



ORGANIZATION, MANAGEMENT AND CONTROL MODEL

(pursuant to Legislative Decree n. 231, 8th June 2001)

adopted by resolution of the Board of Directors on 18/03/2016

GENERAL PART

1. Legislative Decree n. 231, 8th June 2001

1.1 Regime of administrative responsibility of Bodies

Legislative Decree n.231 8th June 2001 (hereinafter also "Legislative Decree 231/2001" or "Decree"), containing Regulations for administrative liability of legal persons or entities, companies and other associative associations, even those devoid of legal persons or entities (so-called "Bodies"), in accordance with art. 11 of Law n. 300, 29th September 2000, introduced the administrative liability of bodies for crimes for the first time in Italy, in addition to the liability of the individual who materially commits the offence.

This is a new and more extensive form of liability which affects the Body for offences committed, in its interest or to its advantage, by subjects which are functionally linked to it (subjects who occupy top positions and those subject to their direction and surveillance).

The Decree foresees that Bodies can be held liable and consequently punished, exclusively in relation to the committing of such crimes (so-called "underlying offences") specified by the law, although said list may be subject to amendments and supplements implemented by the legislator.

The Decree aims to ensure statutory compliance as regards the liability of legal persons or entities, with international conventions which Italy entered some time ago¹.

Therefore the first fundamental criteria for indictment regards the fact that the crime was committed in the interest or to the advantage of the Body: this means that the Body is liable whenever the offence was committed to favour the Body, regardless of whether or not the objective is effectively or tangibly achieved.

The Body is not liable if the offence has been committed by one of the aforementioned subjects in the exclusive interest of themselves or third parties.

The second fundamental criteria for indictment regards the type of subject which commits the crime which may give rise to the body's administrative.

Said subjects may be:

- subjects occupying top positions (such as, for example, legal representatives, the director, general manager or people who, both as to fact and law, manage or exercise control over the Body);
- subordinate subjects, typically employees, but also subjects external to the body, who have been entrusted with an assignment to be carried out under the direction and surveillance of subjects occupying top positions.

In the event that several subjects are involved in committing a crime (art. 110 Criminal Code), it is not necessary that the "qualified" subject directly carries out the offence, their conscious and effective contribution in committing the offence determines liability.

¹ Such as the Brussels Convention, 26th July 1995 on the protection of the European Community's financial interests, the Convention dated 26th May 1997, also signed in Brussels, on the fight against corruption and the OECD Convention dated 17th December 1997 on the fight against corruption of foreign public officials in economic and international operations.

Liabilities foreseen by the aforementioned Decree also regard crimes committed by the Body abroad, under the following conditions:

- the crime was committed by a subject legally linked to the the Body, either in a top or subordinate position, as mentioned here above;
- The Body's main office is located in Italy;
- The Body may only respond in cases and under the conditions foreseen in articles 7, 8, 9 and 10 of the Criminal Code and whenever legislation specifies that the the guilty individual is punished upon request by the Minister of Justice, proceedings are taken against the Body only if the request also refers to the Body;
- The Body is liable only if the State in which the crime was committed does not undertake proceedings against it.

The Body is held administratively liable also in the case that one of the crimes foreseen by the decree is committed, even only in the form of an attempt (art. 56 Criminal Code).

1.2 Sanctions applicable to the Body

Sanctions applicable to the Body as a consequence of committing or attempting to commit underlying offences are:

1. **Fines:** a sanction applicable to all crimes, determined through a system based on "quotas", no less than a hundred and no greater than a thousand, each of a value of at least 258.23 Euros and a maximum of 1,549.37 Euros (therefore the sanction is between a minimum of 25,823 Euros and a maximum of 1,549,370 Euros, except for company crimes, in which case fines are doubled, as laid down in the Savings Law 262/2005, art. 39, paragraph 5).

The judge determines the number of quotas, taking into account the gravity of the offence, the degree of the Body's liability as well as the activities carried out in order to eliminate or attenuate the consequences of the fact and to prevent the commission of further crimes. The amount of the quota is established based on the Body's economic and financial conditions, in order to ensure the effectiveness of the sanction.

The fine is reduced by a third and up to a half if before the opening statement of first instance proceedings:

- a. The Body has fully compensated damages and has eliminated the damaging or dangerous consequences of the crime, or has effectively undertaken actions to achieve such goals;
- b. a suitable Organisational Model has been adopted or implemented for the prevention of crimes similar to the one which has been committed.

The fine is also reduced by half if:

- the offender committed the offence prevalently in their own interest or in the interest of third parties, and the Body did not benefit from it, or benefited only slightly;
- financial damages incurred are particularly tenuous.

The fundamental principle which guides the entire concept of Body liability establishes that only the Body responds to the obligation for the payment of the fine it has been issued with, with its own finances or funds. Therefore legislation excludes the direct financial liability of shareholders or associates, regardless of the status in law of the collective Body.

2. **Bans:**

- 1) Ban from carrying out business;
- 2) suspension or revocation of authorisations, licences or concessions functional to the commitment of the crime;
- 3) ban from negotiating with Public Bodies;
- 4) ban from breaks, funding, contributions, subsidies and the revocation of those which have already been granted;
- 5) ban from advertising goods or services.

Bans are issued together with fines only if explicitly foreseen for that specific type of crime and only in the presence of one of the following conditions:

- i. the company has previously committed a crime (reiteration of an offence);
- ii. the company has obtained considerable profit from the crime.

3. **Confiscation** (and preventive requisition as a precautionary measure) of the profit and price of the crime, also in equivalent form (the confiscation of a sum of money, assets or other valuable utilities which correspond to the price of profit obtained from the crime).
4. **Publication of the judgement** which may be ruled by the judge when the Body is issued with a ban.
5. **Precautionary measures** The Public Minister may request the application of bans, also as a precautionary measure, whenever:
 - a. there is strong evidence of the Body's liability;
 - b. there are grounded and specific elements which support belief of a tangible danger that similar crimes may be committed.

1.3 Underlying offences

Offences resulting in the administrative liability of the Body (**Annex 1**), are listed here below:

- a) **Offences committed in the course of relations with Public Administration** - articles 24 and 25 of the Decree.
- b) **Computer crimes and illicit processing of data**- art. 24-bis of the Decree.

- c) **Organised crime offences**- art. 24-ter of the Decree.
- d) **Crimes relating to the counterfeiting of money, legal tender, revenue stamps and distinctive signs** - art. 25-bis of the Decree.
- e) **Crimes against industry and trade**- art. 25-bis.1 of the Decree.
- f) **Corporate offences**- art. 25-ter of the Decree.
- g) **Offences committed for terrorist purposes or to subvert democratic** - art. 25-
quater of the Decree.
- h) **Female genital mutilation**- art. 25-quater.1 of the Decree.
- i) **Offences against individuals** - art. 25-quinquies of the Decree.
- j) **Market abuse crimes** - art. 25-sexies of the Decree.
- k) **Transnational crimes** - with Law n. 146, 16th March 2006 for the ratification and execution of the United Nations Convention and Protocols against organised transnational crime, administrative liability of Bodies has been extended, pursuant to art. 10, to the following crimes, on the condition that they are committed at a transnational level:
 - criminal conspiracy (art. 416 criminal code);
 - Mafia criminal conspiracy (art. 416-bis criminal code);
 - incitement to not make statements or make false statements to legal authorities (art. 377-bis Criminal Code);
 - aiding and abetting (art. 378 Criminal Code);
 - Criminal conspiracy for the purpose of smuggling tobacco products manufactured abroad (art. 291-
quater Decree of the President of the Italian Republic n. 43, 23rd January 1973);
 - conspiracy with the aim of conducting illegal trafficking of narcotic drugs or psychotropic substances (art. 74 Decree of the President of the Italian Republic n. 309, 9th October 1990);
 - regulations against illegal immigration (articles 12, paragraph 3, 3-bis, 3-ter and 5 of Legislative Decree n.286, 25th July 1998).
- l) **Culpable homicide and serious personal injury or grievous bodily harm and violations of occupational health and safety regulations** - art. 25-septies of the Decree.
- m) **Conspiracy to handle stolen goods, money laundering, the use of laundered money, goods or assets of unlawful origin and self-laundering**- art. 25-octies of the Decree introduced by Legislative Decree n.231, 21st November 2007 extends the list of underlying offences to:
 - conspiracy to handle stolen goods (art. 648 criminal code);
 - laundering (art. 648 criminal code);
 - the use of money, goods or assets of unlawful origin (art. 648-ter criminal code).
 - self-laundering (art. 648-ter 1 criminal code).

As previously indicated, the crimes of laundering and use of money, goods or assets of unlawful origin were already included in the Decree, however only if committed at a

transnational level (pursuant to art. 10 Law 146/2006).

Following the introduction of art. 25-octies, the aforementioned crimes - together with conspiracy to handle stolen goods - are now also punishable if committed at a national level.

n) **Crimes regarding the violation of copyright**- art. 25-novies of the Decree - added by Law n. 99, 23rd July 2009 (art. 15, paragraph 7, lett. 5) and regarding crimes as per Law n. 633, 22nd April 1941, under the heading "Protection of copyright and other rights connected to its exercise (articles 171, first paragraph, lett. a-bis) and third paragraph, 171-bis, 171-ter, 171-septies and 171-octies).

o) **The Crime of incitement to not make statements or making false statements to legal authorities** - art. 25-decies of the Decree introduced by art. 4, paragraph 1, of Law n. 116, 3rd August 2009, regards the offence as per art. 377-bis

Criminal Code ("incitement to not make statements or making false statements to legal authorities").

p) **Environmental crimes** - art. 25-undecies of the Decree which transposes directives - 2008/99/EC and 2009/123/EC of the European Parliament and Council. The new underlying offences are:

- the killing, destruction, capture, removal or possession of protected wild animal or plant species (art. 727-bis criminal code);
- the destruction or deterioration of a habitat within a protected site (art. 733-bis Criminal Code);
- the import, export, possession, use for profit-making purposes, acquisition, sale, exhibition or possession for sale or commercial purposes of protected species (Law n. 150/1992, art. 1 and art. 2);
- the disposal of industrial waste water containing dangerous substances; disposal on soil, subsoil and underground waters; disposal in sea water by ships or aircraft (Legislative Decree n. 152/2006, art. 137);
- unauthorised waste management activities (Legislative Decree n. 152/2006), art. 256);
- illegal waste trafficking (Legislative Decree N. 152/2006, art. 259);
- organised activities for illegal waste trafficking (Legislative Decree 152/2006, art. 260);
- the pollution of soil, subsoil, surface waters or underground waters (Legislative Decree n. 152/2006, n.257);
- violation of obligations for: notification, the keeping of compulsory records and forms (Legislative Decree n. 152/2006, art. 258);
- false declarations on the nature, composition and chemical-physical properties of waste in applications for waste analysis certificates.
insertion in SISTRI of a false waste analysis certificate; omission or fraudulent alteration of the hard copy of a SISTRI - area waste transport sheet (Legislative Decree n. 152/2006, art. 260 bis);
- negligent pollution caused by ships (art. 9 of Legislative Decree 202/2007);
- wilful pollution caused by ships (art. 8 of Legislative Decree 202/2007);

- environmental pollution art. 452-bis (Law n. 68/2015);
 - environmental disaster art. 452-ter (Law n. 68/2015);
 - trafficking and abandon of radioactive material 452-quinquies (Law n. 68/2015);
 - impediment of control 452 sexies and failure to reclaim 452 terdecies (law n. 68/2015).
- q) **The use of citizens from third countries without a residence permit** – art. 25-duodecies of the Decree added by art. 2, paragraph 1, of Legislative Decree. 109/2012: use of citizens from third countries without a residence permit (art. 22, paragraph 12-bis, Legislative Decree 286/1998).

As specified hereinafter, the Special Parts of this document only refer to underlying offences the Company is theoretically capable of committing.

1.4 Extension of administrative liability: the Organisation, Management And Control Model pursuant to Legislative Decree 231/2001

The Decree, in introducing the aforementioned regime of administrative liability, does make provisions for exemption if the Company demonstrates to have adopted all organisational measures which are appropriate and necessary for the prevention of crimes foreseen in the Decree by subjects operating on its behalf. Therefore the presence of adequate organisation is a measure and sign of the Body's diligence when carrying out business, with particular reference to activities where there is a risk that crimes contained in the Decree may be committed. Therefore the ascertained existence of an efficient and effective organisation eliminates the Body's "Guiltiness" and therefore the need to issue foreseen sanctions.

The Board of Directors is responsible for the adoption and effective implementation of the Organisation, Management and Control Model, pursuant to art. 6, paragraph 1, lett. a), as well as the institution of the Supervisory Body and the nomination of its members, pursuant to lett. b) of the aforementioned article.

The Decree indicates the elements of an effective and actual organisation apparatus which prevents liability if implemented.

In particular, the Body is exempted from liability if it proves:

- that before the offence has been committed, it has *adopted* and *effectively implemented* organisation and management models (hereinafter "Model") for the prevention of offences of the same nature as the one which has been committed;
- to have entrusted a Body endowed with independent powers of initiative and control (hereinafter "*Supervisory Body*") with the task of monitoring the functioning and compliance with the model, as well as responsibility for its updating;
- that the perpetrators committed the offence by fraudulently circumventing the Model;
- that surveillance by the Supervisory Body was not omitted or insufficient in nature.

Furthermore, art. 6 paragraph 2 also indicates Model content, which must ensure the following:

- a) identify activities in fields where there is the possibility that crimes listed in the Decree may be committed;
- b) foresee specific protocols for the planning of training and implementation of the Body's decisions regarding offences to be prevented;
- c) identify procedures for the management of financial resources to prevent the commission of said crimes;
- d) foresee training requirements for the Supervisory Body;
- e) introduce an internal discipline system which punishes failure to comply with measures indicated in the Model.

The Decree also states that Models can be adopted which guarantee aforementioned requirements, based on codes of conduct (also known as guidelines), drafted by trade associations.

Guidelines are submitted to the Ministry of Justice who, in conjunction with competent Ministers, may draft and submit observations on the suitability and effectiveness of Models in the prevention of crime, drafted in compliance with trade association guidelines, within 30 days.

It is important to note that failure to comply with specific points of Guide Lines does not compromise the validity of the model.

Indeed the single Model, given that it must be drafted in reference to the tangible and specific situation of its company of reference, may diverge considerably from Guide Lines (which are intrinsically general in nature), to ensure a more effective guarantee of requirements specified by the Decree.

To this purpose the example observations contained in the appendix of aforementioned Guidelines must also be evaluated (so-called "*Case Studies*") as well as the brief list summarising control tools foreseen therein.

2 Adoption of the Model by HS Hospital Service S.p.A.

2.1 Objectives pursued by HS Hospital Service S.p.A with the adoption of the Model

HS Hospital Service S.p.A. (hereinafter also "HS" or the "Company") is a company which was incorporated in 1980 and is one of the most important Italian companies in the sector of the production and commercialisation of devices for surgery, critical care, interstitial, mini-invasive surgery and for oncology, and operates both at a national and international level.

The company's registered office is in Rome (RM) - Via Zosimo 13, and its main corporate objective is the manufacture, concession, trade, import, export, distribution and sale of any kind of product used in medical care, therefore: medicinal, surgical, laboratory, diagnostic products and devices used by doctors, hospitals, laboratories, industries, university faculties, dentists and veterinary surgeons.

HS - Sensitive to the need to ensure conditions of correctness and transparency in carrying out business and company activities, and in order to protect its position, image

and the expectations of its own employees - has proceeded with the implementation of the Model foreseen by Legislative Decree n. 231/2001, insofar as it is in line with its own company policies.

Said initiative has been undertaken with the conviction that the adoption of the Model - regardless of Decree provisions - which refer to the Model as an optional and not compulsory element - may constitute a valid tool for raising awareness among all those who operate in the name and on behalf of the company, so that they commit to correct and linear conduct which prevents the risk of committing offences contemplated in the Decree, in the execution of their own activities.

The aforementioned Model was drafted by the Company taking into consideration not only provisions laid down in the Decree, but also Confindustria guidelines.

In order to implement provisions laid down in said Decree through adopting the aforementioned Model, the Board of Directors entrusted a Supervisory Body (hereinafter "Body" or "SB") with the task of monitoring the functioning, effectiveness and observation of the Model, as well as its updating.

2.2 The HS Hospital Service S.p.A. Corporate Governance System

The HS Hospital Service S.p.A. *Corporate Governance System (Annex 2)* is structured to ensure and guarantee maximum company efficiency and operative effectiveness.

The structure of said system is based on the "traditional" model, specifically:

- The Shareholders' Meeting: responsible for passing resolutions regarding matters as specified by the law or Articles, both under ordinary or extraordinary circumstances.
- The Board of Directors:
 - is currently made up of four members;
 - Company officers serve a term which is established upon their nomination, or until revocation or resignation and in any case no longer than three financial years; they are re-electable;
 - is invested with the broadest powers for the ordinary and extraordinary management of the Company and has the power to execute all acts which it deems necessary for the implementation and achievement of the corporate objective, unless explicitly specified by the Law as being reserved to the Shareholders' Meeting;
 - may delegate all or part of its powers to an executive committee made up of some of its members, or specifically one or more chief executive officers, even severally, determining its powers and relative remuneration;
- legal representation of the Company before third parties and in legal proceedings is the responsibility of the Chairman of The Board, who has the power to promote legal and administrative motions for each degree of jurisdiction.
- The Statutory Board Of Auditors:
 - consists of three regular and two alternate auditors;

- The Statutory Board monitors compliance with the Law and Articles of Association and exercises all powers conferred upon it by the Law and the Articles of Association;
- The Statutory Board of Auditors has been entrusted with accounting management.

2.3 System of commissions and proxies adopted by the Company

Here below is a list of company positions:

	ACRONYM	POSITION
1	B.o.D.	Board Of Directors Chairman, CEO, Director
2	Q.M.M. and Q.E.M.	Quality Management Manager and Quality Assurance Manager
3	R&D	Research and development Manager
4	PPSM*	Prevention and Protection Service Manager
5	H&S M	Hardware and Software Manager
6	ITPS M	Internal Technical Production Sector Manager
7	PO	Purchasing Office
8	MD	Marketing Manager
9	HR	Human Resources
10	AM	Administrative Management
11	FM	Financial Management
12	IT*	Information Technology

* Positions marked with a star indicate those held by individuals who are external to the company: in particular in the case of the PPSM, an external subject has been hired, whereas IT services are executed in collaboration with personnel of the company "DESIDERIO TAGLIANTI".

The system for the attribution of company commissions and proxies is an integral part of the internal control system and constitutes a further provision, within the context of the Model, for the prevention of crimes specified in Legislative Decree 231/2001.

The Board of Directors is responsible for defining criteria for the assignment of commissions and proxies.

The system of commissions and proxies must constitute:

- a) a management tool for the execution of acts which have an impact within or outside the company, necessary in the pursuit of the company's objectives, consistent with the positions of responsibility assigned to each subject;

- b) a factor in the prevention of abuse of attributed functional powers, through the definition of economic limits for each act or series of acts;
- c) an unequivocal element of traceability of company acts, both with external and internal impact, back to the physical persons which adopt them. Hence the system's usefulness both in the prevention of crimes as well as the identification of subjects who adopt acts, directly or indirectly connected to the committing of the crime.

Company policy foresees that only subjects with formal and specific powers may undertake commitments with third parties in the name and on behalf of the company itself. Within this project the Company is drafting and implementing a system of commissions and proxies which is coherent with assigned organisational responsibilities and which actually require representation, whenever appropriate, complete with forecasts and accurate indications of quantitative expense limits established by internal company provisions.

The attributive act must comply with any specific requirements laid down by the law (e.g. proxies and sub-proxies regarding occupational health and safety).

Company divisions which are concerned, and perhaps with the support of the Surveillance Body, periodically check the system of commissions and proxies in force, also through the examination of documentation which proves the activities tangibly enacted by subjects operating on behalf of the Company, suggesting any necessary changes in cases where management functions and/or qualifications do not match conferred powers of representation.

2.4 Procedures and Ethical Code

In order to reinforce its own system of internal checks, the Company has adopted and is implementing a system of internal procedures which aims to discipline sensitive activities and therefore, to prevent the commission of underlying offences.

Said procedures, which constitute an integral part of the Model, are updated in accordance with any new requirements in terms of organisation or crime prevention.

The Ethical Code is an important element of the Company's *governance* system, and ensures compliance with principles. This document contains and elaborates on ethical principles and values which all company officers, employees and collaborators must comply with when exercising their own activities, duly accepting responsibilities, arrangements, roles and rules.

The Ethical Code has been published on the company's website so that it can be spread to recipients and third parties.

In addition, all suppliers, contractors and subcontractors are invited, as per contract, to view the Ethical Code and comply with behaviour principles specified therein.

2.5 Other Prevention Protocols

The protocol system for the prevention of crimes must be enacted through the application of the following General Prevention Principles in the case of single sensitive activities:

- Regulations: the existence of company regulations which supply principles for behaviour, decision-making regulations and operative procedures for the execution of sensitive activities as well as archiving procedures for relevant documentation.
- Traceability; each operation concerning sensitive activities must be, wherever possible, adequately documented; decision, authorisation and execution processes of sensitive activities must be verifiable *ex post*, also through specific document formats;
- The separation of tasks: the separation of activities: those who authorise, who execute and who check. This segregation is guaranteed by the intervention of numerous subjects, within the context of a macro-company process, with the purpose of guaranteeing the independence and objectivity of processes. [The separation of functions is also implemented through the use of IT systems which qualify identified and authorised persons for the execution of determined operations];
- Monitoring activities: To ensure periodic and timely updating of powers of attorney, proxies, procedures as well as the control system, coherently with the decision-making system and the entire organisational system. Process Supervisors monitor process checks.

3 Model Function

3.1 The HS Hospital Service S.p.A. Model

The aim of the Model is the construction of a structured and organic system of control procedures and activities in order to prevent the committing of different types of crimes foreseen in the Decree.

In particular, through the identification of activity areas at risk and consequent execution procedures for said activities, the Model aims to:

- ensure awareness, in the case of all those who operate in the name and on behalf of HS, that should they violate provisions therein in "areas of activities at risk", they risk committing an offence resulting in the punishment of the company as foreseen in paragraph 6.
- Reiterate that such forms of illicit behaviour are strongly condemned by HS insofar as they violate not only the law but also the ethical-social principles which the Company wishes to adhere to when carrying out its activities and business;
- enable the company, through monitoring actions in "areas of activities at risk", to promptly react in order to prevent or oppose the commission of crimes.

Apart from aforementioned principles, the main points of the Model are:

- to raise awareness and spread introduced conduct rules and procedures at all company levels;
- to "map areas of activities at risk", or those activities in fields where it is deemed that there is a greater risk of the commission of crimes;

- Conferring the Surveillance Body with specific surveillance tasks regarding the efficacy and correct functioning of the Model;
- checking and documentation of operations at risk;
- compliance with the principle of separation of functions;
- the definition of authorising powers which are coherent with assigned responsibilities;
- checking of company behaviour and model functioning with consequent periodic updating.

3.2 Preparatory activity of the Model

In drafting the Model, as suggested by the Guide Lines of major trade associations, company activities were accurately mapped, with the purpose of identifying the Company's risk areas, with reference to crimes specified in legislation under examination.

This activity was executed through the analysis of previously supplied company documentation, mainly in three phases carried out in succession over a determined time period:

1. the first phase was executed based on knowledge of the Company and its risk areas; the analysis was executed by the company and in conjunction with an external Law Firm;
2. the second phase consisted of a hearing, also carried out with the support of an external Law Firm, of the Chairman, Chief Executive Officer and managers, in order to verify the existence of previously highlighted risk areas as well as any further risk areas which were not taken into consideration;
3. upon the outcome of the second phase, the company, once more with the support of an external Law Firm, carried out a "gap analysis", identifying existing control systems providing for areas which are considered as at risk from crimes, and compared them to organisational requirements specified in the Decree, also with the purpose of proceeding with the drafting of this Model.

3.3 Approval and transposition of the Model

Based on relevant criteria and directives, the HS Board of Directors was requested to proceed with the adoption of its own Model, through a specific resolution and based on the functions of profile risks within activities carried out by the Company.

Upon adopting the Model, the Company's Board of Directors also proceeded with the nomination of the Surveillance Body, entrusted with monitoring the execution of aforementioned activities and the application of the Model.

The Company is required to draft, adopt and update the Model, based on adjustment requirements which shall arise over time. In particular the HS Board of Directors, also upon the proposal of the Surveillance Body, is required to supplement this Model,

whenever necessary, through specific resolutions, with underlying offences as foreseen in legislation in force.

The Company is also responsible for applying the Model in relation to activities thereof. To this purpose the Surveillance Body has been attributed with the task of exercising power over the implementation of the Model in compliance with procedures described therein.

3.4 Model Structure: General Part and Specific Part for different functional areas affected

This Model consists of a "General Part" and a "Special Part" drafted for the company's functional areas, based on different types of crimes contemplated in the Decree and which the company has been defined as abstractly capable of committing, based on the outcome of *risk assessment* activities.

It is hereby specified that the purpose of introducing certain crimes is merely prudential insofar as there are no specific elements from which the existence of current risks may be deduced, although the company intends to maintain a high level of vigilance for such types of crimes. The Special Part consists of different functional areas grouped together as follows:

- **Special Part Section "A"** regards the functions of the Board of Directors (Chairman, Chief Executive Officer and Directors);
- **Special Part Section "B"** regarding the following functional areas: Regulatory Affairs and Quality;
- **Special Part Section "C"** regarding the following functional area: Administrative, Financial and Human Resources Sector
- **Special Part Section "D"** regarding the following functional area: Research and development Sector;
- **Special Part Section "E"** regarding the following functional area: Hardware and Software Sector;
- **Special Part Section "F"** regarding the following functional area: Internal production (positions: Internal Technical Productive Sector Manager, Clean-Room Supervisor, Warehouse Manger, Assembly & Packaging Manager, Technical Assistance and Quality Control Manager);
- **Special Part Section "G"** regarding the following functional area: Purchase Management;
- **Special Part Section "H"** regarding the following functional areas: Sales Management and Marketing Management National Endo-surgery Sales, National Surgery and ablative therapy sales, National sales critical care Foreign Sales Biopsy & Critical Care, Italy Customer Service Manager, Foreign Customer Sales Manager
- **Special Part Section "I"** regarding the following outsourced functions: Prevention and Protection Service Manager

4 The Surveillance Body (SB)

4.1 Identification of the Surveillance Body

In implementation of the Decree - which requires that the task of monitoring the functioning and compliance with the model is assigned to an organism of the Body, as a condition for exemption from administrative liability, a Surveillance Body has been created in HS, consisting of two effective members, both chosen from professionals who are external to the company.

The SB must possess the following criteria:

1. autonomy: it must have decisional autonomy, which is defined as the essential freedom for self-determination and action, with total exercise of technical discretion in the execution of its own functions;
2. independence in relation to the Company: it must not be conditioned by or dependent on links of subordination with management and must be a third party body in a position of independence, also in hierarchical terms, capable of adopting autonomous resolutions and initiatives;
3. professionalism: it must be professionally capable and reliable, both in terms of its single members and globally. As a body, it must dispose of technical cognitions and professionalism required for it to carry out the functions it has been entrusted with, to the best of its ability;
4. continuity of action: it must carry out functions it has been assigned with in a continuous, albeit not in an exclusive manner;
5. integrity and absence of conflict of interest: the following subjects may not be nominated as members of the SB, or shall forfeit office if:
 - forbidden from doing so, are unequipped or have been condemned for one of the crimes foreseen in the Decree, or in any case one of the crimes which entails banning, even temporary, from public offices or the incapacity to exercise managerial offices;
 - they have business relations (for example, partnerships, sharing agreement contracts, joint ventures, etc.) with the company or other subsidiary companies or parent companies.

In any case should a member of the SB have interests on behalf of itself or third parties within the context of a single resolution, they are required to notify other members of the Body, specifying the nature, terms, origin and extent. Other members shall decide whether the interested subject must abstain from the resolution.

The HS Board of Directors nominates effective members who serve a term of three years.

The SB has the right to seek assistance, within the context of its control functions, from external subjects who professionally carry out auditing and certification activities.

The Body also has the right to choose the Chairman as one of its members, should said person not be nominated by the Board of Directors.

The Chairman coordinates the work of the SB and ensures that its members receive adequate information on topics to be covered on the agenda.

4.2 Convocation and Meeting Procedures of the SB

The SB meets each time the Chairman or one of its members deems it appropriate, or whenever it is requested to do so by the Board of Directors or the Statutory Board of Auditors, in any case no less than once every three months.

Sessions of the SB shall be held at the location designated in the notice of convocation, which shall also contain the agenda, time and place of meeting as well as a list of topics to be covered. The convocation notice, which is to be submitted to each member of the Body (by ordinary mail or email, telegram, fax or by hand), must be sent at least three days before the date which has been established for the session, or in case of urgency, at least one day before.

SM meetings may be also held in audio and/or video conference, on the condition that all participants can be identified and are able to follow the discussion and intervene on topics and vote.

Decisions of the SB on topics under examination may be adopted through written consultation or consent expressed in writing.

Said resolutions, as well as reports regarding checks carried out by the organism itself, directly or through external collaborators, shall be transcribed in the organism's minute book of meetings.

4.3 Functions and powers of the SB

The HS Surveillance Body is required to monitor:

- compliance with provisions of the Model by recipients, explicitly identified in single Special Parts, in relation to the different types of crimes contemplated by the Decree;
- the actual efficacy and effectiveness of the Model, in relation to the company structure, to prevent the commission of crimes as specified in the Decree;
- opportunities for updating the Model, whenever there are requirements for its alignment with changes in company conditions.

In operative terms, the SB is responsible for:

- activating control procedures, bearing in mind that primary responsibility over the control of activities, also for those relating to areas of activities at risk, belongs nonetheless to operative management and forms an integral part of the company process, confirming the importance of a training process for personnel;
- monitor company activity with the purpose of producing an updated map of areas of activities at risk, within the company itself;
- conduct periodic and targeted checks on determined operations or specific acts within the fields of activities at risk, as defined in the Model's single Special Parts;
- promote suitable initiatives for the spreading of knowledge and understanding of the Model and draft internal organisational documentation necessary for the functioning of the Model itself, containing instructions, clarifications or updates;

- collect, elaborate and conserve information which is important for compliance with the Model, and update the list of information which is required to be transmitted to the SB or made available to the SB;
- coordinate with other company functions (also through specific meetings), for the improved monitoring of activities within areas at risk. To this purpose, the SB is constantly informed of the evolution of activities in aforementioned areas at risk, and has free access to all relevant company documentation. The SB must also be notified by management of any situations of company activity which may expose the company to the risk of committing a crime;
- check the actual presence, regular archiving and effectiveness of documentation requested in compliance with provisions laid down in the single Special Parts of the Model for different types of crimes. In particular the SB must be notified of the most significant operations or of operations contemplated by the Special Parts and must have data for the updating of documentation available, in order to enable the execution of checks;
- conduct internal investigations for ascertaining presumed violations of regulations laid down in this model;
- check that elements foreseen in single Special Parts of the Model for different types of crimes (the adoption of standard clauses, the carrying out of procedures, etc.) are in any case adequate and comply with requirements for compliance, as laid down in the Decree, and if otherwise, ensure the updating of said elements;
- coordinate with supervisors of other company functions in different aspects concerning Model implementation (definition of standard clauses, training of personnel, disciplinary actions. etc.).

4.4 Functions of the SB: autonomy with respect to company bodies

The HS SB is an autonomous body with respect to company bodies and is free from all hierarchical constraints.

In any case, the company's Chairman constitutes its company reference point and on a periodical basis, the Board of Directors and/or the Statutory Board of Directors.

The company's SB may be summoned at any moment by the aforementioned, or, in turn, may present a request to be summoned, for issues regarding the functioning of the Model or specific situations.

Furthermore each year the SB submits a written report to the Board of Directors on activities carried out and Model implementation.

The SB is also autonomous in terms of expenditure and is allocated an annual budget of [10,000.00] Euros Any extraordinary expenses must be submitted to the Board of Directors for approval.

4.5 Information flows and the SB

The HS SB must be rapidly informed by all recipients of the Model of any news regarding the existence of possible violations of said Model. In particular, recipients are required to report news regarding the commission or possible commission of crimes or misconduct and deviation from principles contained in the Model.

The SB must always be informed of the following:

- a) Information which may be relevant to potential violations of the model, by way of example:
- any offers or requests for money and gifts (exceeding modest values) or other profits deriving from or received by public officials or representatives of public service;
 - participation in tenders, the awarding of contracts and relations with Public Administration in general;
 - any concession of public supplies, the issuing of new licences, authorisations or other important administrative measures;
 - measures and/or news from police or judicial bodies or from any other authorities, from which it may be deduced that investigations into offences are under way, also involving unknown parties and the Company and/or its company members and/or employees;
 - requests for legal assistance forwarded by company exponents in the event of legal proceedings for crimes;
 - news regarding penal proceedings undertaken by Public Authorities and any measures (including those against company exponents) or provisions for the archiving of said proceedings with relative motivations, should they be linked to the committing of crimes or violations of conduct or procedure rules in the Model;
 - expense anomalies which emerge from authorisation requests;
 - any financial transactions which become particularly significant in terms of value, procedures, risk or atypicality;
 - any omissions or neglect in the keeping of accounts records;
 - any reports which have not been detected in a timely manner by competent functions, concerning both shortcomings and inadequacies of places or work tools or protective equipment which is made available by the Company, as well as all other situations of danger concerning occupational safety.
- b) Information regarding the duties of the SB and which may become important in the execution of its functions, such as:
- news regarding organisational changes within the Company;
 - news regarding the implementation of the Model and sanctions which are issued as a consequence of failure to comply with said sanctions;
 - reports drafted by various functions regarding activities which are deemed to be or may be deemed to be of relevance to areas of risk in the Company;
 - the annual financial balance sheet, complete with note and statement of assets and liabilities;

- notifications from the Statutory Board of Auditors concerning critical issues which have emerged, even if they have been resolved.

Subjects who intent to report anything are to be protected by the SB from retaliation or discrimination of any kind, through confidentiality. Therefore in order to facilitate the submission of reports, any recipient of the Model can send a report to a special email address: odvhsspa@gmail.com. Reports must be conserved at the SB office.

4.6 SB functioning procedures

The SB plans periodic control activities based on the state of company activities and information in its possession.

The programme is approved by the SB during its meetings, and indicates which areas and functions it intends to check as well as the criteria and deadline for the completion of said activities. Members of the SB may be entrusted with checks, or the SB may entrust external consultants for said task.

A report must be drafted at the end of each check, illustrating activities carried out and results. The following information must be indicated:

- Company areas which have been checked and any further useful information;
- the level of conformity or critical situations detected, compared to the *audit*;
- reference to inspection documents;
- any recommendations;
- any other information deemed appropriate for the improved evaluation of activities under inspection.

Findings on activities shall be examined at the next meeting of the SB. Whenever it deems it necessary, the SB may conduct further review *audits*, also with the use of external consultants, or request the company's administrative body to intervene in order to lower the level of risk back to a level which is deemed acceptable.

SB recommendations must be rapidly adopted by functions concerned, and the Board of Directors is responsible for checking effective application.

The SB shall solicit periodic meetings with the Statutory Board of Auditors in order to share checking strategies, shall view inspection notices drafted by the Statutory Board of Auditors and shall send its own findings to the latter.

In all cases in which the Company appoints an external professional certification subject to carry out inspection and certification activities for aspects of company activity which are the competence of the SB, said subject is required to draft a report containing all aforementioned indications. The report must be submitted to the SB on a specific date, in convenient time so that the latter may examine it and relative findings.

5 Recruitment, training and information statement

5.1 Recruitment of personnel

The recruitment and management of personnel and external collaborators (consultants, partners, suppliers, etc.), must comply with the criteria of reasonableness, professionalism, integrity, correctness and transparency, in compliance with company requirements concerning the application of the Decree.

5.2 Training of personnel

The training of personnel is a fundamental activity for the complete and effective enactment of the Model. Therefore the SB drafts and implements training plans which also foresee diversified actions, according to the role of personnel in the Company or the relevance of their respective activities with risk areas indicated in the Model.

5.3 Distribution of the contents of the Model

Once approved by the Board of Directors, the Model is distributed to all employees who are required to comply with the document. Model distribution methods shall be defined case by case for any further subjects which are required to comply with the contents of said document (suppliers, external collaborators and third parties in general).

5.4 Information Statement for external collaborators

External collaborators may be supplied with specific information statements on policies and procedures adopted by the Company and based on this Model, as well as texts of regularly applied contractual clauses of relevance.

6 Disciplinary system and measures in case of failure to comply with provisions laid down in the Model

6.1 General principles

An adequate system of punishment in case of violation of provisions laid down in the

Model is an essential condition in ensuring the effectiveness of said Model and for efficient monitoring action by the SB.

Therefore art. 6, paragraph 2 lett. e) of the Decree specifies that organisation and management models must *"introduce a disciplinary system containing appropriate penalties in case of failure to comply with measures indicated in the model"*.

The application of disciplinary sanctions is irrespective of the outcome of any criminal proceedings as the rules of conduct specified in the Model have been autonomously adopted by the company, regardless of the type of offence which may be determined in case of violation of the Model.

The disciplinary system, as laid down in art. 7, paragraph 1, Law 300/1970 ("Statute of Workers"), shall be affixed on the company noticeboard.

The verification of offences may also be undertaken by the SB if during its inspection and monitoring activities it detects a possible violation of the Model.

In compliance with proxies he has been conferred with, the Chief Executive Officer is responsible for issuing sanctions to supervisors, clerks, workers and managers.

The SB may also be called to provide consultation services during disciplinary proceedings in order to acquire any further useful elements, in view of the constant updating of the Model. The verification of any liability deriving from the violation of the Model and the issuing of consequent sanctions must always occur in compliance with governing legislation in force for the protection of privacy, dignity and reputation of all subjects involved.

The disciplinary system is constantly monitored by the SB and Chief Executive Officer.

6.2 Sanctions for employees and measures for Company officers and external collaborators

Any conduct of employees in violation of single rules of conduct contained in this Model is defined as a disciplinary offence.

With reference to the aforementioned, the Model refers to categories of punishable conduct, according to the importance of single cases at hand, and specific sanctions foreseen if said offences are committed, according to their seriousness.

In particular:

- a) A VERBAL REPRIMAND, WRITTEN WARNING, FINE (which shall not exceed a total amount of 4 hours of normal retribution) OR SUSPENSION FROM WORK AND FROM RETRIBUTION (for a maximum of 10 days), according to the gravity of the violation, shall be issued to workers who violate internal procedures foreseen by this Model, or who in the execution of their own activities, adopt behaviour which does not comply with provisions of said Model and Ethical Code, insofar as said behaviour is also in violation of the contract which undermines the company's discipline and morale;
- b) DISMISSAL FOR CAUSE for workers who adopt behaviour which is in explicit violation of provisions laid down in this Model, in the execution of their own activities, to the extent that it determines that measures foreseen in the Decree are brought against the company, insofar as said behaviour includes the committing of *"crimes"*

determined by the law" or "acts which radically compromise the company's trust in them", or shortcomings as specified above, which determine serious moral and/or material jeopardy for the Company.

The type and entity of aforementioned sanctions which employees are issued with, must be commensurate with the principle of proportionality as laid down in art. 2106 of the Criminal Code, and for each case the following must be taken into consideration:

- the intentionality and degree of recurrence of the behaviour, the degree of negligence, imprudence or malpractice, also bearing in mind the foreseeability of the event;
- the objective seriousness of the fact constituting a disciplinary offence;
- the overall behaviour of the worker, and in particular any disciplinary records, within limits laid down by the law;
- duties of the worker;
- the functional position of people involved in facts constituting the shortcoming;
- any other circumstances of relevance to the disciplinary violation.

By way of example but not of limitation, the following behaviours constitute disciplinary breaches:

- the violation, also through omission or in co-operation with others, of principles and procedures laid down in this Model or established for its implementation;
- the drafting, also in co-operation with others, of untruthful documentation;
- facilitation, through negligent conduct, of the drafting by others of untruthful documentation;
- failure to draft documentation required by this Model or by procedures established for its implementation;
- the removal, destruction or alteration of documentation regarding procedures in order to avoid the system of checks laid down by the Model;
- the obstruction of inspection activities conducted by the SB or of subjects entrusted with said activities by the latter;
- prevention of access to information and documentation requested by subjects entrusted with the inspection of procedures and decisions;
- engaging in any other behaviour in order to evade the system of checks laid down by the model.

6.3 Measures for Company Officers

The company rigorously evaluates breaches of this Model committed by members of the Company' management and who therefore represent its image with employees, shareholders, creditors and the public. The forging and consolidation of a company ethic which is sensitive to correctness and transparency presupposes above all that said values

are adhered to above all by those who guide company decisions so that that said individuals constitute an example and inspiration for all those who operate for the Company, whatever their position.

In case of violation by Company officers of internal procedures and principles of conduct laid down in this Model and/or the adoption, in exercising their own powers, of provisions which do not comply with measures or principles of the Model, the SB shall promptly inform all members of the Board of Directors and all members of the Statutory Board of Auditors who in turn and in accordance with their respective competences, shall undertake the most appropriate and adequate measures in line with the gravity of the violation and powers foreseen by the law and/or Statute (e.g., declaration in the book of minutes, convocation of Shareholders' Meeting to deliberate provisions to be taken against subjects who have committed the violation, including revocation of appointment as Company officer and the adoption of actions of liability foreseen by the law, etc.).

6.4 Measures for members of the Statutory Board of Auditors

With reference to members of the Statutory Board of Auditors, violations of the provisions laid down in this Model are promptly reported to the the SB, all members of the Statutory Board of Auditors as well as all members of the board of Directors. The statutory board of auditors, upon hearing the Board of Directors, undertakes appropriate provisions for auditors who have committed the violations.

6.5 Measures for external collaborators and partners

Any behaviour of external collaborators or partners which violates the code of conduct of this Model and which entails a risk of the committing of a crime which is punishable by the decree, may determine the termination of the work contract, through the activation of appropriate clauses.

6.6 Measures in case of violation of obligations for submitting information to the SB

In case of violation of information obligations or in case of failure to respond to requests for information by the SB, the SB shall promptly inform the Board of Directors who shall apply the most appropriate sanctions.

6.7 Measures in case of disciplinary offences for members of the SB

In the case of disciplinary offences committed by members of the SB, the Board of Directors must be promptly informed and issue the member of the SB with a written reprimand or revoke their office, according to the gravity of the offence committed.

Sanctions foreseen for employees and managers are also applicable to members of the SB who belong to said categories.