



## **B. Braun Avitum Italy S.p.A.**

Via XXV Luglio, 11  
41037 Mirandola (MO) - Italy

# **MODEL 231 PRINCIPLES**

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## 1. Legislative Decree no. 231 of June 8, 2001

### 1.1 Introduction to the legislation

On **June 8, 2001, Legislative Decree no. 231** was issued (came into force on July 4, 2001) regarding the following matters:

**"Regulations concerning the administrative liability of juridical persons  
of companies and associations, including those without juridical personality"**

This Decree, issued in execution of the delegated power referred to in art. 11 of Law no. 300 of September 29, 2000, was intended to bring domestic legislation on the liability of certain parties into line with a number of international conventions to which Italy has already adhered for some time, such as the Brussels Convention of July 26, 1995 on the protection of the financial interests of the European Community, the Convention also signed in Brussels on May 26, 1997 on combating corruption involving officials of the European Community or officials of Member States and the OECD Convention of December 17, 1997 on combating bribery of foreign public officials in economic and international transactions.

The above-mentioned provision introduced into the Italian legal system a **system of administrative liability** - in fact similar to criminal liability - for certain parties ("**Entities**") for offenses committed in the interest of or to the advantage of the same.

The extension of responsibility therefore aims to also involve in the sanction of certain criminal offenses **the Entities that have benefited from the commission of the offense.**

With regard to the type of offenses and, above all, to the characteristics of the sanctioning system, the new regulations are aimed at the following parties

**ALL SUBJECTS (ENTITIES)**  
**WITH OR WITHOUT JURIDICAL PERSONALITY**

**that, within an entrepreneurial reality, inspire their own management - exclusively or prevalently - to the purpose of profit (i.e., profit in the economic sense).**

Article 5 of Legislative Decree no. 231/2001 establishes that the **Entity is liable** for offenses committed in its interest or to its advantage by:

- a) natural persons who hold positions of representation, administration or management of these Entities, or of one of their organizational units with financial and functional autonomy, as well as natural persons who exercise, also de facto, the management and control of these entities;**
- b) natural persons subject to the direction or supervision of one of the subjects indicated above.**

A fundamental aspect of Lgs.D. 231/2001 is the attribution of an exemptive value to the company's organizational, management and control models.

In fact, in the event of an offense committed by a person in a top management position, **the company is not liable if it proves that (art. 6, paragraph 1, of Lgs.D. 231/2001):**

- a) the management body has adopted and effectively implemented, before the commission of the offense, organizational and management models capable of preventing offenses of the kind committed;**
- b) the task of supervising the functioning of and compliance with the models and ensuring that they are kept up-to-date has been entrusted to a company body with autonomous powers of initiative and control;**
- c) the persons committed the offense by fraudulently evading the organizational and management models;**
- d) there has been no omitted or insufficient supervision on the part of the supervisory body.**

The company must, therefore, demonstrate its extraneousness to the facts alleged against the top management by proving the existence of the above-mentioned converging requisites and, consequently, the circumstance that the commission of the offense does not derive from its own "organizational culpability".

However, in the event of an offense committed by persons subject to the management or supervision of others, the company is liable if the commission of the offense was made possible by the violation of the management or supervisory obligations with which the company is required to comply.

In any case, the violation of management or supervisory obligations is excluded if the company, before the offense was committed, adopted and effectively implemented an organizational, management and control model capable of preventing offenses of the type committed.

## **1.2 The predicate offenses on which the company's liability is based**

Pursuant to D.Lgs no. 231/2001, the company is liable if certain individuals commit specific offenses.

The **types of offenses** under discussion fall into the categories set out below:

- ***offenses committed in relations with the Public Administration*** (artt. 24 & 25);
- ***IT offenses and unlawful data processing*** (art. 24-bis);
- ***organized crime offenses*** (art. 24-ter);
- ***offenses against public trust*** (art. 25-bis);
- ***offenses against commerce and industry*** (art. 25-bis.1);
- ***corporate offenses***, limited to certain specific types (art. 25-ter);
- ***offenses for the purposes of terrorism or subversion of the democratic order*** (art. 25c);
- ***offenses against the individual*** (artt. 25-quater.1 e 25-quinquies);
- "market abuse" offenses (art. 25-sexies);
- so-called "***transnational offenses***" (artt. 3 & 10, L. 16.03.2006, n. 146);
- ***culpable homicide and grave or extremely grave personal injuries, committed in violation of the regulations on the protection of hygiene and health at work*** (art. 25-septies);
- ***receiving stolen goods, money laundering and use of money, goods or utilities of illegal origin, as well as self-laundering*** (art. 25-octies);
- ***offenses related to copyright infringement*** (art. 25-novies);
- ***offense of inducement not to make statements or to make false statements to the judicial authority*** (art. 25i);
- ***environmental offenses*** (art. 25-undecies);
- ***employment of citizens of third countries whose presence in the country is irregular*** (art. 25-duodecies);
- ***offenses of racism and xenophobia*** (art. 25 terdecies);

- *offenses of fraud in sporting competitions, unlawful gaming or betting and gambling by means of prohibited devices* (art. 25-quaterdecies);
- *tax offenses* (art. 25-quinquiesdecies);
- *smuggling-related offenses* (art. 25-sexiesdecies).

### 1.3 *The applicable sanctions*

The penalties for administrative offenses resulting from crime - all of which are enforceable by the criminal courts - are as follows:

- a) **financial penalty;**
- b) **prohibitory penalties;**
- c) **confiscation;**
- d) **publication of the judgment.**

The *financial penalty* is always applicable (art. 10, para. 1, Lgs.D. no. 231/2001).

It is applied with the "quota system".

In order to determine this, the judge must take into account various factors. In this regard, the following factors are particularly important: the gravity of the offense, the entity's degree of responsibility, the activity carried out to mitigate the consequences of the offense or to avoid its repetition, and the economic and financial conditions of the entity.

Possible *prohibitory penalties*, which are particularly severe, are:

- a) prohibition of all exercise of the activity;
- b) suspension or revocation of authorizations, licenses or concessions related to the commission of the offense;
- c) prohibition of contracting with the Public Administration;
- d) exclusion from benefits, financing, contributions, subsidies and the possible revocation of those already granted;
- e) prohibition of advertising of goods or services.

## 2. Model 231

The Model adopted, consisting of a set of rules, instruments and behaviors, is aimed at providing the Company with **an effective organizational and management system reasonably suitable for identifying and preventing criminal conduct pursuant to Legs.D. no. 231/2001.**

**The Company promotes and valorizes behaviors that are useful for the development of an ethical culture within the Company and is therefore sensitive to the need for fairness and transparency in the conduct of business.**

**In particular, the Model, pursuant to art. 6 of Lgs.D. no. 231/2001, has the function of:**

- a) identifying the activities within the scope of which offenses may be committed;
- b) envisaging specific protocols aimed at planning the formulation and implementation of the entity's decisions;
- c) identifying methods of managing financial resources suitable for preventing the commission of offenses;
- d) establishing obligations to provide information to the entity's body responsible for supervising the functioning of and compliance with the models;
- e) introducing disciplinary systems suitable for sanctioning noncompliance with the measures indicated in the Model.

The **B. BRAUN AVITUM ITALY** Model has been set up in order to achieve diligent management of an efficient control and monitoring system of sensitive activities, in order to prevent the commission and even the attempt, of offenses subject to the regulations concerning the "administrative liability of entities" pursuant to Legs.D. no. 231/2001.

For the preparation of its Model, **B. BRAUN AVITUM ITALY** referred to the "CONFINDUSTRIA Guidelines" and the "ASSOBIOMEDICA GUIDELINES"(NOW CONFINDUSTRIA MEDICAL DEVICES) (as well as the previously mentioned Code of Ethics, the Organizational Model and the Antitrust Guidelines and Manual of Assobiomedica, now Confindustria Dispositivi Medici).

In particular, with reference to all offenses (intentional and negligent), the most relevant tools of its *internal control system* can be identified as follows:

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- a) the Company's Code of Ethics;
  - b) the Group's Code of Conduct;
  - c) the organizational system;
  - d) the Compliance system;
  - e) organizational guidelines and procedures (manuals and electronic documents);
  - f) authorization and signatory powers;
  - g) control systems (by the various functions involved and the SB) and management systems;
  - h) communication/information to employees and other recipients;
  - i) personnel training;
  - j) disciplinary mechanisms;
  - k) information flows to and from the Compliance Function;
  - l) information flows to and from the SB.

Approval of the Model is the exclusive prerogative and responsibility of the Board of Directors. The Board of Directors is also responsible for approving any amendments and additions deemed necessary in order to allow the Model to continue to comply with the provisions of the Decree and any changes in the Company's structure.

## **2.1 Code of Ethics**

**The Code of Ethics contains the set of principles and the rights, duties and responsibilities that the Company attributes to all those who operate within it and, more generally, to all "stakeholders"**(hereinafter the "*Subjects*"), and constitutes the operational tool in which the specific general guidelines for the correct performance of all company activities are specified.

**The Code of Ethics is an integral part of the Model.**

## **2.2 The Subjects of Model 231 and the Code of Ethics**

The rules contained in the Model apply to all those who carry out, even de facto, functions of management, administration, direction or control in the Company, to employees, consultants, collaborators and, in general, to all third parties who act on behalf of the Company (agents, etc.).

The Subjects to whom the Model is addressed are therefore required to comply with all its provisions, also in fulfillment of the obligations of loyalty, correctness and diligence arising from the legal relations established with the Company.

**The Code of Ethics has a broader scope than Model 231, and is also applicable to all contractual counterparts (i.e., partner companies, external collaborators, consultants, suppliers, customers, etc.).**

The Company requires all Subjects to fully respect the conduct, principles and values expressed by the Code of Ethics.

### **2.3 Ethical values and principles**

In general, relations and conduct must always be based on the **principles** of *honesty, propriety, transparency, impartiality, diligence, loyalty, and mutual respect*.

In no case shall the pursuit of the interests of **B. BRAUN AVITUM ITALY** justify conduct that is not honest or, in any case, does not comply with national and European Union laws, Model 231, the codes of ethics and the rules of conduct as well as with company regulations and protocols.

In particular, **the company's values and ethical principles**, by which all Subjects must always be guided in their daily conduct, are:

- *compliance with and exact observance of all laws, rules and regulations in force in the countries in which the Company operates;*
- *respect, in business relations and relations with the Public Administration, of the principles of propriety, loyalty, transparency, efficiency and openness to the market; this is expressed by the adoption of the general principle of "separation", according to which requests for benefits of any kind in anticipation of sales negotiations are prohibited. Under this principle, for example, funding a physician for research is prohibited if the physician promises to increase product purchases in return;*
- *maximum, full and active collaboration with public authorities;*
- *moral integrity, which must represent a constant obligation and must characterize all the work of the organization, in each of its components;*

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- *commitment and professional rigor* in the performance of all work activities, which must always be oriented towards maximum propriety, transparency, effectiveness and management efficiency;
  - *respect and dignity* in relations with all people with whom the Subject comes into contact;
  - *rejection of all forms of discrimination* (based on race, sex or color, religion, age, political or union affiliation, sexual orientation, disability, etc.), *harassment and intimidation*;
  - *valorization of each individual's professional skills*;
  - *the widest collaboration in the observance, improvement and updating of the Code*, excluding any form of retaliation in the case of reports;
  - *respect for and valorization of the unique qualities of each individual human resource*.

**B. BRAUN AVITUM ITALY** furthermore guarantees:

- *ethical conduct of business and corporate activities*;
- *ethical regard for the labor, protection and valorization of employees*.

Subjects are required to:

- provide - while taking into account confidentiality obligations - *complete, true, transparent, comprehensible and accurate information*, so that, in establishing relations with the Company, third parties are able to make autonomous decisions, aware of the interests involved, the alternatives and the relevant consequences;
- avoid situations or activities that may generate *conflicts of interest* with those of the Company;
- not carry out activities contrary to the interests of **B. BRAUN AVITUM ITALY**;
- not accept gifts or other forms of payment not legally owed from any person or organization that is seeking to transact business or compete with **B. BRAUN AVITUM ITALY**;
- not use, for their own benefit or for the benefit of third parties, business opportunities intended for the Company.

The Subjects shall endeavor to maintain an environment free of all forms of unlawful harassment and discrimination or retaliation, to *prevent the creation of an intimidating, hostile or isolating work environment*, and to ensure equal opportunities.

**B. BRAUN AVITUM ITALY** condemns every form of exploitation of workers and **firmly opposes the phenomenon of illegal recruitment**.

In particular, the Subjects shall endeavor to comply with the following requirements:

- not to use child labor or forced labor;
- respect freedom of association and the right to collective bargaining;
- ensure working conditions that prevent workers from possible injuries and/or illnesses, ensuring compliance with safety regulations, aiming at the full satisfaction of its staff;
- oppose all forms of discrimination and ensure equal opportunities and fair treatment for all employees, regardless of race, class, national origin, religion, disability, gender, sexual orientation, union membership, political affiliation and age;
- fully and impartially apply the national collective labor agreement to all employees, paying the established remuneration on time and paying all the relevant social security, welfare and insurance contributions;
- ensure the protection of maternity, paternity, and disadvantaged persons.

**B. BRAUN AVITUM** is committed to contributing to the development and well-being of the communities in which it operates, constantly pursuing the objective of **reducing environmental impact** and ensuring the **health and safety** of employees, external collaborators, customers and the communities directly affected by its activities.

All activities must be managed in full compliance with applicable prevention, health, safety and environmental regulations.

## **2.4 Ethics in business conduct**

### **ETHICS OF SCIENTIFIC INFORMATION**

Scientific information is the Company's main communicative activity. It must be *accurate, balanced, correct, objective, not ambiguous or misleading, documented* and documentable.

The information must be produced and disseminated in compliance with the relevant regulations.

### **ETHICS IN BUSINESS CONDUCT AND RELATIONS WITH COMPETITORS**

**B. BRAUN AVITUM** conducts its business in compliance with the requirements of competition and procurement laws.

**B. BRAUN AVITUM** *condemns conduct contrary to the principle of competition and undertakes to observe this* by adopting appropriate measures to prevent association meetings or, in any case, meetings with companies operating in the same sector from becoming, even unintentionally, the occasion of anticompetitive conduct. Therefore, Subjects must not be involved, either personally or through third parties, in initiatives or contacts between competitors that may appear to violate competition and market regulations (by way of example, but not limited to: discussions on prices or quantities, division of markets, limitations on production or sales, agreements to share customers, exchanges of price information, etc.).

### **PAYMENTS AND ILLEGAL PRACTICES**

The Subjects shall not directly or indirectly offer, make or authorize the payment of sums of money, or anything of significant value, for the unlawful purpose of: **a)** influencing the judgment or conduct of any person, customer or Company; **b)** winning or retaining business; **c)** influencing any action or decision by any public official; **d)** benefiting in any way.

### **RELATIONSHIPS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANIZATIONS, AND/OR THIRD PARTIES**

Subjects shall implement ethical business practices and maintain socially responsible conduct in connection with interactions with healthcare professionals.

Subjects shall also respect the obligation of healthcare professionals to make independent decisions with respect to clinico-diagnostic practice.

The relations that the Subjects establish at all levels - international, national, regional and local - including promotional and advertising activity towards employees of the Public Administration and towards professionals of the public and private health sector, must be characterized at all times by the *principles of official activity, transparency, and ethical and professional propriety*.

The Subjects **shall not promise or pay sums of money, promise or grant goods in kind, utilities or other benefits to public employees and/or persons similar to them, or to public or private health professionals, who in any capacity intervene in an acquisition process, even in a personal capacity, with the aim of promoting or favoring the Company's interests.**

Furthermore:

- Relationships with healthcare professionals should be guided by the *principle of sobriety*. It should always be ensured that interactions with healthcare professionals comply with current

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national, European and local laws, regulations and professional codes. Relations established, at all levels - international, national, regional or local - with employees of the Public Administration, including public health workers, must be based on the utmost transparency and propriety.

- The overarching principle of *compliance with applicable laws* and *adherence to ethical standards* is important to the need for collaboration between the medical device and pharmaceuticals sector and healthcare professionals. These activities are necessary for the advancement of medical science and the improvement of patient care, but they must occur through interactions characterized by *maximum transparency, propriety and ethicality*.
- Any gifts must be of modest value, for promotional purposes and related to the work of the healthcare professional or for the benefit of patients and, in any event, must be made in compliance with applicable laws and regulations. Gifts should never be in the form of cash or cash equivalents (e.g., vouchers, book vouchers, fuel vouchers, prepaid cards, etc.).
- Any operation involving the Public Administration must be managed with the *utmost transparency and clarity*, and all information and the decision-making process related to it must be *traceable and available* for verification.
- Any situation of conflict of interest, even potential, with representatives of the Public Administration must be avoided.

### 3. The Supervisory Body

As has already been pointed out, art. 6 of Lgs.D. no. 231/2001 provides that the company may be exempted from liability for the commission of the indicated offenses if the management has, among other things, "*entrusted the task of supervising the functioning of and compliance with the model and of keeping it updated to a body of the company with independent powers of initiative and control*" (hereinafter the "SB").

The entrusting of these tasks to the SB and, obviously, the correct and effective performance of these tasks are therefore indispensable prerequisites for exemption from liability, whether the offense has been committed by "top management" or by "subordinates".

The SB defines and carries out the activities of competence according to the rule of **collegiality** and is endowed, pursuant to art. 6, paragraph 1, letter b), of Lgs.D. 231/2001, with "*autonomous powers of initiative and control*".

#### **The Supervisory Board shall:**

- a) monitor the effectiveness of the Model;
- b) verify the adequacy of the Model, assessing its suitability to prevent offenses;
- c) ensure that the above-mentioned requirements of the Model continue to be met over time;
- d) see to the updating of the Model.

All employees and all those who cooperate in pursuit of the Company's aims are required to promptly inform the SB of any violation of the Model and its constituent elements and of any other aspect potentially relevant to the application of Lgs.D no. 231/2001.

The SB shall act in such a way as to indemnify whistleblowers against any form of retaliation, discrimination or penalty, also ensuring the whistleblower's anonymity and the confidentiality of the facts reported by him/her, without prejudice to legal obligations and the protection of the rights of the Company and of persons accused wrongly and/or in bad faith.

## 4. Disciplinary system

The existence of a specific system of sanctions aimed at punishing conduct in violation of the Model's prescriptions (e.g., violation of procedures, the Code of Ethics, the protocol of conduct, etc.) represents one of the key elements of the Model.

In addition to the penalties provided for employees, corporate bodies and the SB, **the system also includes sanctions against third parties.**

In particular, with regard to consultants, collaborators, attorneys, agents, distributors, suppliers and third parties who have relations with the Company, any conduct in contrast with the Code of Ethics, may result - as provided for by specific contractual clauses included in the terms of appointment (for example: express termination clauses pursuant to art. 1456 of the Civil Code) and in agreements, orders and contracts - in the immediate termination of the contractual relationship and the possible claim for compensation from **B. BRAUN AVITUM ITALY**, if such conduct causes damage to the Company.

## 5. Communication

The principles contained in the Model are widely disseminated both inside and outside the company. Training activity must allow for the dissemination throughout the company of effective knowledge of the Model and of the consequences of conduct that constitutes a violation of the rules it introduces.

With regard to the external world, a clause is included in all contractual acts whereby suppliers and collaborators acknowledge and accept the principles of the Model and the Code of Ethics, of which they take note on the **B. BRAUN AVITUM ITALY** website.