

# **MEDINEOS S.U.R.L.**

## **Organisation, Management and Control Model**

### **General Section**

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# GENERAL SECTION

## 1 - Legislative Decree no. 231/2001 and its evolution

### 1.1 The regime of administrative/criminal liability of Entities

Legislative Decree no. 231 of 8 June 2001 introduced into our legal system a regimen of liability, which is defined as administrative but in reality is essentially criminal in nature, of Entities (legal persons, companies, and even associations without legal personalities) in addition to the liability of the natural persons representing these Entities who materially committed the offence.

According to these rules and regulations, Entities may be held responsible and consequently be sanctioned as a result of an exhaustive list of offences committed or attempted by the directors or employees in the interest of or to the advantage of the Entity itself.

Legislative Decree no. 231 of 8 June 2001, which establishes the "Rules of administrative liability of legal persons, companies and even associations without legal personality, pursuant to Art. 11 of law no. 300 of 29 September 2000" (hereinafter "the Decree"), which takes effect next 4 July, is intended to adapt internal regulations in terms of the liability of legal persons to the international conventions of which Italy has long been a part, such as:

- the *Brussels Convention of the European Community of 26 July 1995* regarding the protection of financial interests;
- the *Convention of 26 May 1997*, also signed in Brussels, concerning the fight against corruption involving officials of the European Community or the member states;
- the *OECD Convention of 17 December 1997* concerning the fight against corruption of foreign public officials in economic and international operations.

The Decree introduced a regimen of administrative liability into the Italian legal system (essentially considered criminal liability) against entities (understood as companies, associations, consortia, etc., hereinafter referred to as "Entities") for certain criminal offences committed in the interest or to the advantage of the same by:

- natural persons acting as representatives, administrators or directors of these Entities or one of their organisational units with financial and functional autonomy;
- natural persons who exercise management and control functions of the same Entities, including in a *de facto* manner;
- natural persons subject to the direction or supervision of one of the subjects indicated above.

This liability is added to the (criminal) liability of the natural person who materially committed the offence.

## 1.2 The criminal offences

Not all of the offences committed by the subjects indicated above result in the liability of the Entity, as only certain types of offences are considered relevant.

Below is a list of the categories of offences that in general and according to the Decree are theoretically capable of resulting in the administrative liability of the Entity. With the help of the Company's consultants and the Supervisory Body, the Special Section of this Model identifies the areas that are potentially at risk of a offence in MediNeos, along with the associated criminal offences which may be applicable to the Company.

### CRIMES AGAINST THE PUBLIC ADMINISTRATION<sup>1</sup>

**1** For the purposes of the Decree, **Public Administration** is understood as all private and public subjects that perform a "*public function*" or a "*public service*".

**Public function and public official** **Public function** refers to the activities governed by the provisions of public law, related to functions that are *-legislative* (State, Regions, Provinces with special status, etc.), *-administrative* (members of the state and territorial administrations, Law Enforcement, members of the supranational administrations - for example, the EU - members of the Authorities, the Antitrust, the Chambers of Commerce, members of the Housing Commissions, public works inspectors, experts of the Italian Shipping Register, etc.) and *-judicial* (Judges, Bailiffs and Law Officers, subsidiary bodies of the Administration of Justice, such as trustees or bankruptcy liquidators, etc.). Art. 357 of the Criminal Code defines "**public official**" as a person who "exercises a legislative, judicial or administrative public function".

**Examples of public officials in the pharmaceuticals sector** may be:

- doctors contracted with the Servizio Sanitario Nazionale [National Health Service] (or SSN);
- doctors at nursing homes contracted with the Servizio Sanitario Nazionale;
- attending physicians;
- hospital physicians;
- members of the Parliamentary commissions of inquiry pursuant to Art. 82 Const.;
- members of a Tender Commission for the Aziende Sanitarie Locali [Local Health Authorities] (or ASL), etc..

**More generally, examples of public officials** may include:

- employees of a University when they exercise certifying and/or authorising authority; notaries; soldiers of the Finance Police; soldiers of the Carabinieri Corps; members of the State Police; members of the Municipal Police Corps; administrators of public economic entities; security guards, etc.

**Public service or person charged with a public service**

**Public service** refers to:

- the production activities for goods and services of general interest subject to the supervision of a Public Authority and
- activities intended to protect citizens' rights to life, health, liberty, welfare, social security, instruction, freedom of speech, etc. governed by concession agreements and/or conventions (for example, Hospital Institutions, ASL (Azienda Sanitaria Locale [Local Health Authority]), I.N.P.S. (Istituto Nazionale della Previdenza Sociale [National Social Security Institution]), I.N.A.I.L. (Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro e le malattie professionali [National Institution for Insurance against Occupational Accidents and Diseases]), members of Municipal Councils, Banks, Post Offices, Customs Offices, Railways, Highways, so-called "Oil Companies" owned by the state, Municipal Energy Companies, Airlines, Shipping Companies, Classification/certification bodies, RINA (Registro Italiano Navale [Italian Shipping Register]), SACE (Servizi Assicurativi del Commercio Estero [Italian export credit agency]), Agricultural Associations, etc.).

A public service is an activity governed in the same forms as a public function, but is characterised by the lack of authority typical of the latter (authoritative or certifying powers), and excludes the performance of simple duties and works of a merely material nature. **Examples of persons charged with a public service in the pharmaceutical sector** may be: Doctors working for the SSN or contracted by the SSN, who may or may not be public officials but in any case are charged with a public service.

- misappropriation against the State [or other public entity] (Art. 316bis of the Criminal Code)
- undue receipt of funds [funding, contributions and other funds] to the detriment of the State [or other public entity or the European Community] (Art. 316ter of the Criminal Code)
- extortion (Art. 317 of the Criminal Code)
- corruption (Arts. 318, 319, 319bis, 320, 321 of the Criminal Code)
- corruption in judicial proceedings (Art. 319ter of the Criminal Code in relation to Articles 318 and 319 of the Criminal Code)
- undue incitement to give or promise benefits (Art. 319quater of the Criminal Code)
- corruption between private individuals (regarding the conduct of the corrupting party only, Art. 2635 of the Civil Code)
- corruption for an official act and an act in violation of official duties, penalty for the corrupting party (Art. 321 of the Criminal Code, in relation to Articles 318, 319 and 319ter of the Criminal Code)
- instigation to corruption (Art. 322 of the Criminal Code, in relation to Articles 318 and 319 of the Criminal Code)
- embezzlement, bribery, corruption and instigation to corruption of members of the bodies of the European Community and the officials of the European Community and foreign states (Art. 322bis of the Criminal Code, in relation to Articles 317 to 320 and 322 of the Criminal Code) (law 116/09)
- fraud against the state or any other public entity [or the European Community] (Art. 640 paragraph II no. 1 of the Criminal Code)
- aggravated fraud to obtain public funds (Art. 640bis of the Criminal Code, in relation to Art. 640 of the Criminal Code)
- computer fraud (Art. 640ter of the Criminal Code)

#### CRIMES RELATING TO THE COUNTERFEITING OF CURRENCY AND CRIMES RELATING TO DISTINCTIVE SIGNS

*ART. 25 bis of Legislative Decree 231/2001 (introduced by Legislative Decree 350/01, converted by Law 409/01 and integrated by Art. 15 l. 99/2009)*

- counterfeiting of currency, complicit spending and introduction of counterfeit currency into the State (Art. 453 of the Criminal Code)
- alteration of currency (Art. 454 of the Criminal Code)
- non-complicit spending and introduction of counterfeit currency into the State (Art. 455 of the Criminal Code)
- spending of counterfeit currency received in good faith (Art. 457 of the Criminal Code)
- counterfeiting tax stamps, introduction into the State, buying, holding, or circulation of counterfeit tax stamps (Art. 459 of the Criminal Code, in relation to Articles 453, 455 and 457 of the Criminal Code)
- counterfeiting of watermarked paper used to manufacture public credit instruments

or tax stamps (Art. 460 of the Criminal Code)

◦ manufacture or possession of watermarks or instruments intended to counterfeit currency, tax stamps or watermarked paper (Art. 461 of the Criminal Code)

◦ use of counterfeit or altered tax stamps (Art. 464 of the Criminal Code)

◦ counterfeiting, altering or using brands or distinguishing marks or patents, models and designs (Art. 473 of the Criminal Code)

◦ introduction of products with counterfeit markings into the State (Art. 474 of the Criminal Code)

#### CRIMES AGAINST INDUSTRY AND COMMERCE

*ART. 25 bis.1 Legislative Decree no. 231/2001 (introduced by Art. 15 Law no. 99/09)*

◦ disruption of freedom of trade or industry (Art. 513 of the Criminal Code)

◦ unlawful competition with threats or violence (Art. 513bis of the Criminal Code)

◦ fraud against national industries (Art. 514 of the Criminal Code)

◦ fraud in the exercise of trade (Art. 515 of the Criminal Code)

◦ sale of non-genuine food items as genuine (Art. 516 of the Criminal Code)

◦ sale of industrial products with misleading signs (Art. 517 of the Criminal Code)

◦ production and sale of goods made through unlawful seizure of industrial property rights (Art. 517ter of the Criminal Code)

◦ counterfeiting of geographical origin or denomination of origin of food products (Art. 517quater of the Criminal Code)

#### CORPORATE CRIMES

*ART. 25 ter Legislative Decree no. 231/2001 (introduced by Art. 3 of Legislative Decree 61/02; as amended)*

◦ false corporate communications (Art. 2621 of the Civil Code)

◦ false statements in reports or communications of the statutory auditors (Art. 27 Legislative Decree no. 39/2010)

◦ obstruction of board of directors and board of auditors control activities (Art. 2625 paragraph II of the Civil Code)

◦ unlawful restitution of capital contributions (Art. 2626 of the Civil Code)

◦ unlawful distribution of profits and reserves (Art. 2627 of the Civil Code)

◦ unlawful dealing in the stocks or shares of the company or its parent company (Art. 2628 of the Civil Code)

◦ operations prejudicial to creditors (Art. 2629 of the Civil Code)

◦ omitted disclosure of a conflict of interest (Art. 2629bis of the Civil Code)

◦ fictitiously paid-up capital (Art. 2632 of the Civil Code)

◦ unlawful distribution of company assets by liquidators (Art. 2633 of the Civil Code)

◦ unlawful influence over the shareholders' meeting (Art. 2636 of the Civil Code)

- market manipulation (Art. 2637 of the Civil Code)
- impeding public regulatory authorities in the exercise of their functions (Art. 2638 paragraphs I and II of the Civil Code)

#### CRIMES FOR THE PURPOSE OF TERRORISM AND THE SUBVERSION OF DEMOCRACY

*ART. 25 quater of Legislative Decree no. 231/2001 (introduced by Art. 3 Law no. 7/03)*

Under the Criminal Code (Articles 270 to 270sexies ) and specific laws

#### THE CRIME OF FEMALE GENITAL MUTILATION

*ART. 25 quater-1 of Legislative Decree no. 231/2001 (introduced by Art. 8 Law no. 7/06)*

(Art. 583bis of the Criminal Code)

#### CRIMES AGAINST PERSONS

*ART. 25 quinquies of Legislative Decree no. 231/2001 (introduced by Art. 5 Law no. 228/05)*

- reduction to or maintenance in slavery or servitude (Art. 600 of the Criminal Code)
- prostitution of minors (Art. 600bis of the Criminal Code)
- child pornography (Art. 600ter of the Criminal Code)
- possession of pornographic material (Art. 600quater of the Criminal Code)
- virtual pornography (Art. 600quarter-1 of the Criminal Code, in relation to Articles 600ter and 600quarter of the Criminal Code)
- tourism initiatives designed to aid and abet the prostitution of minors (Art. 600quinquies of the Criminal Code)
- human trafficking (Art. 601 of the Criminal Code)
- buying and selling of slaves (Art. 602 of the Criminal Code)

#### MARKET ABUSE CRIMES

*ART. 25 sexies of Legislative Decree no. 231/2001 (introduced by Art. 9 Law no. 62/05)*

- abuse of privileged information [insider trading] (Art. 184 Legislative Decree no. 58/1998)
- manipulation of the market (Art. 185 Legislative Decree no. 58/1998)

#### CRIMES IN VIOLATION OF OCCUPATIONAL SAFETY AND HYGINE REGULATIONS

*ART. 25 septies Legislative Decree no. 231/2001 (introduced by Art. 9 Law no. 123/07)*

- manslaughter (Art. 589 of the Criminal Code)
- unintentional injuries (Art. 590 of the Criminal Code)

#### CRIMES AGAINST PROPERTY

*ART. 25 octies Legislative Decree no. 231/2001 (introduced by Art. 63 paragraph III of Legislative Decree no. 231/07, integrated by Law no. 40/08 and art. 3*

*I.186/2014)); ART. 24BIS (introduced by Legislative Decree no. 93/13, converted by Law no. 119/13)*

- receiving stolen goods (Art. 648 of the Criminal Code)
- money laundering Art. 648bis of the Criminal Code)
- use of money or other goods or benefits of unlawful origin (Art. 648ter of the Criminal Code)
  - auto money laundering (art. 64ter-1 c.p.)
- computer fraud (Art. 640ter of the Criminal Code)
- computer fraud of a subject providing electronic signature certification services (Art. 640quinquies)

#### CRIMES INVOLVING THE VIOLATION OF COPYRIGHTS

*ART. 25 novies Legislative Decree no. 231/2001 (introduced by Art. 15 Law no. 99/09)*

- public dissemination through telecommunication networks of a protected work of part of the same (Art. 171 paragraph I letter a)bis l. 633/1941)
- public dissemination through telecommunication networks of a protected work of part of the same committed against the works of others not intended for publication, when this causes harm to the author's integrity or reputation (Art. 171 paragraph III Law no. 633/1941)
- unauthorised duplication, to achieve a profit, of software; import, distribution, sale or possession for commercial or business purposes or the rental of programs contained in media not bearing the SIAE mark; the development of equipment to remove or circumvent devices that protect computer programs (Art. 171bis paragraph I Law no. 633/1941)
- reproduction, transfer to another device, distribution, communication, presentation or public demonstration of the contents of a database; extraction or re-use of the database; distribution, sale or rental of databases (Art. 171bis paragraph II Law no. 633/1941)
- unlawful duplication, reproduction, transmission or public dissemination, including in part, of intellectual works intended for the television or film circuit, the sale or renting of discs, tapes, or similar media or other devices containing sound or video recordings; reproduction, duplication, unlawful transmission, sale or trade, transfer of rights or unlawful importation of more than fifty copies of works protected by copyright and related rights; introduction onto telecommunication networks through concessions of any kind of intellectual property protected by copyrights or part of the same (Art. 171ter Law no. 633/1941)
- failure to communicate to the SIAE the identification data of media for which the SIAE mark is not required or false statements (Art. 171septies Law no. 633/1941)
- fraudulent production, sale, importation, promotion, installation, modification, use of equipment or parts of equipment to decode audiovisual transmissions with conditional access over the air, satellite or cable, in analogue or digital form (Art. 171octies Law no. 633/1941)

#### CRIMES AGAINST THE ADMINISTRATION OF JUSTICE

*ART. 25 decies Legislative Decree 231/2001 (introduced by Law no. 116/09)*

- incitement not to make statements or to make false statements to the judicial authorities (Art. 377bis of the Criminal Code)
- aiding and abetting (Art. 378 of the Criminal Code) – only for transnational offences

#### COMPUTER CRIMES IN VIOLATION OF CONFIDENTIALITY

*ART. 24 bis Legislative Decree no. 231/2001 (introduced by Law no. 48/08)*

- unauthorised access to a computer or telecommunications system (Art. 615ter of the Criminal Code)
- unlawful possession and distribution of access codes to computer systems (Art. 615quater of the Criminal Code)
- distribution of equipment, devices or computer programs designed to damage or interrupt a computer or electronic communication system (Art. 615quinquies of the Criminal Code)
- illegally intercepting, preventing or interrupting computer or electronic communication (Art. 617quater of the Criminal Code)
- installation of equipment intended to intercept, prevent or interrupt computer or electronic communications (Art. 617quinquies of the Criminal Code)
- damage to information, data and computer programs (Art. 635bis of the Criminal Code)
- damage to information, data and computer programs used by the state or another public entity or those which are otherwise of public interest (Art. 635ter of the Criminal Code)
- damage to computer or electronic communications systems (Art. 635quater of the Criminal Code)
- damage to computer or electronic communications systems of public utility (Art. 635quinquies of the Criminal Code, in relation to Art. 635quater of the Criminal Code)
- forgery of electronic documents [public documents or those with probative value] (Art. 491bis of the Criminal Code, in relation to Articles 476 to 491 of the Criminal Code)

#### ORGANISED CRIME

*ART. 24 ter Legislative Decree no. 231/2001 (introduced by Law no. 94/09)*

- conspiracy (Art. 416 of the Criminal Code) for the purpose of:
  - reduction into slavery (Art. 416 of the Criminal Code in relation to Art. 600 of the Criminal Code)
  - prostitution of minors (Art. 416 of the Criminal Code in relation to Art. 600bis)
  - child pornography (Art. 416 of the Criminal Code in relation to Art. 600ter)
  - smuggling of foreign-made tobacco (Art. 416 of the Criminal Code in relation to Art. 291quater Presidential Decree no. 43/1973)
  - unlawful trafficking in narcotics or psychotropic drugs (Art. 416 of the Criminal Code in relation to Art. 74 Presidential Decree no. 309/1990)

- entry or stay of illegal immigrants (Art. 416 of the Criminal Code in relation to Art. 12 paragraphs III and V of Legislative Decree no. 286/1998)
  - mafia-type criminal association [including foreign associations] (Art. 416bis of the Criminal Code)
  - political-mafia electoral exchange (Art. 416ter of the Criminal Code)
  - kidnapping for the purpose of extortion (Art. 630 of the Criminal Code)
  - crimes committed by exploiting the conditions set forth in Art. 416bis of the Criminal Code (in other words crimes committed using intimidation through a bond of association and a condition of subjugation and the obligation to remain silent resulting therefrom to commit crimes, earn profits or obtain undue advantages for oneself or for others)
  - crimes committed in order to facilitate the activities of mafia organisations as established by 416bis of the Criminal Code
  - facilitating the entry or stay of illegal immigrants (Art. 12 paragraphs III and V of Legislative Decree no. 286/1998)
  - unlawful manufacturing, introduction into the state, sale, transfer, possession or carrying in a public place or place open to the public of military weapons, parts thereof, explosives and common firearms (excluding Art. 2 paragraph III Law no. 110/1975) (Articles 695 et seq. of the Criminal Code and Art. 4 of Law no. 110/1975)

#### ENVIRONMENTAL CRIMES

*ART. 25 undecies Legislative Decree no. 231/2001 (introduced by Art. 2 Legislative Decree no. 121/11, modified 68/2015):*

- environment pollution (art. 452bis of the Criminal Code)
- environment disaster (art. 452quater of the Criminal Code)
- unintentional offence against the environment (art 452quinques of the Criminal Code)
- trade and abandon of high radioactivity material (art. 452 sexies of the Criminal Code)
- killing, destruction, capture, removal or possession of protected wild animal or plant species (Art. 727bis of the Criminal Code)
- destruction or damage to habitats inside a protected site (Art. 733bis of the Criminal Code)
- unauthorised opening or discharge of industrial wastewater (Art. 137 Legislative Decree no. 152/06)
- unauthorised waste management activities (Art. 256 Legislative Decree no. 152/06)
- pollution of the soil, sub-soil and waters (Art. 257 Legislative Decree no. 152/06)
- violation of the obligation to communicate the mandatory records and forms required of subjects performing disposal and waste collection activities (Art. 258 Legislative Decree no. 152/06)
- illegal waste trafficking (Art. 259 Legislative Decree no. 152/06)

- organised activities for illegal waste trafficking (Art. 260 Legislative Decree no. 152/06)
- violation of the obligation related to the informatics system control of the waste traceability (art 260 bis Legislative Decree no. 152/06)
- excess and violation of the emission minimum values within the factory activities (art 279 Legislative Decree no. 152/06)
- importation, exportation and re-exportation of protected animals, failure to abide by formality requirements concerning their safety, non-compliant use of authorisations regarding protected animals, unauthorised transport or transit of protected species, trade in artificially propagated plants in violation of requirements, possession and use for profit of specimens without the required documentation (Articles 1 - 2 Law no. 150/92)
- possession of live specimens of wild mammals and reptiles or those bred in captivity which are a danger (Art. 6 Law no. 150/92)
- violation of requirements concerning the cessation and reduction in the use of harmful substances (Art. 3 Law no. 549/93)
- intentional pollution of waters (Art. 8 Legislative Decree no. 202/07)
- unintentional pollution of waters (Art. 9 Legislative Decree no. 202/07)
- unauthorised installation or operation of civil thermal plants that produce emissions (Art. 279 Legislative Decree no. 152/06)

#### IMMIGRATION CRIMES

*ART. 25 duodecies of Legislative Decree no. 231/2001 (introduced by Legislative Decree no. 109/12)*

- employment of illegal third-country nationals (Art. 22 paragraph 12bis of Legislative Decree no. 286/1998)

#### TRANSNATIONAL CRIMES

The criminal association, the one aimed at the smuggling of tobacco or the illicit trafficking of drugs or psychotropic substances, the recycling, the use of money or other benefits of illegal origin, the trafficking of migrants, crimes of obstruction of justice if they cover the transnational character are included in the 231 offenses.

#### **1.3 The adoption of the Organisation, Management and Control Model**

In the event that the aforesaid offences are committed, Articles 6 and 7 of the Decree establish specific types of exception from the aforesaid liability when the Company demonstrates:

- a) that before the crime was committed, it had adopted and effectively implemented, through the governing body, organisation and management models suitable to prevent these types of crimes from occurring;
- b) that it entrusted an internal body with the task of monitoring the functioning of and compliance with the models as well as their updating and empowered it with autonomous powers of initiative and control;
- c) that the persons who committed the crime fraudulently eluded the aforesaid

organisation and management models;

d) that the supervisory activities of the body indicated in letter b) above were not lacking or inadequate.

However, if the crime was committed by individuals subject to the direction and supervision of one of the subjects indicated above, the Entity is considered liable if the crime was made possible by a violation of the obligations of direction and supervision (the burden of proof is upon the prosecutor).

The Decree also establishes that with relation to the extension of delegated powers and the risk of the occurrence of crimes, the organisation, management and control models should meet the following requirements:

- 1 identify the areas at risk of the occurrence of the crimes indicated in the Decree;
- 2 prepare specific protocols to schedule training and implementation of the decisions of the entity in relation to the offences to be prevented;
- 3 provide methods for identifying and managing the appropriate financial resources to prevent the commission of these crimes;
- 4 establish reporting obligations with regards to the body assigned to monitor the functioning of and compliance with the Model;
- 5 establish an internal disciplinary system to punish non-compliance with the measures indicated in the Model.

The Model must also be designed dynamically in order to ensure that it is constantly adapted and modified in response to changes occurring in the organisation, company activities, methods of performing these activities and the reference regulations (see Court of Milan, Judge for the Preliminary Investigation Secchi, ruling of 20 September 2004; Court of Milan, Criminal Section XI, sentence no. 2333 of 14 February 2004; Court of Milan, Criminal Section XI, sentence no. 2038 of 28 October 2004; Court of Naples, Judge for the Preliminary Investigation Saraceno, ruling of 20 June 2007).

Decree no. 231/2001 provides that organisation, management and control models may be adapted based on the codes of conduct (for example, Guidelines) drawn up by trade associations, provided that the aforesaid requirements are met.

#### **1.4 The penalties**

The penalties established against the Entity as a result of the commission or attempted commission of one of the aforesaid crimes are the following:

- pecuniary sanctions
- prohibitory sanctions, such as the interdiction of the performance of activities, the suspension or withdrawal of licences or concessions, the ban on contracting with the Public Administration, the exclusion or withdrawal of funding and contributions, and the ban on advertising goods and services;
- confiscation (and preventive seizure as a precautionary measure) of the profit

that the Entity earned from the crime, including in equivalent form;

- publication of the sentence (in case of application of a prohibitory sanction).

For the sake of completeness, it must be observed that the Judicial Authorities may also under the decree proceed with a) the preventive seizure of the objects for which confiscation is permitted (Art. 53); b) the seizure of the movable and immovable assets of the Entity when there is good reason to believe that the guarantees to pay the pecuniary sanctions, the costs of proceedings or other amounts due to the State are lacking or dispersed (Art. 54).

## **1.5 The essential aspects of the Confindustria Guidelines**

Today, the most widely used and recognised reference with regards to the organisation, management and control models governed by Legislative Decree no. 231/2001 is represented by the Guidelines developed by Confindustria on 07/03/2002 and updated on March 2014, which established the following essential points on the basis of which these Models must be created:

- identification of the risk areas in order to verify in which company areas/sectors the prejudicial events indicated in the Decree could occur;
- development of a control system capable of preventing risks by adopting the appropriate protocols.

The most significant components of the control system identified by Confindustria are as follows:

- code of Ethics (or conduct);
- organisational system;
- manual and electronic procedures;
- authorisation and signatory powers;
- control and management systems;
- staff communication and training.

The components of the control system must be aligned with the following principles:

- verifiability, possibility to document, coherence and consistency of every operation;
- application of the principle of segregation of duties (for example, no one person can autonomously manage an entire process);
- documentation of controls;
- development of an appropriate disciplinary system for violation of the standards of the Code of Ethics/Conduct and the procedures established by the Model;
- identification of the requirements of the Supervisory Body, which may be summarised as follows: autonomy and independence; professionalism; continuity of action;
- Supervisory Body reporting obligations.

The guidelines elaborated by Confindustria describe principles specific for the

responsibilities ex-D.lgs 231 in company groups.

It should be noted that non-compliance with the specific points of the Confindustria Guidelines in and of itself does not invalidate the Model. The individual Models, in fact, as they must be drafted based on the concrete reality of the entity to which they refer, may depart from the Guidelines, which, by their nature, are intended as general suggestions.

## **2 - The adoption of the Organisation, Management and Control Model of MediNeos**

### **2.1 The areas of business operations**

MediNeos S.U.R.L. (hereinafter "MediNeos") is a Contract Research Organisation that plans and conducts clinical trials, with particular but not exclusive reference to observational studies.

The Company was created in 2003 and was strongly oriented to achieve the company purpose by focusing on the quality of service and motivated to grow thanks to a flexible, efficient and reliable structure, which is entrusted with the conduct of clinical/epidemiological studies with the utmost safety and professionalism.

Although it was initially small in size, the company grew rapidly and earned a reputation in the field of clinical research as a company that operates with high standards of quality and ethics.

MediNeos is specialised in the design and conduct of observational studies and has contributed significantly to the dissemination of the "culture" of observational clinical research in Italy, also stimulating the institutions to issue specific regulations in this field (non-existent until March 2008).

MediNeos has contributed significantly to many events and conferences, where it has always promoted observational research as a complement to experimental clinical research, culminating in the First National Conference on Observational Studies (22 October 2009).

After 2010, MediNeos has started to address beyond the national borders, proposing itself as CRO capable of conducting international clinical studies, also as CRO coordinating other partners.

As a result of the particular characteristics of the market in which it operates, during the performance of its activities, MediNeos maintains constant attention on the expectations of the community and its clients in order to always guarantee the highest standards of quality, paying particular attention to the ethical aspects of the company.

In this context, it has decided to comply with the provisions of the Decree 231 by implementing a structured system suitable to mitigate the risk of irregularities in the performance of the companies activities and thereby limit the risk of the commission

of the crimes listed in the Decree and guarantee the correctness and transparency of its activities.

## **2.2 The adaptation of MediNeos to the provisions of the Decree**

MediNeos, which is sensitive to the need to disseminate and consolidate a culture of transparency and integrity and aware of the importance of ensuring the proper conditions in the conduct of its business and company activities to protect its position, image and the interests of the shareholders, adopts the Organisation, Management and Control Model in accordance with the requirements of Legislative Decree no. 231/2001 and with the principles of the Code of Ethics and Conduct approved by Board of Directors resolution on 2 October 2009.

In its session on 2 October 2009, the Board of Directors of MediNeos confirmed the appointment as external consultants to the Company of Atty. Francesca Preite and Atty. Antonella Lopopolo, who will proceed to implement the Decree, and it also appointed for this purpose the necessary Supervisory Body, in the person of lawyer Valeria Miari. As will be discussed below, the Supervisory Body will assist the Company and the external consultants in the creation of an Organisational Model appropriate to prevent the offences which result in the legal liability of the entity, pursuant to Legislative Decree no. 231/2001.

The decision of MediNeos to adopt a Model was made in the belief that in addition to the requirements contained in the Decree – which, it is reiterated, indicate that the Model and thus the Code of Ethics and Conduct are an optional method and not mandatory element – this Model can constitute a valid instrument to raise the awareness of all of the Company's employees as well as anyone operating in the name and on the behalf of the Company (i.e. clients, suppliers, *partners*, various types of collaborators) with regards to the importance of proper conduct in the performance of their duties in order to prevent the risk of the offences indicated in the Decree.

## **2.3 Objectives pursued by adopting the Model**

The primary objective of the Model is to create a structured and organic system of procedures and control activities intended to prevent as much as possible any conduct which may lead to the commission of the offences discussed in Decree no. 231/2001.

By the identification of activities exposed to crime risk ("sensitive activities") and their proceduralisation, we mean:

- on the one hand, the cultivation of awareness of all the individuals operating in the name and on the behalf of MediNeos that certain offences are strongly prohibited and not tolerated by the Company as they are contrary to its interests, even when the company could seemingly achieve an immediate economic advantage;
- on the other hand, through constant monitoring of activities, to allow for timely interventions to prevent or thwart the commission of these offences;
- lastly, to inform everyone who operates in any manner in the name of or on behalf of or even in the interests of MediNeos that the violation of the

requirements contained in the Model shall result in the application of the appropriate penalties or the termination of the contractual relationship.

The key points of the Model, in addition to the principles listed above, are as follows:

- the mapping of at-risk activities, or those activities with regard to which the commission of the offences set forth in the Decree are more probable, in other words, the “sensitive activities”;
- the assignment to the Supervisory Body of specific supervisory duties regarding the effective and correct functioning of the Model;
- the verification and documentation of every relevant operation;
- the application of and compliance with the principle of segregation of duties so that no one person can manage an entire process autonomously;
- the allocation of powers consistent with organisational responsibilities;
- the *ex post* assessment of company conduct as well as the functioning of the Model, with consequent periodic updates;
- the dissemination and involvement of all company levels in the implementation of rules of conduct, procedures and company policies.

## **2.4 Structure of the Model: General Section and Special Section**

The Model is divided into the following sections:

- General Section: The document contains a brief but necessary description of the crimes covered by the Decree, the possible sanctions, as well as a brief summary of the activities and mission of the Company; the document also identifies the structure of the Model and the description of the functioning of the Supervisory Body and the disciplinary system, also referencing the recently adopted Code of Ethics and Conduct and the Disciplinary Code;
- Special Section: The document consists of a system of control activities used to identify the areas of possible risks of crimes in the context of those company activities in which there is the highest possibility of these crimes being committed (the so-called Procedure 231). This part also contains, as attachments, the Code of Ethics and Conduct (already adopted by the Company) and the Disciplinary Code (also already adopted), the organisational system of the Company, and in particular the delegation system, the staff training programme and the programme for dissemination of the Model.

## **2.5 Approval of the Model, amendments and additions thereto**

This Model (General Section) was approved in its first version (December 2009) by the Board of Directors of MediNeos by a resolution on 01/12/2009. The first version of the Model (version of December 2010 ) was approved by the Board of Directors by a

resolution on 23/11/2010, the second version (December 2011) by a resolution on 28/02/2012, and the third version (December 2012) by a resolution on 29/11/2012, the fifth revision (December 2015), deliberated on 29/01/2016. The present document is the sixth.

The Special Section of this Model was approved by the Board of Directors in its first version by a resolution on 10/09/2010 (version of September 2010). Its first revision was approved on 29/11/2011 (version of October 2011), and the second by a resolution on 15/11/2013 (version of September 2013), the third by a resolution on 9/10/2014 (version of September 2014), the fourth by a resolution on 12/11/2015, the fifth (version September 2016) one will be examined on the first Board of Directors that will take place.

As stated by the Decree, the Model is "an official document issued by the managing body". Consequently, its subsequent amendments as well as any substantial addition are the responsibility of the Board of Directors of MediNeos.

The same, at the instruction of the Supervisory Body, will proceed to update this Model in accordance with the findings and controls of the Supervisory Body as well as the introduction of other types of offences which may be subsequently included in the scope of application of Decree no. 231 as a result of the introduction of new regulations or changes in the case law.

In addition, a review is conducted of all reports received over the course of the year, actions taken by the Supervisory Body and the other interested parties, events which were deemed risky, and the knowledge of the staff with regard to the criminal violations provided for by the Decree, through spot-checking.

## **2.6 Recipients of the Model**

The rules contained in the Model apply to anyone who performs management, administration, direction or control functions at MediNeos, even in a de facto manner, and to all employees, including those who, although not directly employed by the Company, act on the behalf thereof or are related to the company through service relationships, etc....

MediNeos disseminates this Model using the appropriate means to ensure that all interested parties are familiar with it.

As regards employees, when they are hired they are provided by the company with a copy of the Code of Ethics and Conduct and the company policies.

A copy of the documentation associated with the training courses as well as a copy of the Code of Ethics and Conduct, the Disciplinary Code and the Model are published on the company's intranet.

The individuals for which the Model is intended are required to comply with all of its provisions in a timely manner and to fulfil the duties of loyalty, correctness and diligence that arise from the legal relations between them and the Company. All employees are required to submit a signed statement to the company in which they certify that they received (or reviewed) the Code of Ethics, the Disciplinary Code and the Model and agree to comply with these requirements.

The texts of the contractual clauses must also be adapted from the functions involved in the Company in accordance with the aforesaid principles, policies and procedures.

### **3 - Supervisory Body**

If the stated criminal offences occur, the Decree stipulates as a condition to grant the exemption from administrative liability the fact that a Supervisory Body (equipped with autonomous powers of initiative and control) has been entrusted with the task of monitoring the functioning of and compliance with the Model as well as seeing to its updating.

#### **3.1 Identification and appointment of the Supervisory Body**

In accordance with this provision of the Decree, the body entrusted with this task is identified in the person of lawyer Valeria Miari pursuant to the Board of Directors resolution of 2 October 2009, that represent integral and substantial part of the present Model.

This choice was determined by the fact that this individual was identified, based on her professional expertise, as the most suitable to assume the role of a member of the Supervisory Body, taking into account the requirements of autonomy, independence, professionalism, continuity of action, integrity and lack of conflicts of interests required for this role. Atty. Miari was selected based on her technical knowledge in the field of creating internal company control systems and her legal expertise. Her *curriculum vitae* is kept on file at the Company.

#### **3.2 Functions and powers of the Supervisory Body**

The functioning of the Supervisory Body is governed by special internal regulations drafted by the Body itself. These regulations, which were delivered to the directors, establish, among other factors, based on the principles of conduct specified in this document, the functions, powers and duties of the body.

The Supervisory Body is entrusted with the task of supervising:

- the effectiveness of the Model: in other words, ensuring that the conduct carried out within the Company corresponds to the Model created;
- the efficacy of the Model: in other words, verifying that the Model is actually suitable to prevent the occurrence of the crimes indicated in the Decree and the subsequent laws that extend its scope of application;
- the updating of the Model: identifying and proposing to the Board of Directors updates and amendments to the Model itself in relation to regulatory changes or changes in company conditions.

On a more operational level, the Supervisory Body is entrusted with the task of:

- periodically verifying the map of areas at-risk of a crime (or the "sensitive areas") in order to adjust the map to changes in activities and/or the structure of the company. For this purpose, the Supervisory Body must be notified by the management and by the employees assigned to perform control activities in the context of their individual functions of any situation that may expose the Company to the risk of an offence. All communications must be exclusively in writing, to include via e-mail;
- periodically performing inspections to ascertain compliance with the provisions

of the Model, including using external professionals, in particular to ensure the required procedures and controls are properly implemented and documented and that the ethical principles are respected.

- verifying the appropriateness and efficacy of the Model in the prevention of the crimes specified in the Decree;
- periodically performing targeted assessments of certain operations or specific acts carried out, in particular, as part of the sensitive activities, the results of which are summarised in an appropriate report and presented to the company bodies;
- coordinating with the other company functions (including by holding the appropriate meetings) to exchange information in order to update the map of at-risk/sensitive areas to:
  - verify their evolution in order to provide constant monitoring;
  - verify the various aspects related to the implementation of the Model (definition of standard clauses, staff training, regulatory and organisational changes, etc.);
  - guarantee that the corrective actions necessary to make the Model adequate and effective have been taken in a timely manner;
- collecting, processing and retaining all relevant information received in accordance with the Model and updating the list of information that must be sent to the Supervisory Body. For this purpose, the Supervisory Body has free access to all significant company documentation and must be kept constantly informed by management:
  - of the aspects of the company's activities that could expose the Company to the risk of the occurrence of one of the crimes indicated in the Decree;
  - of the relationships with Consultants and Partners;
- promoting initiatives for the training and communication of the Model and providing the documentation necessary for this purpose, coordinating with the HR department;
- periodically reporting to the Chief Executive Officer, Board of Directors and Board of Auditors regarding the implementation of company policies for the implementation of the Model.

However, the Supervisory Body is not assigned operational duties or decision-making powers, not even of a preventative nature, regarding the performance of the company's activities.

## 4 – Flow of information

### 4.1 Reporting of the Supervisory Body to the Company Bodies

The Supervisory Body is responsible to communicate the following to the Board of Directors:

- immediately: any significant problems arising from activities;
- Periodically (at least annually): actions taken or to be taken with regard to the implementation of the Model by MediNeos. These relations are retained in the company's records.

The Supervisory Body may be invited to periodically report on its activities to the Board of Directors.

The Supervisory Body may also provide reports evaluating individual circumstances regarding:

- 1) the results of its assessments to the managers of the departments and/or processes, when areas for improvement are identified during activities. In this case, the Supervisory Body will need to obtain the outcome of any implementation activities which the responsible bodies may decide to adopt from the process managers;
- 2) any conduct/actions not consistent with the Code of Ethics and Conduct and the company procedures in order to:
  - i) acquire all information needed for reporting to the structures responsible for the evaluating and applying disciplinary measures;
  - ii) prevent the recurrence of the event, providing directions for elimination of deficiencies.

The activities indicated in point 2) must be communicated by the Supervisory Body to the Board of Directors as soon as possible as they require the support of other company structures, which may assist in the assessment and identification of activities intended to prevent the recurrence of these events.

The copies of the associated minutes will be retained by the Supervisory Body and the bodies which may become involved at any given time.

### 4.2 Reporting to the Supervisory Body: general requirements and specific mandatory requirements

The Supervisory Body must be informed, through the appropriate reporting by the subjects required to comply with the Model, of events which could generate liability for MediNeos pursuant to the Decree.

In this regard, the following general requirements apply:

- reports must be collected from each Department Manager regarding the commission or the reasonable risk of commission of the crimes covered by the Decree or in any case behaviour which in general is not consistent with the rules of conduct contained in the Model;
- each employee must report the violation (or alleged violation) of the Model by contacting the Supervisory Body (the Supervisory Body will

institute “dedicated information channels” to facilitate the flow of official reporting and information in order to preserve the confidentiality of the reporting party and prevent reprisals);

- the Supervisory Body evaluates the reports received and the actions to be taken; any resulting measures are defined and applied as provided below in accordance with the disciplinary system.

Reports in good faith are guaranteed against all forms of reprisals, discrimination or penalisation, and, in any case, the confidentiality of the identity of the reporting party will be preserved, without prejudice to legal obligations and the protection of the rights of MediNeos or persons accused wrongly or in bad faith.

In addition to the reporting concerning the general violations described above, information must be provided to the Supervisory Body regarding the following:

- disciplinary measures for violation of the Model;
- penalties imposed (including measures taken against employees) or dismissal orders for such proceedings, with the proper justifications.

### **4.3 Reporting by company representatives or third parties**

Within the company, any other information of any type whatsoever, including information from third parties, which affects the implementation of the Model in the areas of at-risk activities must be brought to the attention of the Supervisory Body.

The following requirements apply in this regard:

- any reports regarding the commission of the crimes covered by the Decree in relation to company activities or, in any case, conduct not consistent with the rules of conduct adopted by MediNeos, must be collected;
- the inflow of reports, including official reports, must be directed to the Supervisory Body, which will evaluate the reports received and any resulting measures at its discretion, consulting as necessary with the author of the report and/or the person responsible for the alleged violation, providing written justification for any refusals to proceed with an internal investigation;
- the reports, in accordance with the provisions of the Code of Ethics and Conduct, may be in written form and may concern any violation or suspected violation of the Model. The Supervisory Body will act so as to guarantee the reporting parties against any form of reprisals, discrimination or penalisation, also ensuring the confidentiality of the identity of the reporting party, without prejudice to the obligations of law and protection of the rights of company or persons accused wrongly and/or in bad faith;
- “dedicated information channels” will be established (“Dedicated channel”) with a double function: to facilitate the flow of reporting and information to the Supervisory Body and to quickly resolve cases of doubt.

## **5 - Selection and training**

### **5.1 Employees**

For the purposes of the efficacy of this Model, the objective of MediNeos is to guarantee that its on-site employees as well as the so-called “externals” are fully aware of the rules of conduct contained herein . This objective concerns all company resources that fall within the two aforesaid categories, whether these are resources already present in the Company or resources to be introduced.

The training and information varies by level of depth in relation to the level of involvement of the resources themselves in the “sensitive activities”.

The training plan is implemented in close collaboration with the HR Department, Legal Department and the Supervisory Body. Training, which is an essential element in the proper implementation of the Model, has already been initiated by MediNeos. In fact, on 10 November 2009, MediNeos organised for all of its employees a course entitled “the administrative liability of legal persons” held by Atty. Francesca Preite in collaboration with the Supervisory Body.

Following the implementation of the model and the the mapping of areas at risk of crimes is complete, a specific training plan has been adopt to follow the continuous improvement of the company organization, the new rules and regulations entered into force and the opportunities of improvement highlighted by the Supervisory Body in its report to the Board of Directors. For this purpose the Supervisory Body may use external consultants for certain topics, such as the issue of safety in the workplace.

To any new resource introduced in the Company it’s delivered a training, comprehensive of the contents and aspects of the D.Lgs. 231/2001, of the Code of Ethics and Conduct, of the organizational model and of the role covered by the Supervisory Body.

### **5.2 External Consultants and Partners**

The appropriate information regarding the policies and procedures adopted in accordance with this organisational model may also be provided to subjects outside of MediNeos (for example, Consultants, Partners and suppliers), as may the texts of the contractual clauses typically used in this regard.

## **6 - Disciplinary system**

### **6.1 General principles**

Pursuant to Articles 6, paragraph 2, letter e), and 7, paragraph 4, letter b) of the Decree, the Model may only be considered effectively implemented when it provides for a disciplinary system which is capable of punishing non-compliance with the measures indicated therein. This disciplinary system refers to employees and directors and establishes appropriate disciplinary measures.

The establishment of an adequate disciplinary system for violations of the requirements contained in the Model is an essential condition to ensure the

effectiveness of this Model.

The application of the disciplinary measures is independent of the outcome of any criminal proceedings, as the rules of conduct imposed by the Model are assumed by MediNeos in full autonomy and independently of the type of crime which may be involved in the violations of the Model.

The Company has developed a Disciplinary System in accordance with the principles set forth above and which forms an integral and essential part of the Model (in its last version approved by the Board of Directors with deliberation of the 06/09/2017).

## **6.2 Measures against Directors**

In a case of violation of the applicable regulations, the Model or the Code of Ethics and Conduct by the Directors of MediNeos, the Supervisory Body informs the Board of Directors, which will proceed to take the necessary actions required by the applicable regulations.

## **6.3 Measures against Collaborators, Consultants, and other third parties**

Any conduct engaged in by employees, consultants or third parties associated with MediNeos through a contractual relationship that is not an employment relationship which is in violation of the provisions of the Model and/or the Code of Ethics and Conduct may, according to the provisions of the specific contractual clauses contained in the letters of appointment or even in the absence thereof, result in the termination of the contractual relationship, without prejudice to any claims for compensation when this conduct causes damages to the company, independently of the termination of the contractual relationship.

## **7- Code of Ethics and Conduct**

The adoption of ethical principles - also - for the prevention of crimes 231 constitutes an essential part of the preventive control system: MediNeos has included these principles in a Code of Conduct approved on 08/10/2009, subsequently merged, with modifications and innovations, into a Code of Ethics and Conduct, in its first version of October 2016, approved on 15/09/2016 and which forms an essential part of this Model.