions): in **Appendix VI, section VI.6.1**.
- (b) Policy for the interactions with healthcare professionals: in **Appendix VI, section VI.6.2**.

### ***Preparation of documentation***

Once the risk area has been identified, as described above, and acknowledging the existence of Company tools and regulations, the Company documentation relating to the Company's MODEL has been progressively updated.

The following have been prepared and revised:

- The MODEL (general section): the document describing the Company's situation and the audit system in place preventing crimes from being committed;
- The Code of Conduct: the document setting out the ethics principles and conduct that the Company aspires to in carrying out its business (see APPENDIX III);
- Protocols: (which are all the organizational and management documents aimed at mitigating the risk of crimes being committed) (see APPENDIX VI and VII), and the Procedures (internal rules and policies adopted at group level to guarantee the compliance with the core values of the MODEL and the Code of Conduct) (the special section of the MODEL).

***Recipients of the MODEL***

The recipients of the MODEL, including the Code of Conduct and the PROCEDURES referred to therein, are the members of the Company's corporate bodies and the meeting as well as in general, all employees and other personnel collaborating with the Company, in addition to commercial partners, pursuant to the clauses which will be included in the contracts with respect only to the sensitive activities they may be involved in (the "RECIPIENTS").

The RECIPIENTS must timely comply with all the provisions of the MODEL, also with respect to their obligations of loyalty, professional conduct and diligence, which derive from their relationship with the Company.

The Company reprimands and punishes any conduct that is not compliant not just with the law, but also with the provisions of the MODEL and the Code of Conduct, and any behavior that is aimed at circumventing the law, the MODEL and/or the Code of Conduct, also if such behavior is engaged in even in the partial conviction that it is in the interest of the Company or with the intention of gaining an advantage of some sort.

The Company circulates the MODEL using suitable means that ensure it is effectively known to all the RECIPIENTS. The MODEL and the Code of Conduct are published and available for consultation on the Company intranet (with their relevant updates).

The training of personnel aimed at informing them of the implementation of the MODEL is managed by the Brainlab Group's Compliance Team.

Training must: a) be aimed at informing the RECIPIENTS of the risk of committing crimes when carrying out their activities for the Company; b) inform them of the content of the MODEL and the Code of Conduct; c) increase the RECIPIENTS' awareness of the application of the rules therein, during all stages of their activities for the Company.

***Setting up a Supervisory Body***

Once the MODEL has been approved by the Board of Directors, a Supervisory Body was set up by the Company, a set of rules governing that body was created and specific obligations were established concerning information flows to said body. Please see section B.2.3. for information in that respect.

## **B. GENERAL SECTION**

### **B.1. Business and Description of Company**

#### ***B.1.1. COMPANY SNAPSHOT***

Brainlab Italia S.r.l. have registered offices in Via Gabriele Rossetti 9, Milan. The Company has a corporate capital of €10,400.00 and is wholly owned by Brainlab Sales GmbH, which has registered offices in Feldkirchen (Germany), whose ethical standards were the inspiration for the MODEL and the Code of Conduct. The Company is part of the group led by the German Company Brainlab AG (the "Brainlab Group"), which specializes in the manufacturing and marketing of machines and software for diagnostics for computerized images and radiotherapy. The Company does not have investments in other companies.

#### ***B.1.2. COMPANY BUSINESS***

The Company:

- (1) Markets digital medical technology, software and medical materials for consumption;
- (2) Installs digital medical technology;
- (3) Provides preventive maintenance of medical technology;
- (4) Supports and trains customers on the use of their digital medical technology.

The Company's business (commercial and technical) is supported throughout the country (at clients' premises) by individual experts: the Company does not have premises hosting Brainlab employees, nor do they own premises for said purpose.

There are commercial premises managed by a third party Company (premises and personnel).

Customers include public and private hospitals, where Brainlab is entitled to operate under:

- Article 26 of Legislative Decree 81/08;
- Title IV of said Decree.

The management of the Company accounts and administrative documents is carried out from Milan (outsourced to an accountant).

Brainlab takes part in public tenders and private bids according to the legal status of the customer.

There are third party distributors (agents) throughout the country working on an exclusive basis for certain product lines or persons with whom Brainlab works regularly, on a non-exclusive basis.

The Company also takes part in public negotiated procurement procedures relating - with respect to digital medical technology - to the following activities, as defined with the commissioning Company, in the relevant offer:

- Supplies
- Planned maintenance on request
- Installation of hardware components
- Installation and modification of software
- Customer care

The sales process is comprised of the following operational stages:

- Acquiring information on the tender/specifications relating to the field of the Company
- Analyzing the tender/specifications
  - Retrieval of details and qualifications of sub-suppliers if required
- Preparation of the offer
- Sending or delivering the offer directly
- Demonstration of the product at client premises (if requested by the institution)

The Company provides the following services:

- analyzing the tender information and checking the consistency with the required services
- contacting subcontractors so they may make an offer that is consistent with the services to be provided
- supporting subcontractors with demonstrations or presentations of the product to the relevant institution

## **B.2. Governance, Organization Structure, Internal Audit and Risk Management System**

### ***B.2.1. CORPORATE GOVERNANCE***

Corporate governance is one of the fundamental requirements in guaranteeing the efficacy of the MODEL, in so far as it is connected with the division of powers and responsibilities amongst the Company bodies (Shareholders' meeting, Board of Directors) and the Company positions.

The Company adopts a traditional management system, and its Company bodies comprise the Shareholders' Meeting and the Board of Directors, whereas for the time being a Board of Statutory Auditors has not been appointed as it is not compulsory.

In accordance with the bylaws, the sole ordinary management of the Company is the task of a management body which comprises a sole director or a Board of Directors with two to five members, as voted by the shareholders; the special management is reserved to the shareholders, who may from time to time delegate such tasks to the management body. The Management Body currently comprises a Board of Directors which has 3 members.

The management powers may be delegated by the Board of Directors to one or more of its members, including the power to represent the Company vis-a-vis third parties, which in any event, is granted to the Chairman pursuant to the bylaws.

In accordance with the bylaws, the Board of Directors has indeed appointed a Managing Director, granting him signatory powers for ordinary management with a limited spending cap (Euro 6000/8000 as the case may be).

### ***B.2.2. CORPORATE GOVERNANCE***

The organizational structure is approved and formalized using a chart which details all the business departments and the respective operating responsibilities (see **Appendix VIII**).

The organizational chart is circulated to all the employees, and in the case of its revision, a timely communication is issued in said respect.

The Company determines the internal rules using a set of rules which discipline the Company procedures and provide the rules relating to conduct for all levels within the Company.

The Company's rules are rendered official, documented and circulated via:

- the Company intranet, where all the main internal rules may be accessed immediately;

## Organizational, management, and control model Legislative Decree 231/2001

- hard copies (Procedures, Organizational Communications, Internal Communications and Circulars).

From a commercial perspective, the Company's organizational structure comprises two sectors specialized respectively in IGS (Image Guided Surgery) and RT (Radio Therapy).

The administrative roles and core businesses are to some extent carried out by Brainlab Group departments, in particular:

1. *Finance & Control*: is in charge of administrative, tax, and corporate management, overseeing all related activities from the management of accounts payables through to processing payments, keeping accounts, preparing financial statements, and liaising with banks and credit institutions.
2. *Sales Department*: oversee the sales procedures for medical machinery and for coordinating the supply of post-sales technical support.
3. *Operations*: supports the Sales Team operating from the central offices providing information about products and relevant certification/documentation.
4. *Legal team*: provides legal advice to all departments. They manage litigation.
5. *Human resources*: directly responsible for managing personnel, and coordinating occupational health and safety procedures.
6. *Risk, Treasury & Internal Audit*: provide support and advice to Company departments.
7. *IT*: oversee the management and the functioning of the Brainlab's Group's IT systems, providing support to the Company's departments. Responsible for the security of IT systems and training employees on how to use them.

### **B.2.3. INTERNAL AUDIT AND RISK MANAGEMENT SYSTEM (SB)**

The Company has set up an internal audit and risk management system in accordance with best practice with respect to Company governance and internal audits.

As part of its strategy and organizational tasks, the Board of Directors is ultimately responsible for the internal audit system and must monitor that it is complete, functioning, and efficient.

The Board must also ensure that the risk management system allows for the identification, the assessment and checks on the material risks.

In addition, the Internal Audit role of the Brainlab Group - which operates directly for the Group companies - provides continuous risk assessment monitoring and the prevention of Company risks.

The Company policies and procedures are a fundamental part of the internal audit system, including the Internal Audit Charter (policies attached to Appendix VII, which sets out the objectives and the tools used by said function), the Integrity and Compliance Policy and the Enterprise Risk Management Policy (attached as well to Appendix VII).

In accordance with the provisions of Law 179/2017, the internal audit system is further strengthened by the establishment of communication channels operating via telephone (*compliance helpline*) at the number **800-786907** and by ordinary post to the Supervisory Body of the Company, through which each employee may report illegal conducts which are relevant under the Decree.

The Company has also established an alternative communication channel, which operates by using IT-based methods through an external service provider, reachable at the following website <https://secure.ethicspoint.com/domain/media/en/gui/31056/index.html>.

Such communication channels ensure the confidentiality of the personal identity of whistleblower as expressly provided for by paragraph 2-*bis* of article 6 of Decree (as amended by Law 179/2017).

Any act of retaliation or direct or indirect discriminatory action against the whistleblower - for reasons connected to the report itself - is expressly prohibited.

The Company has provided sanctions both for those who violate the measures to protect the whistleblower, as well as for whistleblowers themselves who make malicious or grossly negligent reports that prove to be unfounded.

### **SUPERVISORY BODY**

Article 6 (i)(b) of Decree provides for a condition for the exemption of a Company's liability - in addition to the adoption of an organizational model suitable for preventing crimes - which is setting up a body in the Institution, which has autonomous power for taking action and adopting controls, whose function is to supervise the function of and the compliance with the models and revising them accordingly.

### **COMPOSITION**

Given the sensitivity and the high strategic importance of the Supervisory and Audit Body, the role of the monocratic Supervisory Body is held by the individual who from time to time acts as "Compliance Officer" for Brainlab AG, which ensures that it is someone with the necessary professional expertise, acting in accordance with criteria of autonomy and independence. The current SB was appointed on 9 December 2013, at the time of the adoption of the MODEL.

### **TASKS**

In particular, the activities allocated by the Decree to the supervisory body are detailed in article 6 (i)(b) and article 7 thereof, and can be summarized as follows:

- (1) supervising the functioning of the organizational models adopted by the Company and the effective compliance with the principles and criteria set forth by the same;
- (2) overseeing updates to the organizational and management system and its compliance with applicable regulations and the changing needs of the Company, also by obtaining information on the Company and drafting the relevant revision proposals.

The appointment of the Supervisory Body, as well as its revocation, are the tasks of the Company's Board of Directors.

The Supervisory Body is responsible for supervising:

- (a) the efficacy and the suitability of the MODEL according to the Company structure and the effective capacity to prevent crimes from being committed;
- (b) the compliance with the MODEL by the corporate bodies, employees, and advisors;
- (c) the need to revise the MODEL, if the need arises to amend it further to a change in the Company's situation and/or regulations.

For that purpose, by way of mere example, the Supervisory Body is responsible for:

- checking that Company policies are adequate;
- coordinating with the head of personnel on setting up training courses for employees;
- indicate the business activities relevant for the purpose of the updates;
- carry out specific checks periodically;
- coordinate with management to assess whether to take disciplinary measures.

#### ***B.2.4. THE SANCTIONS SYSTEM***

For the purpose of the effective implementation of the organizational model, the Company integrates the conduct subject to disciplinary action to also include the breach of the rules on conduct contained in the organizational model.

In particular, breaches of the following are deemed to trigger the application of the sanctions system:

- the Code of Conduct, alongside the Policy on Interactions with Healthcare Professionals and the Quality Management System for the Brainlab Group;
- the protocols relating to procedures relating to sensitive areas and, in particular, the policy for the interactions with healthcare professionals;
- reporting obligations to the Supervisory Body;

In the event of any such breach, the sanctions set out in the “**sanctions system**” apply, approved as part of this organizational model (see Special Section - Appendix V).

Those breaches compromise the trust between the parties and justify the application by the Company of disciplinary action, whether or not criminal proceedings are commenced, as the rules governing conduct under the MODEL are put in place by the Company on a fully autonomous basis, irrespective of whether certain conduct constitutes unlawful behavior.

When creating the sanctions system, the Company adopted the principle of proportionality of the sanctions, which must always be assessed in view of two criteria:

- the seriousness of the breach;
- the type of relationship with the perpetrator (employee, freelancer, executive, etc.), taking into account the specific disciplinary remedies available by law and contract.

Given the specifics of the system, the Company provides broad information on the existence of and the content of the “**sanctions system**”:

- with respect to employees via the strict compliance with employment law rules, as well as via training - in collaboration with the Supervisory Body - at the time of adopting the organizational model;
- with respect to other collaborators (advisors), by inserting contractual clauses referring to the content thereof.

#### **B.3 TRAINING AND INFORMATION**

In order to ensure the efficient adoption of the organizational model, the Company acknowledges that an essential part of its implementation is training personnel, whatever the grade or contractual

## Organizational, management, and control model Legislative Decree 231/2001

level, as well as information directed externally on the ethical, organizational, and procedural content of the organizational model.

In particular, with reference to training, the Company is convinced that the adequately verified and updated knowledge of the general principles of the law, the failings which the prevention activities, the rules system and the procedure of the MODEL are aimed at, significantly contribute to the creation of a Company atmosphere and the awareness in people of the need to engage in behavior that are consistent with the principles of loyalty, correct conduct, and compliance with laws that the Company deems are relevant for its own business.

In order for the objective of the widespread awareness of the MODEL and its functions to be achieved and maintained, working with the Supervisory Body, the Company promotes:

- the presentation of the organizational model at the times of its adoption and the circulation of its main documents;
- the availability for all personnel of a full copy of the MODEL so that it may be promptly consulted;
- checking via the activity of the Supervisory Body, the level of awareness of the MODEL in the Company's divisions;
- the updating via specific training sessions, on changes to applicable laws or in the event of any changes to the MODEL and in any case, every two years;
- the creation at the request of the division manager, of *ad hoc* training sessions;

Likewise, the constant flow of information to third parties operating even temporarily, constitutes an effective way of implementing the organizational model.

For that reason, the Company requires that:

- in relevant contractual relationships, a clause is inserted relating to the fact that the Company has adopted an organizational model pursuant to Legislative Decree 231/01 and that it deems a breach of the principles and the rules on conduct therein to constitute a material contractual breach;
- in relevant contractual relationships, a clause is inserted stating that it is compulsory to read the Company's Code of Conduct, with the express obligation to comply with the provisions thereof.

In accordance with the above, starting on 14 November 2014, in Milan, the Company conducted several subsequent training sessions, the minutes to which are kept with the Company's records.

## C. SPECIAL SECTION - PROTOCOLS

### C.1. GENERAL CRIME PREVENTION PRINCIPLES

In order to prevent CRIMES from being committed in the identified risk areas, the COMPANY creates and develops procedures that must in any case comply with the following general principles:

- (a) the decisions taken by the corporate bodies and their implementation are governed by the principles and the provisions set out by applicable law, the deed of incorporation, the bylaws, the MODEL, the Code of Conduct, the PROCEDURES, and the instructions and guidelines issued by the Authority, and the supervisory and audit bodies and all other relevant public or judicial authorities;
- (b) it is mandatory for directors (and statutory auditors, if any) to communicate to the Board of Directors (and the Board of Statutory Auditors) the information relating to the positions or the stakes they hold in other companies or corporations, and the termination or any amendments to the same, which due to their nature or type, could reasonably give rise to a conflict of interest pursuant to article 2391 of the Civil Code;
- (c) the truthful and correct communications required by law and regulations are promptly and correctly made to the supervisory and audit Authority or bodies (including corporate) (Italian, supranational or foreign), for the market or shareholders;
- (d) the full and immediate collaboration with the Authority and supervisory and control bodies, providing the full documentation and information requested in a timely manner;
- (e) the adoption of IT systems which guarantee the precise identification of the beneficiary and the reason for the operation with customers, counterparties, or other companies, on terms that allow for the identification of whoever is ordering or processing the operation. The system must make it impossible for changes to be made to the information recorded;
- (f) when carrying out their activities, the RECIPIENTS must not only comply with the MODEL but also with the PROCEDURES to the extent applicable in the Code of Conduct.

The PROCEDURES and the internal rules applicable to the Company are constantly revised, including at the proposal or the instruction of the Supervisory Body, in order to ensure compliance with the core principles of the MODEL and the Code of Conduct.

With respect to material operations falling within the types identified, specific procedures apply, according to which:

- (a) actions and the relevant authorization levels may be reconstructed, to ensure the transparency in choices that are made;
- (b) there is not the same person taking decisions, compiling accounts documenting specific operations and having the task of running the checks required by law and by the procedures forming the internal audit system (known as the separation of functions principle);
- (c) the access to the personal data in the possession of the Company and their processing comply with Legislative Decree 196 - 2003 as amended, including regulatory aspects;
- (d) the access to and the processing of such data is only possible for authorized persons with user names and passwords issued to whoever holds such role;

## Organizational, management, and control model Legislative Decree 231/2001

- (e) the documentation relating to the Company is filed and kept online by the relevant function, under conditions that do not allow for changes to be subsequently made, unless with specific evidence and by authorized persons;
- (f) all access to the Company's IT system - both intranet and internet - for the purpose of carrying out operations or for documenting such operations is possible using two-way asymmetrical encryption (user ID and password), which is changed periodically, or using another procedure which is just as effective, which allows the user to connect to the system for the purpose of the stages relevant to him/her, and, where possible, to leave evidence that may not be modified of the actions taken by such user;
- (g) if the service for filing or keeping documents is carried out on behalf of the Company by an external provider, the service must be governed by a contract whereby the provider rendering the service to the Company complies with specific audit procedures which do not allow for documents to be amended subsequently, unless clearly noted;
- (h) the access to already filed documents, including those contemplated in the three letters above, is always justified and allowed only for authorized persons under internal rules, the Board of Statutory Auditors, the auditing Company (if any) or the Supervisory Body;
- (i) external advisors are selected according to their professional capacity, independence, and expertise and the choice must be grounded according to those requirements;
- (j) goods and service suppliers are selected by the relevant department, on the basis of professional capacity, reliability, and competitiveness, as required by the PROCEDURES;
- (k) the amount of compensation, fees or commissions paid to advisors, collaborators, agents or public authority officers must appropriately reflect the services they render to the Company and the effective engagement, which shall be reasonably assessed taking into account the existing market conditions and practices or established by set fees;
- (l) bonus systems for employees and collaborators, if any, are linked to realistic objectives, which are consistent with the relevant position and the assigned activities and responsibilities;
- (m) for the purpose of deciding how to use financial resources, the Company uses financial intermediaries and banks that are subject to transparency and correct conduct regulations in accordance with European Union provisions;
- (n) in the event of ordinary transactions and they are below the established quantity threshold, the reason can be linked to the class or the type of cost that the transaction falls within; for transactions that are not ordinary and exceed the established quantity threshold, a detailed reason must be provided.

The Supervisory Body oversees that the PROCEDURES and the internal operating practices, including those contemplated in the MODEL, are suitable to obtain compliance with said provisions and the principles underlying the Code of Conduct. The Supervisory Body proposes the terms and any additions to the PROCEDURES relating to the above provisions.

It is possible to derogate from the PROCEDURES in the MODEL - under the responsibility of whoever implements such derogation - in the event of an urgency, when taking or implementing decisions or if it is temporarily impossible to comply with the procedures. In that case, the Supervisory Body must be informed immediately, and in any event, the subsequent ratification by the competent subject is necessary.

## **Organizational, management, and control model Legislative Decree 231/2001**

For the purpose of this MODEL, transactions are classified as “material” by the relevant person in charge, by taking into account their value and economic scope in terms of the Company’s business in the relevant department, their impact on decision and production processes, and if they are taken as part of the Company’s ordinary business or not.