

MEDINEOS S.U.R.L.
Organisation, Management and Control Model

General Section

April 2020

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GENERAL SECTION

1 – Legislative Decree no. 231/2001 and its development

1.1 Administrative-penal liability on the part of Organisations

Legislative Decree no. 231 of 8 June 2001 introduced a kind of liability which has been defined as administrative but is essentially of a penal nature, on the part of Organisations (legal persons, companies and associations, also without legal personality), as well as of the individuals who represent them and actually committed the offence.

According to its provisions, Organisations may be held responsible, and as a consequence sanctioned, in relation to specific crimes included in a mandatory list and committed or attempted in the interest or to the advantage of the Organisation itself, its directors or employees.

With Legislative Decree no. 231 of 8 June 2001 concerning the "Administrative liability of legal persons, of companies and associations, even without legal personality, according to Art. 11 of Law 29 September 2000, no. 300" (hereinafter also referred to as "Decree"), which entered into force on 4 July the next year, an attempt was made to adjust domestic regulations on the subject of the liability of legal persons to international conventions signed by Italy years ago, more specifically the following:

- Brussels Convention of 26/07/95 on the protection of the European Communities' financial interests;
- the *Convention of 26 May 1997*, also signed in Brussels, on the subject of combating bribery of officials of the European Community or of Member States
- the OECD Convention of 17/12/97 on combating bribery of foreign public officials in economic and international transactions.

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The Decree introduced into Italian legislation an administrative liability (essentially assimilated to penal liability) on the part of organisations (which includes, more specifically, companies, association, syndicates, etc., hereinafter referred to as "Entities") in regard of specific offences committed in the interest or to the advantage of the latter by:

- individuals in the capacity of representative, directors or executives of the said Entities or of one of their organisational units which has financial and functional independence;
- individuals who are in charge, even if *de facto*, of managing and controlling the said Entities;
- individuals acting under the management and supervision of one of the persons listed above.

The said liability is added to the (penal) responsibility of the individual who actually committed the crime.

1.2 Specific offences

Not all crimes committed by the persons listed above are regarded as entailing liability on the part of the Entity; as a matter of fact only a clearly defined set of specific offences is relevant in this regard.

Below is a list of the specific offences which – in general and according to the Decree – are related in theory to administrative liability on the part of the Entity. The Specific Section of this Model is dedicated to selecting, with the support of Company consultants and of the Supervisory Authority, any areas within MediNeos where there is a potential crime risk and any related specific offences potentially applicable to the Company.

CRIMES AGAINST THE PUBLIC ADMINISTRATION¹

- embezzlement in respect of the Government [or of a public entity] (Art. 316bis P.C.)
- illicit [funds, contributions and other] benefits received to the detriment of the Government [or of another public entity or of the European Communities] (Art. 316ter C.P.)
- graft (Art. 317 P.C.)

1 For the purposes of the Decree, by **Public Administration** reference is made to individuals and persons under public law, in charge of a “*public office*” or of a “*public service*”.

Public office and public official By **public office** reference is made to activities regulated by public law, pertaining to the following functions: *-legislative* (Central Government, Regional Government, Provinces with special statute, etc.), *-administrative* (members of Government and local authorities, Police Forces, members of cross-border administrations, for example the E.U. -, members of supervisory Authorities, Antitrust, Chambers of Commerce, members of Building Commissions, professionals in charge of testing public works, experts in the Italian Naval Registry, etc.) and *-judiciary* (Judges, bailiffs, auxiliary bodies for the administration of justice, for example liquidators or court-appointed receivers, etc.). According to Art. 357 P.C. a “**public official**” is anyone in charge of a legislative, judiciary or administrative function”.

Examples of a public official in the pharmaceutical industry are:

-doctor approved by the National Health Service (or NHS); -doctor in a care home approved by the National Health Service; -doctor on call; -hospital doctor; -members of Parliamentary judiciary committees pursuant to Art. 82 of the Constitution; -members of a Contract Board for Local Health Units (or LHU); -etc..

Examples of public official more in general are:

-employees of a University when they are exercising a certification and/or authorisation power; -civil law notaries; -members of the Tax Police; -officers of the Arma dei Carabinieri; -officers of the State Police; -officers of the Municipal Police; -managers of public economic bodies; -security guards; -etc..

Public service and person in charge of public service

By **public service** reference is made to:

-production activities of goods and services of general interest and subject to supervision by a Public Authority, and

-activities aimed at safeguarding a person's rights to life, health, freedom, welfare and social security, education, freedom of communication, etc., through concession or approval (for example, Hospital Trusts, LHU, I.N.P.S. [National Institute for Social Security], I.N.A.I.L. [National Institute for Insurance against Labour Accidents], members of Municipal Councils, Banks, Post Offices, Customs Offices, National Railways, Motorways, “Oil Companies” with Government shareholding, Municipal Energy Companies, Airline companies, Shipping Companies, classification/certification Bodies, RINA, SACE, Farmers' Cooperatives, etc.).

Public service is an activity regulated in the same way as civil service but without the typical functions of the latter (authority and certification powers) and excluding basic routine tasks and the provision of merely material services. **Examples** of persons in charge of public service **in the pharmaceutical sector** are: doctors employed by the NHS, or approved by the NHS; they may be civil servants or not, but they are still in charge of a public service.

- bribery (Art. 318, 319, 319bis, 320, 321 P.C.)
- bribery in judicial acts (Art. 319ter P.C. pursuant to Art. 318 and 319 P.C.)
- illicit giving or promising of benefits (Art. 319quater P.C.)
- bribery of individuals (only with regard to the corruptor's conduct, Art. 2635 C.C.)
- bribery in relation to an official act and to an action contrary to official duties, penalties for corruption (Art. 321 P.C., pursuant to Art. 318, 319 and 319ter C.P.)
- instigation to bribery (Art. 322 P.C., pursuant to Art. 318 and 319 P.C.)
- embezzlement, graft, bribery and instigating to bribery of members of European Community bodies, officials of the European Communities and Member States (Art. 322bis P.C., pursuant to Art. 317 to 320 and 322 P.C.) (Law 116/09)
- fraud against the Government or any other public body [and against the European Communities] (Art. 640 (II) (1) P.C.)
- aggravated fraud aimed at receiving public funding (Art. 640bis P.C., pursuant to Art. 640 P.C.)
- computer fraud (Art. 640ter P.C.)
- exercising illicit influences (Art. 346bis P.C.)

COINAGE OFFENCE AND FORGING IDENTIFICATION INSTRUMENTS OR INSIGNIA

ART. 25 bis LGS. D. 231/2001 (introduced by Law Decree 350/01, converted by Law 409/01 and integrated by Art. 15 L. 99/2009)

- coinage offence, spending and introducing into the country, in concert, forged money (Art. 453 C.P.)
- forging of money (Art. 454 P.C.)
- spending and introducing into the country, without concert, forged money (Art. 455 C.P.)
- spending forged money received in good faith (Art. 457 P.C.)
- forging revenue stamps, introducing into the country, buying, storing or circulating forged revenue stamps (Art. 459 P.C., pursuant to Art. 453, 455 and 457 P.C.)
- counterfeiting security paper in use for manufacturing public credit cards or revenue stamps (Art. 460 P.C.)
- producing or storing watermarks or instruments used to forge money, revenue stamps or security paper (Art. 461 P.C.)
- using forged or altered revenue stamps (Art. 464 P.C.)
- counterfeiting, altering or using trade marks or insignia, or patents, models and drawings (Art. 473 P.C.)
- introducing into the country products with forged insignia (Art. 474 P.C.)

CRIMES AGAINST INDUSTRY AND TRADE

ART. 25 bis (1) LGS D. 231/2001 (introduced Art. 15 L. 99/09)

- disruption of industry or trade (Art. 513 P.C.)
- unfair competition using threats or violence (Art. 513bis P.C.)

- fraud against domestic industries (Art. 514 P.C.)
- fraud in exercising trade (Art. 515 P.C.)
- sale of food products as if they were unadulterated (Art. 516 P.C.)
- sale of industrial products with fake insignia (Art. 517 P.C.)
- manufacturing and trading in goods produced usurping industrial property rights (Art. 517ter P.C.)
- counterfeiting geographical indications or denominations of origin of food products (Art. 517quater P.C.)

CORPORATE CRIMES

ART. 25 ter LGS D. 231/2001 (introduced by Art. 3 Lgs. D. 61/02; amended)

- false corporate accounting (Article 2621 and 2622 C.C.)
- forged reports or accounting by persons in charge of independent auditing (Art. 27 Lgs. D. 39/2010)
- obstructing control by shareholders and the board of auditors (Art. 2625 (II) C.c.)
- illicit refund of payments (Art. 2626 C.C.)
- illegal sharing of profits and reserves (Art. 2627 C.C.)
- unlawful transactions on shares or stock of the parent company (Art. 2628 C.C.)
- transaction to the detriment of creditors (Art. 2629 C.C.)
- failure to report conflict of interests (Art. 2629bis C.C.)
- false capital formation (Art. 2632 C.C.)
- unlawful sharing of corporate assets by liquidators (Art. 2633 C.c.)
- illegal influence on the General Meeting (Art. 2636 C.C.)
- market rigging (Art. 2637 C.C.)
- obstructing the work of public supervisory authorities (Art. 2638 (I) and (II) C.C.)

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CRIMES RELATED TO TERRORISM AND SUBVERTING LAW AND ORDER

ART. 25 quater D.LGS 231/2001 (introduced by Art. 3 L. 7/03)

- subversive associations (Art. 270 P.C.)
- associations with terrorism purposes, also at international level, or aimed at subverting law and order (Art. 270bis P.C.)
- aiding and abetting subversion, sedition or terrorism (Art. 270ter P.C.)
- enrolment for terrorism purposes, also at international level (Art. 270quater P.C.)
- training and funding in respect of terrorism, also at international level, and theft goods or cash which have been seized (Art. 270 quinquies C.P.)
- actions with terrorist purposes (Art. 270sexies P.C.)
- terrorist attack (Art. 280 C.P.)
- terrorism using deadly, explosive or nuclear weapons (Art. 280bis and 280ter P.C.)
- kidnapping for purposes of terrorism or sedition (Art. 289bis P.C.)

- instigation to crimes related to terrorism or sedition (Art. 302 C.P.)
- political conspiracy by agreement or association (Art. 304 and 305 P.C.)
- armed groups (Art. 306 P.C.)
- aiding and abetting conspiracy or armed groups (Art. 307 P.C.)
- taking over, hijacking or destroying an aeroplane (Art. 1 L. 342/76)
- damaging ground installations (Art. 2 L. 342/76)

CRIME INVOLVING MUTILATION OF FEMALE GENITAL ORGANS

ART. 25 quarter-1 LGS. D. 231/2001 (introduced by Art. 8 L. 7/06)
(Art. 583bis P.C.)

CRIMES AGAINST AN INDIVIDUAL

ART. 25 quinquies LGS. D. 231/2001 (introduced by Art. 5 L. 228/05, integrated by Art. 3 L. 39/2014)

- reducing to or keeping a person in a condition of slavery or servitude (Art. 600 P.C.)
- child prostitution (Art. 600bis P.C.)
- child pornography (Art. 600ter P.C.)
- keeping pornographic materials (Art. 600quater P.C.)
- virtual pornography (Art. 600quarter-1 P.C., pursuant to Art. 600ter and 600quarter P.C.)
- tourism aimed at exploiting child prostitution (Art. 600quinquies P.C.)
- human trafficking (Art. 601 P.C.)
- buying and conveyance of slaves (Art. 602 P.C.)
- illegal brokerage and exploitation of labour (Art. 603bis P.C.)
- child grooming (art. 609 undecies P.C.)

CRIMES RELATED TO MARKET ABUSE

ART. 25 sexies LGS. D. 231/2001 (introduced by Art. 9 L. 62/05)

- misuse of privileged information (Art. 184 Lgs. D. 58/1998)
- market manipulation (Art. 185 Lgs.D. 58/1998)

CRIMES AGAINST ACCIDENT PREVENTION AND HYGIENE ON THE WORKPLACE

ART. 25 septies D.LGS 231/2001 (introduced by Art. 9 L. 123/07)

- manslaughter (Art. 589 P.C.)
- unintentional injuries (Art. 590 P.C.)

PROPERTY CRIMES

ART. 25 octies D.LGS 231/2001 (introduced by Art. 63 (III) Lgs. D. 231/07, integrated by L. 40/08 and Art. 3 L. 186/2014); Art. 24BIS (introduced by L.D. 93/13, converted by L. 119/13)

- receiving stolen goods (Art. 648 P.C.)
- money laundering (Art. 648bis P.C.)

- using money or other benefits of illegal origin (Art. 648ter P.C.)
- self-laundering (Art. 648ter-1 P.C.)
- computer fraud (Art. 640ter P.C.)

CRIMES INVOLVING THE VIOLATION OF COPYRIGHT

ART. 25 novies D.LGS 231/2001 (introduced by Art. 15 L. 99/09)

- making available to the general public, through an online system, work protected by intellectual property rights or part thereof (Art. 171 (I) (a)bis L. 633/1941)
- making available to the general public, through an online system, work protected by intellectual property rights or part thereof with regard to other people's work not intended for publication, if this offends honour or reputation (Art. 171 (III) L. 633/1941)
- illegal copying, to make a profit, of software programs; import, distribution, sale or storage for trade, business purposes or leasing of software on supports without a SIAE marking; preparing of means to remove or elude protection devices on software programmes (art. 171bis (I) L. 633/1941)
- reproduction, transfer onto another support, distribution, communication, presentation or showing to the public the contents of a database; extraction of information or reuse of the database; distribution, sale or leasing of databases (Art. 171bis (II) L. 633/1941)
- unlawful copying, reproduction, transfer or divulging in public, also in part, of intellectual property intended for television, cinema, sale or rental of records, tapes or analogue supports, or of any other support containing sound or video; illegal reproduction, broadcasting, sale or trade, transfer by any means or illicit importing of more than fifty copies or specimens of work protected by copyright and related rights; entering through an online network system, using any kind of connection, intellectual property material protected by copyright or part thereof (Art. 171ter L. 633/1941)
- failure to transfer to SIAE any identification data of supports not subject to marking or false statement (Art. 171septies L. 633/1941)
- fraudulent, production, sale, import, promotion, installation, alteration, use of equipment or parts of equipment aimed at decoding audio-visual broadcasts with controlled access via radio, satellite, cable, analogue or digital (Art. 171octies L. 633/1941)

CRIMES AGAINST THE ADMINISTRATION OF JUSTICE

ART. 25 decies LGS. D. 231/2001 (introduced L. 116/09)

- inducing not to give statement or to give false statements to a judiciary authority (Art. 377bis P.C.)
- aiding and abetting (Art. 378 P.C.) – only in cross-border crimes

COMPUTER CRIMES AND PRIVACY VIOLATIONS

Art. 24 LGS. D. 231/2001 (introduced L. 48/08)

- illegal access to an IT or online system (Art. 615ter P.C.)
- unlawfully storing or divulging access codes to IT systems (Art. 615quater P.C.)
- divulging of IT equipment, devices or software for the purpose of damaging or

interrupting an IT or online system (Art. 615quinquies P.C.)

- tapping, impeding or illegally interrupting IT or online communications (Art. 617quater P.C.)
- installing equipment aimed at tapping, impeding or interrupting IT or online communications (Art. 617quinquies P.C.)
- tampering with information, data and software (Art. 635bis P.C.)
- tampering with information, data software used by the Government or any other public entity, or for public service in general (Art. 635ter P.C.)
- tampering with IT or online systems (Art. 635quater P.C.)
- tampering with public service IT or online systems (Art. 635quinquies P.C., pursuant to Art. 635quater P.C.)
- forgery of IT documents [published or intended as evidence] (Art. 491bis P.C., pursuant to Art. 476 to 491 P.C.)
- computer fraud against the person providing electronic signature services (Art. 640quinquies)

ORGANISED CRIME

Art. 24 ter LGS. D. 231/2001 (introduced by L. 94/09)

- criminal conspiracy (Art. 416 P.C.)
 - criminal conspiracy for the following purposes:
 - enslavement (Art. 416 P.C. pursuant to Art. 600 P.C.)
 - child prostitution (Art. 416 P.C. pursuant to Art. 600bis P.C.)
 - child pornography (Art. 416 P.C. pursuant to Art. 600ter P.C.)
 - smuggling of foreign processed tobacco (Art. 416 P.C. pursuant to Art. 291quater D.P.R. 43/1973)
 - illegal trafficking in drugs or psychotropic substances (Art. 416 P.C. pursuant to Art. 74 D.P.R. 309/1990)
 - helping illegal immigrants enter or stay in the country (Art. 416 P.C. pursuant to Art. 12 (III) and (V) Lgs. D. 286/1998)
- criminal conspiracy of a mafia type [also foreign] (Art. 416bis P.C.)
- politics-mafia electoral exchange (Art. 416ter P.C.)
- kidnapping to ask for a ransom (Art. 630 P.C.)
- crimes committed under the conditions of Art. 416bis P.C. (i.e. crimes committed using the force of intimidation, association and subjecting or wall of silence derived from it to commit crimes, make a profit or gain unfair advantages, for oneself or others)
- crimes committed with a view to facilitating mafia-type associations according to Art. 416bis P.C.
- aiding and abetting the arrival or stay of illegal immigrants (Art. 12 (III) (V) Lgs D. 286/1998)
- illegal manufacturing, introduction into the country, sale, transfer, storing or

carrying in a space which is public or open to the public assault weapons, parts thereof, explosives, several shooting weapons (except for Art. 2 (III) L. 110/1975) (Art. 695 and ff. P.C., as well as Art. 4 L. 110/1975)

ENVIRONMENTAL CRIMES

Art. 25 undecies D.LGS 231/2001 (introduced Art. 2 Lgs. D. 121/11, amended by L. 68/2015)

- Environmental pollution (Art. 452bis P.C.)
- Environmental disaster (Art. 452quater P.C.)
- Unvoluntary crimes against the environment (Art. 452quinques P.C.)
- Trafficking and abandoning highly radioactive materials (Art. 452sexies P.C.)
- Killing, destroying, capturing, taking, keeping specimens of protected wild animals or plant species (Art. 727bis P.C.)
- Destroying or damaging habitats inside a protected site (Art. 733bis P.C.)
- Unauthorised opening or discharging of industrial wastewater (Art. 137 Lgs. D. 152/06)
- Unauthorised waste management activities (Art. 256 Lgs. D. 152/06)
- Ground, underground, water pollution (Art. 257 Lgs. D. 152/06)
- Violation of reporting duties as regards mandatory bookkeeping and form-filling by the persons in charge of waste disposal and collection (Art. 258 Lgs. D. 152/06)
- Illegal waste trafficking (Art. 259 Lgs. D. 152/06)
- Organised illegal waste trafficking (Art. 452quaterdecies P.C.)
- Violation of duties related to the computer system for online waste traceability (Art. 260bis Lgs. D. 152/06)
- Exceeding and violating the minimum values for emissions in the operations of a plant (Art. 279 (V) Lgs. D. 152/06)
- Import, export, re-exporting of specimens of protected animals, failing to follow the provisions for their safety, use differing from the authorisations of protected animals, transport or transit without authorisation of protected specimens, trading in plants reproduced in a lab going against the regulations, keeping and using for profit any specimens without the required authorisation (Art. 1 - 2 L. 150/92)
- Keeping live specimens of mammals and reptiles of wild species or bred in the wild which might constitute a danger (Art. 6 L. 150/92)
- Violation of norms on the subject of stopping and reducing the use of harmful substances (Art. 3 L. 549/93)
- Voluntary water pollution (Art. 8 Lgs. D. 202/07)
- Involuntary water pollution (Art. 9 d.lvo 202/07)
- Unauthorised installation or operation of thermal plants producing immissions (Art. 279 Lgs. D. 152/06)

CRIMES RELATED TO IMMIGRATION

Art. 25 duodecies Lgs. D. 231/2001 (introduced by Lgs. D. 109/12)

◦ Employing citizens from third countries staying illegally (Art. 22 (12bis) Lgs. D. 286/1998).

CROSS-BORDER CRIMES

Criminal conspiracy for the purpose of smuggling tobacco products or illegally trafficking in drugs or psychotropic substances, money laundering, use of cash or other benefits of illegal origin, trafficking in migrants, obstruction of justice, aiding and abetting on a cross-border level, are all included among crimes listed under Art. 231.

CRIMES RELATED TO RACISM AND XENOPHOBIA

Art. 25 terdecies D.LGS 231/2001 (introduced by L. 167/17, amended Lgs. D. 21/18)

◦ Propaganda and instigation to crime associated with racial, ethnic or religious discrimination (Art. 604bis).

FRAUD IN SPORTS COMPETITIONS AND GAMING OR GAMBLING

Art. 25 quaterdecies Lgs. D. 231/2001 (introduced L.D. 124/2019)

◦ Fraud in sports competitions (Art. 1 L. 401/1989)

◦ Illegal gaming or gambling activities (Art. 4 L. 401/1989)

TAX CRIMES

Art. 25 quinquiesdecies Lgs. D. 231/2001 (introduced L.D. 124/2019)

◦ false statement using non-existent invoices or other documents (Art. 2 Lgs. D. 74/2000).

◦ false statements using other illegal means (Art. 3 Lgs. D. 74/2000).

◦ issuing invoices or other documents for non-existent transactions (Art. 8 Lgs. D. 74/2000)

◦ hiding or destroying accounting documents (Art. 10 Lgs. D. 74/2000)

◦ voluntarily evading taxes (Art. 11 Lgs. D. 74/2000)

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Art. 12 L. 9/13, also introduced predicate offences for organisations operating in the area of virgin olive oils (Art. 440, 442, 444, 473 P.C.).

It is to be expected that the list of predicate offences provided by Lgs. D. 231/2001 will be extended to include fraud in supplies, in the agricultural sector and any crime related to smuggling.

1.3 Selection of the Organisation, Management and Control Model

In the event of the aforesaid crime being committed, Art. 6 and 7 of the Decree stipulate specific forms of exemption from liability, if the Company can prove:

a) that it has selected and effectively implemented before the offence as committed, through its management body, suitable organisation and management models for the prevention of crimes of the same kind as the one which occurred;

b) to have entrusted to an in-house body, with independent powers of action and inspection, the task of watching over the operation and compliance with the models, as well as of updating them;

c) that the persons who committed the crime acted by voluntarily eluding the said organisation and management models;

d) that the Organisation referred to in item b) above did not fail to supervise or did not exercise insufficient supervision.

If, on the other hand, the crime is committed by persons acting under the management or responsibility of one of the persons listed above, the Entity is responsible if the crime in question was made possible by failure to observe the said duties of management and supervision (to be proved by the public prosecution).

The Decree also stipulates that, in relation to the extending of powers by proxy and to the risk of crimes being committed, the organisation, management and control models should meet the following requirements:

- 1 select any areas at risk of the crimes listed in the Decree being committed;
- 2 draft specific protocols with a view to planning the formation and implementing of the organisation's decisions with regard to the crimes to be prevented;
- 3 establish procedures for singling out and managing financial resources suitable to prevent crimes from being committed;
- 4 provide for duties of information in respect of the organisation in charge of supervising the operation and compliance with the Model;
- 5 lay out an in-house disciplinary system suitable for sanctioning failure to comply with the measures provided in the Model.

Moreover, the Model is expected to follow a dynamic approach, meaning that it needs to be constantly adjusted and changed based on changes within the organisation, in terms of corporate activities, procedures for implementing the latter, reference standards).

Decree 231/2001 stipulates that the organisation, management and control models may be selected – making sure that the requirements listed above are met – on the basis of codes of behaviour (for example Guidelines) drafted by the relevant trade associations.

1.4 Sanctions

Below is a detail of possible sanctions which may be imposed on the organisation for committing or attempting the crimes listed above:

- fines
- disqualification measures, such as being banned from conducting business, suspension or revoking of licenses or concessions, ban on contracts with the Public Administration, exclusion or revoking of financing and contributions, ban on advertising goods and services;
- seizure (and preventive confiscation as a protective measure) of any profit which the Organisation may have made from the crime, also equivalent in form;
- publishing of the court order (if a disqualification measure is applied).

It is also worth mentioning that the Judiciary Authority, according to the decree, may provide: a) preventive seizure of the items whose confiscation has been allowed (Art. 53); b) preventive confiscation of movable or immovable assets of the Organisation if it appears that there is good reason to believe that any fine, legal expenses or other sums due to the Government may be unavailable or wasted (Art. 54).

1.5 Outline of the Guidelines by Confindustria

To date, the most widely used reference with regard to organisation, management and control models pursuant to Lgs. D. no. 231/2001, is represented by the Guidelines issued by Confindustria on 07/03/2002, updated in March 2014, which set out the following main points for the construction of Models (including, in its latest review, one section dedicated both to company groups and to small-sized enterprises):

- outlining the areas of risk, with a view to determining in which company area/department it is possible that the offences listed in the Decree may be committed;
- preparing a control system with a view to preventing risks through the adoption of suitable protocols.

Below are the main components of the control system selected by Confindustria:

- Code of Ethics (or of Ethics and Behaviour); organisation system;
- mechanical and electronic procedures;
- authorisation and signature powers;
- control and management systems;
- notification to staff and training.

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The components of the control system shall follow the principles listed below:

- all operations should be verifiable, documented, consistent and congruous;
- application of the principle of separation of functions (for example, nobody may be in charge of a whole process);
- documentation of inspections;
- introduction of a system of sanctions in case of violations of the Code of Ethics / of Behaviour and of the procedures of the Model;
- selecting the requirements of the Supervisory Authority, summed up as follows:
 - . autonomy and independence;
 - . professionalism;
 - . continuity of action;
- obligations of reporting to the control organisation.

The Guidelines drafted by Confindustria include ad hoc principles for responsibility pursuant to Lgs. D. 231 in groups of companies.

After Law 179/2017 entered into force (amending Art. 6 of Lgs. D. 231/2001 extending what is known as whistleblowing protection – already applicable in the case of government employees according to Art. 54bis of D.Lgs 165/2001 – to the private

sector) Confindustria added further clarifications on the subject.

The mechanisms for managing whistleblowing chosen by Confindustria, based on the principle of integrity of the organisation, essentially entail having channels reserved to reports and their concrete implementation, as well as suitable guarantees for the confidentiality of the person reporting, in setting requirements for the reports and adjusting the disciplinary system accordingly (adding the possibility, unlike government employees, of anonymous reporting).

It is worth noting that any difference in respect of specific points in the Guidelines by Confindustria does not make the Model any less valid. An individual Model must be drafted taking into account the actual organisation to which it refers, therefore it may differ from the Guidelines which – by nature – are intended as a general suggestion.

2 – Selection of the Organisation, Management and Control Model by MediNeos

2.1 The company's core business

MediNeos S.U.R.L. (hereinafter also "MediNeos") is a Contract Research Organization involved in the design and implementation of clinical studies, with reference - specifically though not exclusively - to observational studies.

The Company was established in 2003 as an enterprise strongly committed to its business purpose, focusing on the quality of services, and motivated to grow thanks to a flexible, efficient and reliable structure, in charge of running clinical-epidemiological projects with the highest level of safety and professional skills.

The company has rapidly grown from a small-sized enterprise, to the point of achieving a high standing in the area of clinical research as a business operating with high quality and ethical standards.

MediNeos is specialised in the design and implementation of observational Studies and has strongly contributed to divulging in Italy the "culture" of observational research, encouraging Institutions to issue specific regulations on the subject (which had never been done before March 2008).

MediNeos has strongly contributed to organising numerous events and conferences, where it has promoted observational research as complementary to clinical research of an experimental kind, finally reaching the goal of organising the First National Conference on Observational Studies (22 October 2009).

After 2010 MediNeos also started to operate beyond the domestic borders, becoming a CRO able to conduct international clinical Studies, also as CRO coordinating other partners.

In conducting its business, due to the specificity of the market in which it operates, MediNeos is always attentive to expectations of the community and its customers,

with a view to constantly guaranteeing a very high standard of quality, mindful as it has been since the beginning of the ethical aspects in an enterprise.

Within this framework it has decided to follow the provisions in Decree 231 aimed at implementing a structured system suitable to mitigate the risk of misdemeanours occurring in the course of its business, so as to reduce the danger of the crimes mentioned in the Decree being committed and to ensure fairness and transparency in its dealings.

2.2 Adjustment by MediNeos to the provisions in the Decree

MediNeos, ever mindful of the need to spread and consolidate the culture of transparency and integrity, as well as being aware of the importance of guaranteeing conditions of fairness in running its business and corporate activities to safeguard its own position and to meet customer expectations has chosen the organisation, management and control model in line with the provisions in Lgs. Decree 231/2001 and with the principles of the Code of Ethics and Behaviour.

During the meeting of 2 October 2009 the Board of Directors of MediNeos confirmed the assignment to the external consultants of the company, attorneys Francesca Preite and Antonella Lopopolo to continue their efforts aimed at implementing the Decree; for this purpose it also appointed the required Supervisory Authority, represented by attorney Valeria Miari. As will be detailed below, the Supervisory Authority is expected to support the external consultants and the Company in establishing an Organisation Model suitable for preventing predicate crimes in respect of the organisation's legal responsibility, as stipulated by Lgs. Decree 231/2001.

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MediNeos decided to adopt the said Model because it is convinced that, over and above the provisions in the Decree – which, it should be noted, provide for a Code of Ethics and Behaviour as an optional element and not an obligation – the latter can be a valid instrument for raising awareness in respect of all employees in the Company, as well as of all those who operate in the name and on behalf of the said Company (i.e.: customers, suppliers, partners, staff members in various capacities), to make sure that their behavior on the job is appropriate and straightforward, to prevent the risk of the crimes listed in the Decree from being committed.

2.3 Objectives pursued in selecting the Model

The main objective of the Model is to outline a structured and organic system of inspection procedures and actions, aimed at preventing – to the largest possible extent – the crimes mentioned in Decree 231/2001 from being committed.

The selection of activities at risk of crimes being committed (aka “sensitive activities”) and the relevant procedures entail the following:

- on the one hand, raising awareness, among all those who operate in the name and on behalf of MediNeos, about specific offences strongly disapproved and not tolerated by the Company, because they always go against its interests, even when – apparently they might lead to an immediate economic advantage in economic terms;
- on the other side, thanks to constant monitoring of the business, it allows for promptly intervening to prevent and counteract the crimes in

question;

- finally, informing all those who operate in any capacity in the name, on behalf or anyway in the interest of MediNeos, that violation of the provisions in the Model will lead to sanctions being applied, or to the contract being terminated.

Below are the pivotal elements in the Model, in addition to the principles listed above:

- mapping the activities at risk, namely those activities as part of which it is most likely that the crimes listed in the Decree may be committed, also known as “sensitive activities”;
- assigning to the Supervisory Authority specific tasks related to watching over the effective and appropriate operation of the model;
- checking and documenting any relevant operation;
- implementing and respecting the principle of separation of functions, i.e. that nobody may be independently in charge of one whole process;
- assigning powers consistent with organisational duties;
- *ex post* checks on corporate behaviours, as well as of the operation of the Model, which subsequently needs to be updated on a regular basis;
- divulging and involving all levels of the company in respect of corporate rules of behaviour, procedures and policies.

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There are other pivotal elements in the Model, aimed at fostering cooperation on the part of employees, in order to make it easier to reveal instances of corruption within public or private organisations, namely:

- boosting the action aimed at preventing and counteracting corruption, crime and irregularities within the Company, to safeguard the integrity of MediNeos;
- inclusion of systems which make it possible for employees to report, in conditions of safety, any offences of which they might become aware;
- inclusion of requirements for reporting which allow for not wasting the effectiveness of the measure and for revealing any unlawful behaviour;
- ban on any act of retaliation or discrimination, even if indirectly, against those filing a report for reasons in any way related to the report in question;
- adjusting the disciplinary system in respect of the provision of sanctions against those who violate the measures aimed at protecting the person filing a report, as well as against anyone who is proved to have filed, by negligence or in bad faith, reports without merit;
- provisions on the subject of labour law which involve the possibility of reporting to the Italian Labour Inspectorate any discriminatory measures adopted by the Company;
- at least one of the recipients of the report should be an independent party.

2.4 Structure of the Model: General Section and Specific Section

The Model consists of the following sections:

- General Section: This document includes a short, though indispensable, outline of the crimes mentioned in the Decree, of possible sanctions, as well as a short summary of the Company's core business and mission; the document also sets out the structure of the Model, as well as describing the operation of the Supervisory Authority and of the sanction procedures, with reference to the Code of Ethics and Behaviour and to the Disciplinary Code which have been selected;
- Specific Section: The document describes a system of control actions whose purpose is to identify areas possibly at risk as part of the corporate activities where the possibility of crimes being committed is considered highest (aka: 231 Procedures). This section also includes, as annexes, the Company's Code of Ethics and Behaviour, disciplinary Code, organisation system, and most notably the proxy system, the schedule for staff formation and divulging in respect of the Model.

2.5 Approval of the Model, changes and integrations of the latter

This Model (General Section), in its first version (December 2009), was approved by the Board of Directors of MediNeos with a decision dated 01/12/2009. The first revision of the Model (December 2010 version) was approved by the Board of Directors with a decision dated 23/11/2010, the second revision (December 2011) with a decision dated 28/02/2012, the third revision (December 2012) with a decision dated 29/11/2012, the fourth revision (December 2013) with a decision dated 15/11/2013, the fifth revision (December 2013) with a decision dated 06/05/2014, the sixth revision (December 2014) with a decision dated 30/01/2015, the seventh revision (December 2015) with a decision dated 29/01/2016, the eighth revision (December 2016) with a decision dated 09/11/2016, the ninth revision (December 2017) with a revision dated 23/12/2017, the tenth revision (April 2019) with a decision dated 27/09/2019. This is the eleventh revision (dated April 2020).

The Specific Section of this Model was approved by the Board of Directors, in its first version, with a decision dated 10/09/2010 (September 2010 version). Its first revision was approved on 29/11/2011 (October 2011 version), the second with a decision dated 15/11/2013 (September 2013 version), the third with a decision dated 09/10/2014 (September 2014 version), the fourth (September 2015 version) with a decision dated 12/11/2015, the fifth (September 2016 version) with a decision dated 15/09/2016, the sixth (September 2017 version) with a decision dated 23/12/2017, the seventh (September 2018) with a decision dated 07/08/2018, the eighth (April 2019 version) with a decision dated 27/09/2019.

According to the Decree, the Model is "an official document issued by the management body". Therefore any subsequent amendments, as well as any substantial integrations, are the responsibility of the Board of Directors at MediNeos.

The latter, following the instructions given by the Supervisory Authority, shall

complement this Model based on reporting and audits by the SA, as well as possibly adding other specific offences which, by virtue of the introduction of new regulations or of changes in case law, may be further associated with the application of Decree no. 231.

Moreover, a review is conducted on all reports received during the year, on the actions undertaken by the SA and by other persons involved, of events considered at risk, on awareness on the employees' part with regard to the specific offences mentioned in the Decree, by means of sample inspections.

2.6 Recipients of the Model

The rules contained in the model apply to those who have, even *de facto*, functions of management, administration, director or control at MediNeos, to employees, as well as those who, even though they are not part of the Company, operate based on its mandate or are associated with the latter by service relationships, etc...

MediNeos, through this Model, informs all persons involved using appropriate procedures aimed at ensuring its effective knowledge.

As regards employees, when they are hired, they are given by the company a copy of the Code of Ethics and Behaviour and of the corporate policies.

A copy of the documentation related to training courses, as well as a copy of the code of Ethics and Behaviour, of the Disciplinary Code and of the Model are published on the company's intranet.

All persons for which the Model is intended are expected to strictly abide by all its provisions, also in respect of duties of loyalty, correctness and diligence which derive from legal relations established with the Company; in this regard they are expected to issue to the company an affidavit where they confirm that they have received (or reviewed) the Code of Ethics, the disciplinary code and the Model and commit to follow the relevant provisions.

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Also the texts of contractual clauses need to be approved by the relevant offices in the company, according to the said principles, policies and procedures.

3 – Supervisory Authority

In the event of specific crimes being committed, the Decree sets as a prerequisite exempting from administrative responsibility, the fact that a clearly defined structure within the Entity (with independent powers of action and control) shall be assigned the task of watching over the operation and compliance with the model, as well as of introducing any updates thereto.

3.1 Selecting and appointing the Supervisory Authority

In accordance with the Decree, the person entrusted with this task is attorney Valeria Miari, following a decision by the Board of Directors dated 2 October 2009, which is an integral and substantial part of this Model.

This choice is related to the fact that the said person has been acknowledged, based on professional experience, as the most suitable to take on the position of member of the Supervisory Authority, taking into account the requirements of autonomy, independence, professionalism, continuity in action, honourability and having not

conflicts of interest with regard to the said office. The choice of counsel Miari was made based on technical knowledge in respect of the creation of in-house control systems and of legal expertise. The relevant *professional resume* has been saved in the Company files.

3.2 Functions and powers of the Supervisory Authority

The operation of the SA is regulated by the relevant in-house standards, drafted by the said Organisation. These regulations, delivered to the Directors, based on the ethical principles set out in this document, shall also include the functions, powers and duties of the organisation.

The Supervisory Authority is expected to watch over:

- the effectiveness of the Model: i.e. making sure that the actions inside the Company are in line with the established Model;
- the efficacy of the Model: i.e. making sure that the model is actually suitable to prevent the crimes mentioned in the Decree and in laws which might have subsequently extended its scope;
- updating of the Model: selecting and submitting to the Board of Directors possible updates and amendments to the Model as a consequence of changes in regulations or corporate conditions.

On a more operational level, the Supervisory Authority has the following tasks:

- checking on a regular basis the map of activities where there is a crime risk (aka "sensitive areas"), then adjust it to any changes in the corporate activity and/or structure. For this purpose, the Supervisory Authority needs to receive the relevant reports from the management and persons in charge of inspection activities in individual offices, about any situations which might expose the Company to the risk of a crime. All correspondence shall be exclusively in writing, also by e-mail;
- conducting on a regular basis, possibly also using external professionals, audits aimed at verifying compliance with the Model, more specifically to guarantee that the procedures and inspections are implemented and documented accordingly, and that ethical principles are followed;
- checking that the Model is adequate and effective in preventing the crimes mentioned in the Decree;
- conducting on a regular basis targeted audits on specific operations or actions, especially with regard to sensitive activities; the results of the latter shall be summarised in the relevant report, whose contents shall be notified to the corporate bodies;
- liaising with other company offices (possibly by organising meetings) for an exchange of information aimed at an updated mapping crime risks / sensitive areas, for the following purposes:
 - keep them under control, with a view to constantly monitoring them;
 - check the various aspects pertaining to implementation of the model Model (drafting of standard clauses, training of staff, changes at regulatory and organisation level, etc.);

- make sure that the corrective actions necessary to make the Model adequate and effective are undertaken promptly;
- collecting, processing and saving all of the relevant information with regard to the Model, as well as updating the list of relevant information to be passed on to the SA. For this purpose, the Supervisory Authority shall be given free access to all company documents and kept constantly informed by the management:
 - on any aspects of the corporate activity which might expose the Company to a risk deriving from one of the crimes mentioned in the Decree;
 - on relations with Consultants and Partners;
- collecting, always in an anonymous form if requested, or ensuring confidentiality, reports of offences committed by employees according to Law 179/2017, as well as of any retaliation or discriminatory measures undertaken following the said reports, reviewing their content, possibly asking for clarifications and documents, informing the company management thereof;
- promoting initiatives related to training and information about the Model, and prepare the necessary documentation for this purpose, in coordination with the HR office;
- reporting on a regular basis to the Chief Executive Officer, to the Board of Directors with regard to the implementation of corporate policies in respect of the Model.

The Supervisory Authority, on the contrary, shall not be allowed any decision-making powers, not even of an impeding nature, in respect of the company's business.

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4 – Information flows

4.1 Reporting to Corporate Bodies

The Supervisory Authority is responsible for reporting to the Board of Directors as follows:

- immediately: any significant issues arising in respect of the business;
- on a regular basis (at least once a year): any actions undertaken or to be undertaken with regard to the implementation of the Model by MediNeos. These reports shall be saved in the Company files.

The Supervisory Authority may be invited to report to the Board of Directors with regard to its activities.

Moreover, the Supervisory Authority, depending on the individual circumstances, may:

- 1) forward the results of its inspections to manager of offices and/or processes, if the activities appear to be susceptible to improving. In this case, the Supervisory Authority needs to receive from the process managers reports on any implementation activities which the bodies in charge might choose to undertake;

- 2) report any behaviours/actions not in line with the code of Ethics and Behaviour and with corporate procedures, in order to:
- i) acquire all the elements required for notifications to the department in charge for assessment and application of disciplinary actions;
 - ii) make sure that the event does not occur again, giving instructions for removal of any shortcomings.

The activities listed under item 2) shall be reported by the Supervisory Authority to the Board of Directors as soon as possible, also asking for support from other corporate structures which may cooperate in activities related to inspection and selection of actions aimed at preventing the occurrence of repeat offences.

Copies of the relevant transcripts will be saved by the Supervisory Authority and by the organisations involved in the specific case.

4.2 Reporting to the Supervisory Authority: provisions of a general nature and specific mandatory provisions

The Supervisory Authority shall be informed, through appropriate reports sent by persons required to comply with the Model, about events which might entail a responsibility on the part of MediNeos according to the Decree.

In this regard the following provisions of a general nature shall apply:

- each Office Manager shall collect any reports concerning crimes being committed or the reasonable danger of crimes provided in the Decree being committed, or in any case behaviours which, in general terms, are not in line with the rules of behaviour listed in the Model;
- each employee shall report the violation (or alleged violation) of the Model by contacting the Supervisory Authority (in this regard, "dedicated information channels" shall be established in order to facilitate the flow of reports and information, with a view to preserving the confidentiality or the anonymity of the person reports, as well as providing suitable guarantees to prevent the likelihood of any retaliation, also according to the provisions in the Regulation with regard to reporting offences and misdemeanours – whistleblowing);
- the Supervisory Authority shall evaluate the reports, as well as any formal complaints received and the activities to be implemented; any subsequent action shall be defined and applied according to the provisions below with regard to the disciplinary system.

Those reporting in good faith are protected against any form of retaliation, discrimination or penalisation and, in any case, the confidentiality of the person reporting will be guaranteed, notwithstanding any legal obligations and the protection of the rights of MediNeos or of persons being accused in error or in bad faith. In accordance with the provisions in Art. 6 Lgs. D. 231/2001, as amended by Law 179/2017, all retaliation and discriminatory measures against the person filing a report during a phase subsequent to the formal report associated with it in any way, shall be regarded as null and void. The employee filing the report and the relevant trade union may lodge a complaint with the Italian Labour Inspectorate detailing any discriminatory or retaliation measures adopted by the Company. Moreover, sanctions shall be levied against those who violate any measures to protect the person filing the

report, as well as against anyone who, through wilful misconduct and gross negligence, files a report which proves to be without merit.

Apart from the reports pertaining to violations of a general nature as outlined above, the Supervisory Authority shall be sent information with regard to the following:

- disciplinary proceedings started in respect of a notice that the Model has been violated;
- sanctions which have been levied (including proceedings against employees), or the possible dismissal of the relevant cases with the relevant reasons.

4.3 Reporting by company staff or by third parties

The company needs to forward to the Supervisory Authority all other information, of any kind, also from third parties and related to the implementation of the Model in the business areas at risk.

In this regard the following provisions shall apply:

- possible reports shall be collected with regard to crimes provided in the Decree being committed which affect the company's business, or – in any case – to behaviours not in line with the code of conduct approved by MediNeos;
- all incoming reports, including those submitted unofficially, shall be forwarded to the Supervisory Authority; the latter will evaluate the reports received and any subsequent measures, at its reasonable discretion and under its own responsibility, possibly hearing the author of the report and/or the person responsible for the alleged violation, then motivating in writing its possible refusal to conduct an in-house investigation;
- the reports, in line with the provisions in the Code of Ethics and Behaviour, may be filed in written form, and their subject may be any violation or suspected violation of the Model. The Supervisory Authority shall act in order to protect those filing a report against any form of retaliation, discrimination or penalisation, also making sure that the identity of the person filing a report is kept confidential, notwithstanding obligations arising by law and for the protection of the rights of companies or of persons being accused in error and/or in bad faith;
- there will be “dedicated information channels” (hereinafter “dedicated Channels”), which shall serve a dual purpose: facilitate the flow of reports and information to the Supervisory Authority and allow for prompt resolution of dubious cases.

4.4 Reporting by and to the IQVIA Supervisory Authority

The Supervisory Authorities at IQVIA and at MediNeos shall conduct cross-checks on a regular basis.

In any case, the Supervisory Authority at MediNeos shall notify without delay the

IQVIA Supervisory Authority of any violations of its own Organisation Model or, in all instances, of situations entailing the potential risk of a predicate offence which might involve the parent company.

The Supervisory Authority at IQVIA shall report without delay any possible violation, remark or situation which might be relevant in any way for the purposes of its monitoring and prevention activity.

4.5 Communication channels with the Supervisory Authority

All correspondence with the Supervisory Authority shall be:

- sent to the dedicated e-mail address: odv@medineos.com
- sent to the private e-mail account: valeria@miaripreiteavv.it
- by telephone: 0522308943 – 3476107458
- by fax: 0522308864
- by mail to the address: Via Carso 2 - 42124 Reggio Emilia
- hand-delivered (possibly anonymously) in the dedicated letterbox located in the ante-bathroom on the company premises at number 54/A/B.

5 - Recruitment and training

5.1 Employees

For purposes of efficiency of this model, it is the objective of MediNeos to guarantee correct knowledge and dissemination of the rules of conduct contained therein, both in respect of in-house employees and of those known as "external staff". This objective covers all corporate resources included in the two aforesaid categories, both those already working for the Company and those to be recruited.

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The required level of training and information is implemented at a different level of depth depending on the different level of involvement of the said human resources in what are known as "sensitive activities".

The training plan is implemented in close collaboration between the Legal Department and the Supervisory Authority. Training, as pivotal element for the purpose of concretely implementing the Model, has already started at MediNeos. More specifically, on 10 November 2009 MediNeos organised, for all its employees, a course on the subject of "the administrative liability of legal persons" held by Francesca Preite, attorney-at-law in collaboration with the Supervisory Authority.

Following the selection of a Model and mapping of areas where there is a crime risk, a specific training plan has been implemented, continuously following the development of the company's business and the new regulations gradually introduced, also with regard to the inputs for improvement reported by the Supervisory Authority in its six-monthly report to the board of Directors and to the outcome of individual audits.

The Supervisory Authority, for this purpose, may avail itself of external consultants for specific topics, for example safety on the workplace.

Each new recruitment by the Company shall include basic training, also in respect of the significance and meaning of Lgs. D. 231/2001, as well as of the principles of the Code of Ethics and Behaviour, of the Organisational Model and role of the Supervisory Authority.

5.2 External Staff and Partners

It is also possible that persons outside MediNeos (for example Consultants, Partners, and suppliers) may be informed about the relevant policies and procedures based on this organisation Model, as well as the texts of the contractual clauses generally used in this regard.

6 – Disciplinary system

6.1 General principles

Pursuant to Art. 6, (2) (e), and 7 (4) (b) of the Decree, the Model may be considered as being effectively implemented only if it includes a disciplinary system suitable to punish failure to abide by the measures included therein. This disciplinary system is addressed to employees and executives, with appropriate sanctions of a disciplinary nature.

The drafting of a suitable sanctioning system, in cases where the provisions in the Model have been violated, is a prerequisite for the effectiveness of the Model in question.

The application of disciplinary sanctions is irrespective of the outcome of penal proceedings, because the rules of conduct provided in the Model have been approved by MediNeos in a fully independent manner and regardless of the type of offences which the violations of the Model may determine.

The Company has drafted a Disciplinary System, according to the aforementioned principles, which is an integral and substantial part of the Model (in its most recent version, approved by the Board of directors with a decision dated 05/12/2018).

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6.2 Measures in respect of Directors

In the event of the regulations in force, the Model or the Code of Ethics and Behaviour, as well as the Regulation on the procedure for reporting offences and misdemeanours (whistleblowing) being violated by the Directors of MediNeos, the Supervisory Authority shall notify the Board of Directors, which then takes the actions required by the regulations in force.

6.3 Measures in respect of staff members, consultants and other third parties

Any action by staff members, consultants or other third parties connected with MediNeos by a contractual relationship without being employees, which violates the provisions of the Model and/or of the Code of Ethics and Behaviour may determine, according to specific contractual clauses in the letter of assignment or even if the latter are absent, termination of the contractual relationship, notwithstanding the request for reimbursement if the said actions should damage the company, even irrespective of termination of the contractual relationship.

7 – Code of Ethics and Behaviour

The selection of relevant ethical principles – also – for the prevention of “231 crimes” is a fundamental element in the preventive inspection system: MediNeos has included these principles in a Code of Ethics, approved on 08/10/2009, which then became part, with changes and innovations, of a Code of Ethics and Behaviour, whose first

version is dated October 2016, approved on 15/09/2016, which is an integral and substantial part of this Model.

8 – Regulation on reporting offences and misdemeanours - whistleblowing

Pursuant to the issuing of Law 179/2017 MediNeos has approved, with a decision dated 05/12/2018, a Regulation aimed at implementing principles targeted to revealing corruption and illicit behaviours on the workplace, and – more in general – to further consolidating the integrity of the Company, by means of suitable mechanisms to safeguard the person filing the report. This Regulation is an integral and substantial part of this Model.