Organisation, Management and Control Model pursuant to Legislative Decree No. 231 of 8 June 2001

GENERAL SECTION

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TERUMO

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1. FOREWORD - SUBJECTIVE SCOPE OF APPLICATION OF TERUMO ITALIA S.R.L. MODEL

Before describing the principles contained in this General Section, Terumo Italia S. r. l. (hereinafter, for the sake of brevity, also referred to as "**Terumo Italia**" "**TIT**" or the "**Company**") considers it appropriate to specify the criteria according to which it has identified and classified the persons to which this organization, management and control Model (hereinafter, for the sake of brevity, also referred to as the "**Model**") adopted pursuant to Legislative Decree no. 231/2001 (hereinafter, for the sake of brevity, also referred to as the "**Decree**") applies.

In particular, a classification was made based, on the one hand, on the recipients of the sanctioning instruments adopted by the Company in order to enforce compliance with the Model, as set out in paragraph 13 below, and, on the other hand, on those who are the recipients of training activities on the Decree (as defined in paragraph 2 below) and/or on the Company's Model.

Under the first profile, a threefold distinction has been made between:

i. Recipients, such as persons against whom compliance with the Model is ensured through warning and possible exercise of powers characterising the employer-employee relationship or of powers substantially similar to it;

ii. Other Recipients, who are required to comply with the Model at the time of their appointment; and

iii. Third parties, such as parties connected to the Company by contractual relationships other than employment, within which specific clauses have been signed to ensure compliance with the Model (e.g. consultants, suppliers, Business Partners, etc.).

The above being clarified, the following terms shall have the meaning set out below:

Senior Management: means the persons who hold positions of representation, administration or management of the Company or of one of its organisational units with financial and functional autonomy, as well as the persons who exercise, also de facto, the management and control thereof.

Subordinates: means the persons subject to the management or supervision of the Senior Management and who must carry out, in a subordinate or non-subordinate position, the directives of the latter or who are subject to their supervision.

Recipients: means the Senior Management over whom the Company may exercise a power of control of an employer nature or substantially similar to it and the Subordinates.

Other Recipients: means the Senior Management over whom the Company cannot exercise a power of control of an employer nature or substantially similar to it and with respect to whom compliance with the Model is required at the time of their appointment (including directors, de facto directors, any liquidators appointed, members of the Board of Statutory Auditors).

Third parties: jointly means all natural and legal persons who are neither Recipients nor Other Recipients and to whom compliance with the Model is required through the imposition of contractual constraints for this purpose. By way of example and without limitation, this category includes:

- all those who have a non-subordinate working relationship with the Company (e.g. consultants, project collaborators, etc.);
- contractors and business partners;
- service providers;
- attorneys, agents and all those acting in the name of and/or on behalf of the Company;
- persons assigned, or otherwise carrying out, specific functions and tasks in the field of health and safety at work.

2. LEGISLATIVE DECREE NO. 231/2001

2.1 The introduction of so-called administrative liability for offences

In execution of the delegation granted by the Parliament through Law no. 300 of 29 September 2000, the Delegated Legislator enacted, on 8 June 2001, the Legislative Decree no. 231/2001, having as its object the "Regulation of the administrative liability of legal persons, companies and associations also without legal personality".

Italian legislation on the liability of legal persons has thus been aligned to certain International Conventions already signed by Italy: the Brussels Convention of 26 July 1995 on the protection of financial interests; the Brussels Convention of 26 May 1997 on the fight against corruption involving public officials of the European Community and its Member States; and the OECD Convention of 17 December 1997 on the fight against corruption involving foreign public officials in international business transactions. The legislator ratified, by Law No. 146/2006, the United Nations Convention and Protocols against Transnational Organized Crime adopted by the General Assembly on 15 November 2000 and 31 May 2001.

Until the Decree was enacted, it was legally excluded that a company could appear as a "defendant" in a criminal trial.

By the introduction of the Decree, the principle according to which "*societas delinquere non potest*" has been superseded and a liability regime has been introduced for entities (hereinafter, for the sake of brevity, also collectively referred to as the "**Entities**" and individually as the "**Entity**"), which is similar, in particular from the sanctioning standpoint, to a criminal liability coming up alongside that of the natural person who has acted as the material author of the offence.

2.2 The objective requirements for administrative liability for offences

Article 5 of the Decree identifies the *objective criteria for attributing liability*, providing for three conditions in the presence of which it is possible to attribute the offence committed by the natural person to the Entity:

- **(i)** the offenders must be natural persons in a senior or subordinate position;
- **(ii)** the offence must have been committed in the interest or to the advantage of the Entity;
- **(iii)** the offenders must not have acted solely in their own interest or that of third parties.

The natural persons whose criminal conduct gives rise to the liability of Entities are identified by Article 5, paragraph 1, of the Decree which - by virtue of the theory of so-called organic identification - states that the Entity is liable for offences committed in its interest or to its advantage:

a) by persons who hold functions of representation, administration or management of the entity or one of its organisational units with financial and functional autonomy as well as persons who exercise, including de facto, management and control;

b) by persons subject to the direction or supervision of one of the persons referred to in letter a).

With reference to the persons referred to in letter a), for the purposes of administrative liability for offences, it is not necessary for the senior management position to be held "formally", but it is sufficient that the functions exercised, even "de facto", are actually the expression of powers of management and control (to be exercised jointly, as stated in the Ministerial Report to the Decree). Moreover, according to the Decree, the Entity's liability also exists where the offender has not been identified but it is nevertheless ascertained that he certainly falls within the category of persons referred to in letters a) and b) of Article 5 of the Decree, or even where the offence is extinguished against the natural person for a reason other than amnesty.

The "interest" of the Entity always presupposes an *ex ante* assessment of the criminal conduct of the natural person, whereas the "advantage" which may be gained by the Entity even when the natural person has not acted in its interest, always requires an *ex post* assessment. "Interest" and "advantage" each have a specific and autonomous relevance, since it may well happen that the conduct concerned may a posteriori result as not being advantageous at all (the legal requirement of the commission of offences "*in its interest or to its advantage*" does not contain an hendiadys, as the terms refer to different concepts under legal standpoint, it being possible to distinguish an upstream interest as a result of undue enrichment, as a consequence of the offence, from an advantage objectively achieved by the commission of the offence, albeit not envisaged *ex ante*, so that the interest and the advantage are in actual concurrence: *ex plurimis,* Court of Cassation, Criminal Division, Sec. II, 30 January 2006, no. 3615).

The Entity shall not be liable, on the other hand, if the persons referred to above - whether in a senior management position or not - acted in their "exclusive" interest or that of third parties. The Entity's liability must also be excluded "*if it nevertheless receives an advantage from the unlawful conduct carried out by the natural person, where it appears that the offender acted "in his own exclusive interest or that of third parties" (...): in this case, indeed, it would be a "fortuitous" advantage, as such not attributable to the Entity's will*" (Court of Cassation, Criminal Division, Section VI, 2 October 2006, no. 32627).

The reference is to all those situations in which, obviously, the offence committed by the natural person is in no way attributable to the Entity, as it was not carried out even in part in the interest of the latter (in such cases, the Judge is not required to assess whether or not the Entity gained an advantage). Conversely, if the offender has committed the offence in his own "predominant" interest or in the interest of third parties and the Entity has not gained any advantage or has gained a minimum advantage, the Entity shall in any case be liable, except for the special mitigating circumstance provided for in Article 12, paragraph 1, let. a) of the Decree (i.e. the pecuniary sanction shall be reduced by half and shall not exceed EUR 103,291.00).

2.3 The subjective requirements of administrative liability for offences

Articles 6 and 7 of the Decree identify the *subjective criteria for attributing liability*, providing for specific forms of exemption from administrative liability of the Entity, since, for the purposes of establishing administrative liability for an offence, it is not sufficient merely to refer the offence objectively to the Entity, but it is necessary to be able to formulate a judgment of guilt on the part of the Entity itself.

In this sense, in accordance with Article 6, paragraph 1, of the Decree, if the offence is attributed to the Senior Management, the Entity shall not be held liable if it proves that:

- has adopted and implemented, before the commission of the offence, a Model suitable to prevent one of the offences indicated in the Decree (hereinafter the "**Predicate Offence**") of the same type as the one actually committed;
- has appointed an independent body, with autonomous powers, to supervise the functioning of and compliance with the Model and taking care of the updating thereof (hereinafter, for the sake of brevity, also referred to as the "**Supervisory Board**" **or** even only as "**SB**" or "**Board**");
- the Predicate Offence has been committed by fraudulently circumventing the measures laid down in the Model;
- there has been no omission or insufficient supervision by the Supervisory Board.

In the case of Subordinates, the adoption and effective implementation of the Model means that the Entity will be held liable in the event that the commission of the Predicate Offence was made possible by the failure to comply with the obligations of management and supervision (combined provisions of Article 7, paragraphs 1 and 2, of the Decree). Differently from the case of an offence committed by a person in an senior management position, in this case, it is up to the prosecution to prove the failure to adopt and the ineffective implementation of the models.

Lastly, it should be noted that, pursuant to Article 23 of the Decree, the Entity is also liable in the event:

- of non-compliance with disqualifying sanctions, or if, having a disqualifying sanction or precautionary measure been applied pursuant to the Decree, the entity violates the obligations or prohibitions inherent therein;
- offences committed abroad by a person who is functionally connected to the entity, provided that the State of the place where the offence was committed does not prosecute for them.

2.4 Predicate offences of the administrative liability of Entities

The Entity's administrative liability is not "linked" to the commission of any kind of offence, but may be established only in connection with certain criminal offences expressly referred to by the Decree and by Law No. 146/2006.

Indeed, in order to establish a liability attributable to the Entity, only specific types of so-called predicate offences are identified as relevant, in the event of which the direct liability of the Entity is connected.

In its original text, the Decree listed among the offences from whose commission the administrative liability of Entities arose, exclusively those against the Public Administration and those against property committed to the detriment of the State or another public body (Articles 24 and 25).
Compared to the original range of relevant offences introduced in 2001, the list of Predicate Offences giving rise to the liability of the Entity has considerably been extended (**Annex no. 1** to this Model) and is constantly being expanded[1].
The latest additions to the catalogue of Predicate Offences include:

[1] In fact, from a first point of view, there has been a strong push from the EU bodies; from a second point of view, also at national level, various proposals have been submitted with a view to introducing further relevant offences. Moreover, the hypothesis of including the liability of Entities directly in the Criminal Code has also been examined (see the work of the Pisapia Commission), with a consequent change in the nature of liability (which would become, to all intents and purposes, criminal and no longer - formally - administrative) and the extension of the relevant offences. More recently, proposals have been put forward to amend the Decree in order to take advantage of the experience gained in applying it and, ultimately, to 'remedy' certain aspects that appeared excessively burdensome.

- Law no. 3 of 9 January 2019, setting out "*Measures for fighting offences against the public administration, as well as in the matter of statute of limitation of offences and in the matter of transparency of political parties and movements*" (the so-called "*Spazzacorrotti*"), which introduced "*Trafficking in unlawful influences*" pursuant to Article 346 *bis* of the Italian Criminal Code (as amended by the same new legislation) among the predicate offences referred to in Article 25 of the Decree, as well as increasing the sanctioning system for the entity in the event of commission of offences against the Public Administration. The legislation concerned is also notable for having made the offences of "*Corruption among private parties*" and "*Incitement to corruption among private parties*" prosecutable *ex officio;*
- Law no. 39 of 3 May 2019, concerning the "*Ratification and implementation of the Council of Europe Convention on sports manipulation, made in Magglingen on 18 September 2014*", which introduced among the predicate offences the offences of "*Fraud in sports competitions*" and "*Unauthorised gaming or betting and gambling exercised by means of prohibited devices*", referring to them in the new Article 25 *quaterdecies* of the Decree;
- Law no. 105 of 18 December 2019, containing urgent measures in matter of the national cyber security perimeter, which introduced within the predicate offences referred to in Article 24 *bis* of the Decree the case of "*Violation of the rules in matter of the national cyber security perimeter*", referred to in Article 1, paragraph 11, of Law 105/2019;
- Law no. 157 of 19 December 2019, which converted with amendments Law Decree no. 124 of 26 October 2019, containing "*Urgent provisions on tax matters and for non-deferrable demands*", which resulted in the inclusion in Legislative Decree no. 231/2001 of Article 25 *quinqueisdecies*, entitled "*Tax crimes*", which extends the liability of entities for offences to fraudulent tax declaration through the use of invoices or other documents for non-existent operations (Article 2 of Legislative Decree no. 74/2000), fraudulent tax declaration by means of other expedients (Article 3 of Legislative Decree no. 74/2000), issuing invoices for non-existent operations (Article 8 of Legislative Decree no. 74/2000), concealment or destruction of accounting documents (Article 10 of Legislative Decree no. 74/2000) and fraudulent evasion of tax payments (Article 11 of Legislative Decree no. 74/2000);
- Legislative Decree no. 75 of 14 July 2020, on "*Implementation of Directive (EU) 2017/1371 on the fight against fraud affecting the financial interests of the Union through criminal law*", which introduced the following offences among the predicate offences: i. "*Fraud in public supplies*" (Article 356 of the Italian Criminal Code, referred to in Article 24 of Legislative Decree 231/2001), ii. "*Embezzlement*", "*Embezzlement by profiting from the error of others*" and "*Abuse of office*" (respectively, pursuant to Articles 314, paragraph 1, 316, 323 of the Italian Criminal Code, referred to in Article 25 of Legislative Decree 231/2001), iii. "*False tax declaration*", "*Failure to make tax declaration*" and "*Undue offset*" (pursuant to Articles 4, 5 and 10 *quater* of Legislative Decree 74/2000, committed, also in part, within the territory of another Member State of the European Union for the purpose of evading VAT, referred to in Article 25 *quinquiesdecies* of Legislative Decree 231/2001); iv. *Smuggling offences* under Presidential Decree no. 43 of 1973 (referred to in the new Article 25 *sexiesdecies* of Legislative Decree 231/2001).

At present, the predicate offences giving rise to the Entity's administrative liability fall into the categories set out in the following table:

Legislative Decree 231/01	Category of offences
Article 24	Misappropriation of funds, fraud against the State or a public body or for obtaining public funds and IT fraud against the State or a public body and fraud in public supplies
Article 24-bis	IT crimes and unlawful processing of data
Article 24-ter	Organised crime offences
Article 25	Embezzlement, graft, undue inducement to give or promise other benefits, corruption and abuse of office
Article 25-bis	Forgery of money, public credit cards, revenue stamps and identification instruments or signs
Article 25-bis.1	Crimes against industry and trade
Article 25-ter	Corporate offences
Article 25-quater	Crimes for the purpose of terrorism or subversion of the democratic order provided for by the Criminal Code and special laws
Article 25-quater.1	Practices of mutilation of female genital organs
Article 25-quinquies	Crimes against the individual
Article 25-sexies	Market abuse offences
Article 25-septies	Offences of manslaughter and serious or very serious injuries, committed in breach of the rules on accident prevention and protection of hygiene and health at work
Article 25-octies	Receiving of stolen goods, money laundering and use of money, goods or benefits of unlawful origin as well as self-money-laundering
Article 25-nonies	Copyright infringement offences
Article 25-decies	Inducement not to make statements or to make false statements to the judicial authorities
Article 25-undecies	Environmental offences
Article 25-duodecies	Employment of illegally staying third-country nationals
Article 25-terdecies	Racism and xenophobia
Article 25-quaterdecies	Fraud in sports competitions, unlawful gaming or betting and gambling by means of prohibited devices
Article 25-quinquiesdecies	Tax offences
Article 25-sexiesdecies	Smuggling offences
L. 9/2013	Liability of entities for administrative offences within the virgin olive oil chain
L. 146/2006	Transnational offences

Having clarified the above, it should be highlighted that pursuant to Article 26 of the Decree, the Entity is held liable for the offences indicated above (with the exception of the offences referred to in Article 25 *septies* of the Decree) even if they have been committed in the form of an attempt. An attempt to commit an offence occurs when conducts are carried out which are suitable to and unambiguously aimed at committing an offence if the action is not committed or the event does not occur (Article 56 of the Criminal Code).

It should be specified that, in the event of commission of the offences indicated in Chapter I of the Decree (Articles 24 to 25 *sexiesdecies*, with the exception of Article 25 *septies* of the Decree) in the form of an attempt, the pecuniary sanctions (as regards amount) and, where applicable, the disqualifying sanctions (as regards duration) are reduced by one third to one half (see Article 26, paragraph 2, of the Decree).

The imposition of sanctions is, on the contrary, excluded in cases where the Entity voluntarily prevents the action from being carried out or the event from occurring (so-called voluntary desistance, see Article 26, paragraph 2, of the Decree). In such circumstances, the exclusion of sanctions is justified by the elimination of any relationship of identification between the Entity and the persons acting in its name and on its behalf.

2.5 The sanctions provided for in the Decree

In the event that the persons referred to in Article 5 of the Decree commit one of the Predicate Offences, the Entity may be subject to the imposition of certain highly penalising sanctions.

Pursuant to Article 9 of the Decree, the types of sanctions (referred to as administrative sanctions) that may be applied are as follows:

- pecuniary sanctions (Articles 10 - 12 of the Decree): these are always applied for any administrative offence and are of an afflictive and non-compensatory nature. Only the Entity is liable for the obligation to pay the pecuniary sanction with its assets or with the mutual fund. The sanctions are calculated on the basis of a system "*by quotas in a number not less than one hundred and not more than one thousand*", whose commensuration is determined by the Judge on the basis of the seriousness of the conduct and the degree of liability of the Entity, the activity carried out by the Entity to eliminate

or mitigate the consequences of the offence and to prevent the commission of further offences; each individual quota ranges from a minimum of Euro 258.23 to a maximum of Euro 1,549.37. The amount of each quota is determined by the Judge taking into account the economic and patrimonial conditions of the Entity; the amount of the pecuniary sanction, therefore, is determined by multiplying the first factor (number of quotas) by the second factor (amount of the quota).

Article 12 of the Decree provides for a series of cases in which the pecuniary sanction is reduced. These cases are schematically summarised in the following table, with an indication of the relevant reduction and the requirements for its application.

Reduction	**Requirements**
½ (and may not in any case exceed EUR 103,291.00)	• The offender committed the offence in his own interest or in the interest of a third party and the Entity did not gain an advantage or gained minimum advantage; *or* • the pecuniary damage caused is particularly minor.
From 1/3 to 1/2	[Before the declaration of the opening of the first instance trial] • The Entity has fully compensated for the damage and eliminated the harmful or dangerous consequences of the offence or has taken effective steps to do so; *or* • an organisational model suitable for preventing offences of the kind committed has been implemented and made operating.
From 1/2 to 2/3	[Before the declaration of the opening of the first instance trial] • The Entity has fully compensated for the damage and eliminated the harmful or dangerous consequences of the offence or has taken effective steps to do so; *and* • an organisational model suitable for preventing offences of the kind committed has been implemented and made operating.

- disqualifying sanctions (Articles 13 to 17 of the Decree): these apply only in cases where they are expressly provided for and are (Article 9, paragraph 2, of the Decree):
  - debarment from running the business;
  - suspension or revocation of authorisations, licences or concessions functional to the commission of the offence;
  - prohibition on contracting with the Public Administration, except for the purpose of obtaining a public service; this prohibition may also be limited to certain types of contracts or to certain administrations;
  - exclusion from benefits, financing, contributions or subsidies and possible revocation of those granted;
  - prohibition on advertising goods or services.

Disqualifying sanctions have the characteristic of limiting or conditioning the company's activity, and in the most serious cases they may paralyse the Entity (debarment from running the business); they also have the purpose of preventing conducts connected with the commission of offences. Indeed, Article 45 of the Decree provides for the application of the disqualifying sanctions indicated in Article 9, paragraph 2, of the Decree as a precautionary measure, when there are serious circumstantial evidence that the Entity is liable for an administrative offence resulting from a crime,

and there are well-grounded and specific elements which make it appear that there is a real danger that offences of the same kind as the one in respect of which proceedings are being brought may be committed.

These sanctions shall apply in the cases expressly provided for in the Decree when at least one of the following conditions is met:

- the Entity has gained a significant profit from the offence and the offence was committed by persons in a senior management position or by persons subject to the direction of others and, in this case, the commission of the offence was determined or facilitated by serious organisational deficiencies;
- in the event of repeated offences.

In general, disqualifying sanctions have a duration of no less than three months and no more than two years; however, an exception is made, as a result of the amendments made by Law no. 3/2019 (the so-called "*Spazzacorrotti*" Law), for cases of conviction for the offences set out in Article 25, paragraphs 2 and 3, of Legislative Decree no. 231/2001 (Graft, Corruption, Undue inducement to give or promise benefits, Corruption in judicial proceedings), in relation to which the applicable disqualifying sanction has a duration of "*not less than four years and not more than seven years*" where the predicate offence was committed by senior management, or a duration of "*not less than two years and not more than four years*" where the predicate offence was, instead, committed by a person subject to the management and control of the senior management[2]. Moreover, as an exception to the rule of temporariness, it is possible to apply disqualifying sanctions on permanent basis in the most serious situations described in Article 16 of the Decree.
Finally, it should be referred to again that Article 23 of the Decree punishes the failure to comply with disqualifying sanctions, which occurs when the Entity has been subject to a disqualifying sanction or precautionary measure under the Decree and, despite this, fails to comply with the obligations or prohibitions relating thereto;

- confiscation (Article 19 of the Decree): this is an autonomous and compulsory sanction which is applied with the conviction of the entity, and concerns the price or the profit of the offence (except for the part which can be returned to the damaged party), or, if this is not possible, sums of money or other utilities with a value equivalent to the price or the profit of the offence; the rights acquired by the third party in good faith are not affected. The purpose is to prevent the Entity from exploiting unlawful conducts for "profit"; as regards the meaning of "profit", given the important impact that confiscation may have on the assets of the Entity, scholars and jurisprudence have expressed different and oscillating opinions due to the novelty of the topic with reference to the "confiscation-sanction" provided for by the Decree. Article 53 of the Decree provides for the possibility of ordering the preventive seizure for the purpose of confiscating the assets of the entity which constitute the price or the profit of the offence where the conditions provided for by law are met; the procedure provided for in Article 321 et seq. of the Code of Criminal Procedure on preventive seizure applies;
- publication of the judgment (Article 18 of the Decree): it may be ordered when a disqualifying sanction is imposed on the Entity; the judgment is published, in full or in excerpt, on the website of the Ministry of Justice, as well as by posting on the notice board of the municipality where the

[2] However, the duration of disqualifying sanctions becomes again to be of the ordinary duration established by Article 13, paragraph 2, of the Decree (i.e. not less than three months and not more than two years) "*if, before the judgment of first instance, the entity has effectively taken steps to prevent the criminal activity from having further consequences, to ensure the evidence of the offences and the identification of the offenders, or the seizure of the sums or other benefits transferred, and has eliminated the organisational deficiencies that led to the offence by adopting and implementing organisational models suitable to prevent offences of the kind committed*".

Entity has its registered office. The publication is at the expense of the Entity and is carried out by the clerk of the Judge; the purpose is to bring the conviction to the attention of the public.

From a general point of view, it should be noted that the assessment of the liability of the Entity, as well as the determination of the *an* and *quantum* of the sanction, are assigned to the criminal Judge having jurisdiction over the proceedings relating to the offences on which the administrative liability depends.

2.6 Precautionary measures

The Decree provides for the possibility of applying to the Entity the disqualifying sanctions provided for in Article 9, paragraph 2, also as a precautionary measure.

Precautionary measures meet a need for procedural precaution, since they can be applied in the course of proceedings and therefore to a person who is under investigation or indicted, but who has not yet been convicted. For this reason, precautionary measures may be ordered, upon request of the Public Prosecutor, under certain conditions.

Article 45 of the Decree sets out the requirements for the application of precautionary measures, subordinating their use on the existence of serious circumstantial evidence of guilt concerning the liability of the Entity, thus following the provision contained in Article 273, paragraph 1, of the Code of Criminal Procedure. The assessment of serious circumstantial evidence relating to the applicability of precautionary measures under Article 45 of the Decree must take into account of:

- the complex of administrative offence attributable to the Entity;
- the dependence relationship with the predicate offence;
- the existence of an interest or advantage for the Entity.

The procedure for the application of precautionary measures is modelled on the one outlined in the Code of Criminal Procedure, albeit with some exceptions. The Judge competent to apply the measure, at the request of the Public Prosecutor, is the Judge in charge of the proceedings, or rather, in the phase of the preliminary investigations, the Judge for the Preliminary Investigations. The applicative order is the one provided for by Article 292 of the Criminal Code, a regulation expressly referred to in Article 45 of the Decree.

Once the Public Prosecutor's request is received, the Judge sets an ad hoc hearing to discuss the application of the measure; this hearing is attended not only by the Public Prosecutor, but also by the Entity and its defence attorney, who, prior to the hearing, may access the Public Prosecutor's file and examine the elements on which the request is based.

2.7 Requirements and purpose of the adoption and implementation of an Organisation, Management and Control Model

Generally speaking, the methods for constructing a valid Model are set out in Article 6 of the Decree, which, in paragraphs 2 and 2 *bis*[3], provides for that such Models must meet the following requirements:

a. identify the activities within the scope of which the Predicate Offences may be committed;

[3] Paragraph 2 *bis* was introduced by Law No. 179 of 30 November 2017 in matter of whistleblowing, which, with specific reference to the private sector, intervened precisely in matter of the administrative liability for offences of entities pursuant to Legislative Decree 231/2001, integrating the requirements of suitability and effectiveness of the models referred to in Article 6 of the Decree.

b. provide for specific protocols aimed at planning the making and implementation of the Entity's decisions in relation to the Predicate Offences to be prevented;

c. identify modalities of managing financial resources suitable for preventing the Predicate Offences;

d. provide for information obligations vis-à-vis the Supervisory Board;

e. provide for one or more channels enabling Senior Management and Subordinates to submit, in order to protect the integrity of the entity, detailed reports of unlawful conduct, relevant under the Decree and based on precise and consistent facts, or of violations of the Model, of which they have become aware by virtue of their functions; these channels ensure the confidentiality of the identity of the reporting party in the management of the report[4];

f. provide for at least one alternative reporting channel suitable for ensuring, by IT means, the confidentiality of the reporting party's identity[5];

g. in relation to the reports referred to in letters e) and f) above, provide at least for the prohibition of retaliatory or discriminatory acts, whether direct or indirect, against the reporting party for reasons connected, directly or indirectly, with the report[6];

h. introduce a disciplinary system suitable for sanctioning failure to comply with the measures indicated in the Model (hereinafter, for the sake of brevity, also referred to as the "**Disciplinary System**").

Paragraphs 3 and 4 of Article 7 of the Decree also provide for that:

- the Model must provide for appropriate measures, both to ensure that the activity is carried out in compliance with the law, and to promptly detect risk situations, taking into account the type of activity carried out and the nature and size of the organisation;
- the effective implementation of the Model requires a periodic assessment and amendment of the same if significant violations of the provisions of the law are discovered or if there are significant changes in the organisation or law; the existence of an appropriate Disciplinary System is also important.

It should also be added that, with specific reference to the preventive efficacy of the Model with reference to (culpable) crimes relating to health and safety at work, Article 30 of Legislative Decree no. 81/2008 states that "*the organisation and management Model capable of being effective in exempting the administrative liability of legal persons, companies and associations, including those without legal personality, referred to in Legislative Decree no. 231 of 8 June 2001, must be adopted and effectively implemented, ensuring a corporate system for the fulfilment of all the legal obligations relating to:*

- *compliance with legal technical and structural standards relating to equipment, facilities, workplaces, chemical, physical and biological agents;*
- *risk assessment activities and the arrangement of the connected prevention and protection measures;*
- *activities of an organisational nature, such as emergencies, first aid, contract management, periodic safety meetings, consultation of workers' representatives for safety;*
- *health surveillance activities;*
- *information and training activities for workers;*

[4] Requirement introduced by Law No 179 of 30 November 2017, referred to in the footnote above.
[5] See previous footnote.
[6] See previous footnote.

- *supervisory activities with regard to workers' compliance with safe working procedures and instructions;*
- *the acquisition of documents and certifications required by law;*
- *periodic checks on the application and effectiveness of the procedures adopted*".

Again in accordance with the aforementioned Article 30 of Legislative Decree no. 81/2008: "*The organisational and management model must provide for suitable systems for recording the actual performance of activities. The organisational model must in any event provide, to the extent required by the nature and size of the organisation and by the type of activity carried out, for a structure of functions which ensures the technical skills and powers necessary for the verification, assessment, management and control of the risk, as well as a disciplinary system suitable for sanctioning failure to comply with the measures set forth in the Model. The organisational Model must also provide for a suitable control system on the implementation of the Model and on the maintenance over time of the conditions of suitability of the measures adopted. The review and possible amendment of the organisational Model must be adopted when significant violations of the rules on accident prevention and hygiene at work are discovered, or when changes in the organisation and activity occur in relation to scientific and technological progress*".

The provision of law also states that upon first application, corporate organisation models defined in accordance with the UNI-INAIL Guidelines for an occupational health and safety management system (SGSL) of 28 September 2001 or the British Standard OHSAS 18001:2007 are supposed to comply with the requirements of this article for the corresponding parts. Currently, the OHSAS 18001:2007 standard has been replaced by ISO 4500:2018.

It is self-evident, therefore, that, although it is not mandatory by law, the adoption and effective implementation of a suitable Model is, for Entities, an essential requirement to benefit from the liability exemption provided for by the Legislator.

By a special decree of the Ministry of Labour and Social Policies, published in the Official Gazette no. 45 of 24 February 2014, "*simplified procedures for the adoption and effective implementation of organisational and safety management models in small and medium-sized enterprises*" drawn up by the Permanent Advisory Commission on Occupational Health and Safety were finally implemented.

The document aims to "*provide SMEs that decide to adopt an organisational and management model for health and safety with simplified organisational indications, of an operational nature, useful for the arrangement and effective implementation of a company system suitable for preventing the offences provided for in Article 25 septies of Legislative Decree no. 231/2001*", i.e. the offences of "*manslaughter or serious or very serious injury committed in violation of the law provisions on health and safety at work*".

3. BENCHMARKS: GUIDELINES DEVELOPED BY TRADE ASSOCIATIONS

3.1 Guidelines developed by CONFINDUSTRIA and ASSOBIOMEDICA

Paragraph 3 of Article 6 of the Decree provides for that the Model may be adopted on the basis of codes of conduct drawn up by the trade associations representing the Entities and communicated to the Ministry of Justice, which may make remarks.

The first Association to draw up a guidance document for the construction of models was Confindustria which, in March 2002, issued Guidelines, which were then partially amended and updated, lastly, in June 2021 (hereinafter, also "Confindustria Guidelines"). The update of the Confindustria Guidelines, which

concerned both the general section and the appendix relating to single offences (so-called case study), is aimed at providing indications on the measures suitable to prevent the commission of the alleged offences envisaged as at June 2021.

The Confindustria Guidelines for the drawing up of Models provide associations and companies - whether or not affiliated to the Association - with methodological indications on how to prepare an organisational model suitable for preventing the commission of the offences indicated in the Decree.

The indications of the latter document, which is also recognised by the Decree, can be summarised as follows:

- ✓ identification of risk areas, aimed at verifying in which area/sector of the company the offences provided for in the Decree may be committed;
- ✓ identification of the modalities in which offences may be committed;
- ✓ performing the risk assessment;
- ✓ identification of control points aimed at mitigating the risk of offence;
- ✓ gap analysis.

The most relevant components of the control system designed by Confindustria are:

- ✓ code of ethics and conduct;
- ✓ organisational system;
- ✓ manual and IT procedures;
- ✓ powers of authorisation and signature;
- ✓ control and management systems;
- ✓ communication to and training of personnel.

These components should be oriented to the following principles:

- ✓ verifiability, documentability, consistency and congruence of each operation;
- ✓ application of the principle of segregation of duties (no one can manage an entire process autonomously);
- ✓ documentation of controls;
- ✓ provision of an adequate system of sanctions for violations of the procedures laid down in the model;
- ✓ identification of the requirements of the Supervisory Board, which can be summarised as follows:
    - o autonomy and independence;
    - o professionalism;
    - o continuity of action;
- ✓ establishment of information flows to and from the Supervisory Board.

In any case, it should be noted that non-compliance with specific points of the Guidelines does not in itself adversely affect the validity of the Model, since these are general indications requiring subsequent adjustment to the specific situation of the Entity in which they will operate.

Indeed, each Model must be constructed bearing in mind the characteristics of the company to which it applies. The risk of offence for each company in fact is closely connected to the economic sector, the organisational complexity - not only in terms of size - of the company and the geographical area in which it operates.

Moreover, the fact that the Models comply with the Guidelines does not mean that they are not subject to censorship (see Court of Cassation, judgment no. 3307 of 18 December 2013).

Finally, it is worth noting that also Assobiomedica, another association of reference for the Company, issued, in February 2003, its own "*Guidelines for the construction of organisation, management and control models pursuant to Legislative Decree no. 231/2001*" ("**Assobiomedica Guidelines**"), subsequently updated in November 2013.
The above-mentioned guidelines (Confindustria and Assobiomedica) are an indispensable starting point for the correct design and drafting of a Model that is adequate pursuant to the Decree and have been taken into due consideration for this purpose when drafting this Model.

4. THE ORGANISATION, MANAGEMENT AND CONTROL MODEL OF TIT

4.1 The purpose of this Model

The Company has decided to adopt this Model in order to ensure a more transparent and homogeneous interface between the public and private sectors.

In this perspective, this Model - which takes into account the Company's business reality - represents a valid instrument for raising awareness of and informing the Recipients, the Other Recipients and Third Parties in general, so that, in carrying out their activities, the aforesaid parties behave correctly and transparently in line with the values that inspire the Company in pursuing its corporate object and, in any case, in a way to prevent the risk of commission of the offences provided for in the Decree.

This Model has been drawn up by the Company on the basis of the identification of the areas of possible risk in the company's activities in which the possibility of offences being committed is considered to be higher and aims at:

- ✓ setting up a prevention and control system in order to reduce the risk of commission of offences related to the company's activities;
- ✓ making all those who work on behalf of the Company, and in particular those engaged in the "areas of activity at risk", aware of that, in the event of violation of the provisions contained therein, they may incur in an offence punishable by criminal and administrative sanctions, not only against themselves but also against the Company;
- ✓ informing all those who work with the Company that the violation of the provisions contained in this Model will result in the application of specific sanctions such as, for example, termination of the contractual relationship;

- ✓ confirming that the Company does not tolerate unlawful conduct of any kind and for any purpose whatsoever, and that, in any case, such conduct is always and anyway contrary to the principles inspiring the Company's business activity, even if the latter was apparently in a position to benefit from it.

4.2 The construction of the Model and its adoption

On the basis, inter alia, of the indications contained in the trade associations Guidelines, the Company set up a Working Group, composed of Company resources and supported by external professionals with specific skills in the relevant matters and subject of the applicable legislation. The purpose of this Working Group was to map out the areas at risk, as well as to identify and assess the risks relating to the types of offences covered by the legislation and the related Internal Control System. On the basis of the results of these activities, the Company has drawn up this Model.

The drafting of this Model was divided into the following stages:

a) preliminary examination of the corporate framework by conducting interviews with the persons informed within the corporate structure in order to identify and specify the organisation and the activities carried out by the various corporate functions, as well as the corporate processes into which the activities are organised and their concrete and effective implementation;

b) identification of the areas of activity and of the corporate processes at "risk" of or instrumental to the commission of offences (hereinafter, for the sake of brevity, cumulatively referred to as the "Offence Risk Areas"), carried out on the basis of the preliminary examination of the corporate framework referred to in letter a) above;

c) identification, for each risk area, of the main risk factors, as well as the detection, analysis and assessment of the adequacy of existing corporate controls;

d) identification of the aspects to be improved in the Internal Control System;

e) adjustment of the Internal Control System in order to reduce the identified risks to an acceptable level.

In particular, the Working Group carried out an inventory and a specific mapping of corporate activities (so-called "risk mapping"), mainly by conducting interviews with Company's personnel.

At the end of the above-mentioned activities, the Working Group drew up a list of the offence risk areas, i.e. those sectors of the Company and/or corporate processes in respect of which, in the light of the results of the mapping, the risk of commission of offences, among those indicated in the Decree, which may theoretically be connected to the type of activity carried out by the Company, was deemed to exist.

The Working Group then surveyed and analysed the corporate existing controls - as-is phase - as well as identified points for improvement, and made specific suggestions to enable the definition of an action plan to address the relevant topics.

With reference to Law no. 123/2007, which introduced liability for certain types of offences related to the violation of health and safety at work regulations, the organisational structure was subjected to a specific analysis, which, as suggested by the Confindustria Guidelines, was conducted on the entire company structure, since with regard to the offences of manslaughter and serious or very serious injuries committed in breach of the rules for the protection of health and safety at work (hereinafter also "**OSH**"), it is not

possible to exclude a priori any field of activity, given that this type of offences may, in fact, involve all the company's components. In particular, the Working Group has collected and analysed the relevant documentation on OSH (including the risk assessment documents, etc.) necessary both for understanding the Company's organisational structure and the areas relating to OSH, and for defining the activities at the sites under analysis. In particular, the Working Group verified the legal and similar requirements applicable to activities and workplaces.

4.3 The structure of the Model

This Model consists of a "**General Section**" and certain "**Special Sections**".

The "General Section" points out the contents of the Decree, the purpose of the Model, the tasks of the Supervisory Board, the applicable sanctions in the event of violations and, in general, the principles, logic and structure of the Model itself.

The "Special Sections" contain the description of the predicate offences considered relevant for the Company, as well as the identification of the offences risk areas and the related sensitive activities, identified on the basis of the organizational structure and business activities carried out by TIT. In the Special Sections are also set out the principles of conduct and the specific controls defined by the Company and TERUMO Group with a view to prevention, together with the information flows to the SB. For details of the structure of the Special Sections, please refer to the description contained in the introductory section of the same.

In addition to the above structure, the following documents form an integral part of the Model:

- Disciplinary system: a document describing the sanctionable conduct and the relevant sanctions applicable in the event of violation of the principles/rules provided for by the Model.
- Regulatory section: document describing the types of offence considered relevant in view of TIT's activities and organisational structure.

5. THE COMPANY AND THE GOVERNANCE MODEL

5.1 The Company

TIT is a company incorporated under Italian law that is part of the international TERUMO Group, a leader in the medical devices market.

TIT has its registered office in Via Paolo di Dono 73, 00142 Rome, Italy, and is entirely controlled by TERUMO EUROPE N.V. (hereinafter "TE"), which acts as the holding company of TERUMO Group (hereinafter also only the "Group") in the EMEA area.

TE carries out direction and coordination activities with respect to all local subsidiaries of the Group operating in the EMEA area, including TIT. This activity is carried out through guidelines that the Italian company implements independently with its own resolutions and is achieved thanks to the presence - within the organisational chart - of direct reporting lines to certain corporate functions of the Group, capable of guaranteeing the necessary information flow for the coordination activity.

TIT operates as a distributor on the Italian, Greek and Cypriot markets of medical devices manufactured by the Terumo Group, purchased from the parent company TE, and intended for hospital and non-hospital

use. TIT also receives from TE certain goods and services of minor value, such as administrative services and product samples.
With particular reference to administrative services, it should be noted that TE supports TIT in the management of the so-called "Shared Services" (i.e. HR; Accounting; IT), creating efficiency and cost optimisation by reducing the need for support staff within TIT, and manages the Internal Audit and Compliance functions for the entire Group in the EMEA area.

The transactions carried out with the parent company TE are concluded at normal market conditions. In particular, the purchase prices of the products are negotiated in accordance with the arm's length principle and to the extent that TIT achieves an operating result within a range identified on the basis of a specific comparative study carried out with reference to the main European markets.

The method of determining the transfer prices of products and verifying their compliance with the arm's length principle is therefore the so-called "transactional net margin method".

TIT operates in a single sector, namely the marketing - on the national, Greek and Cypriot territory - of medical devices purchased by TE, which can be grouped into the following product lines:

- Interventional Endovascular Diagnostics Line;
- Cardiovascular Line;
- Medical Products Line;
- Diabetes Line.

The main market in which TIT operates is the public health sector to which the private sector comes up alongside. Export (to Greece and Cyprus) represents a marginal share of the market.

In terms of sales methods, TIT concludes different types of agreements with customers, depending on the nature of the counterparty (public/private) and/or the nature of the products. In particular, with public counterparts, sales are generally concluded through public tenders, while with private parties, the relationships are governed by specific sales contracts. As for the type of products, a distinction should be made between so-called quantity products, generally sold through tenders and/or contracts, and high-tech products, generally sold on the basis of individual orders.

At the strategic level, TIT implements activities aimed at making Terumo's products known and promoted to dealers and the medical-hospital class, thus promoting sales. The aforementioned strategy is facilitated by the activity of Agents and dealers (i.e. Distributors), who - on the basis of special contracts that define their powers and scope of activity (i.e. product lines and relevant territory) - operate in close contact with end users, meeting their specific needs through a customized service.

Moreover, dealers perform two of the most important functions in the commercial chain, namely, maintaining an available stock of products for hospitals and facilitating commercial credit due to the chronic delay of payments by the public counterparty.

In addition to the core business described above, TIT provides consultancy, organisation and brokerage services for the purchase, sale, import and export, management of any business, including retail, wholesale and commission sales of any medical product. In particular, the main services offered by the Company include:

- advising and monitoring the use of the products marketed;
- installation, maintenance and after-sales service;
- training in the use and handling of products.

Lastly, it should be noted that within TE there are the so-called Control Committees [(i.e. Risk management and Compliance Committee (RMC); Grant and Donation Committee (G&DC); Management Committee (MC)] that operate in relation to the entire perimeter of the Group in the EMEA area and that TIT is part of the centralised treasury system (cash - pooling) of the Group to which it belongs and that, on the basis of infragroup agreements and/or duly formalised purchase orders, TIT receives and provides other companies of the Group with certain coordination and strategic support services in certain business areas.

5.2 TIT's governance system

TIT's governance model and, in general, its entire organisational system is structured to ensure that the Company implements its strategies and achieves its defined objectives.

TIT's structure has been created taking into account the need to provide the Company with an organisation that guarantees maximum efficiency and operational effectiveness.

In light of the peculiarities of its organisational structure and the activities carried out, the Company has opted for the so-called "*traditional system*", which provides for the presence of a Board of Directors with management functions and a Board of Statutory Auditors with functions of control over the management, both appointed by the Shareholders' Meeting.

The Company's corporate governance system is therefore currently structured as follows:

Shareholders' meeting:

It is the competence of the Shareholders' Meeting to resolve, in its ordinary and extraordinary sessions, on matters reserved to it by law or by the By-laws.

Board of Directors:

The Board of Directors is vested with all powers of ordinary and extraordinary administration for the implementation and achievement of the Company's purpose, within the limits of what is allowed by law and by the By-laws. In particular, the Board of Directors has the power to define the Company's strategic guidelines and to verify the existence and efficiency of its organisational and administrative structure. The Company's Board of Directors is composed of no. 2 Directors.

Board of Statutory Auditors:

The Board of Statutory Auditors consists of three regular members and two alternate members. The Board of Statutory Auditors is entrusted with the task of supervision:

- ✓ on compliance with the law and the articles of association;
- ✓ on compliance with the principles of correct administration;
- ✓ the adequacy of the Company's organisational structure, the Internal Control System and the administrative and accounting system, including with regard to the reliability of the latter to correctly represent management events.

In addition, the Board of Statutory Auditors, whose members are registered in a special register, is entrusted with the task of auditing and controlling the Company's accounts.

Supervisory Board (SB):

Appointed following the adoption of the Model, in accordance with the provisions of Legislative Decree 231/2001, it currently has a collegial composition.

The Supervisory Board is an independent supervisory body responsible for monitoring and controlling the correct and effective application of the rules laid down in the Organisational Model adopted and for proposing any necessary updates.

6. THE ORGANISATIONAL STRUCTURE OF TERUMO ITALIA

The organisational structure of the Company, designed to ensure, on the one hand, the segregation of roles, tasks and responsibilities between the various functions and, on the other hand, the utmost possible efficiency, is characterised by a precise definition of the competences of each corporate area and the related responsibilities.

The Company has drawn up an Organisational Chart outlining its entire organisational structure.

In particular, the Organisational Chart points out:

- the areas into which the company's activities are divided;
- the hierarchical reporting lines of the single company functions;
- the persons working in the single areas and their organisational role.

The Organisational Chart, with the relevant hierarchical and functional reporting lines, can be freely consulted by all the Company's personnel through the company intranet.

7. THE ORGANISATIONAL STRUCTURE IN THE MATTER OF HEALTH AND SAFETY

In accordance with the Confindustria Guidelines, the Company has adopted an organisational structure that complies with the provisions of the prevention regulations in force, with a view to eliminating or, where this is not possible, reducing - and therefore managing - risks to workers.

The Company, in relation to its registered office and its laboratories, has drawn up a Risk Assessment Document, as well as setting up an appropriate organisational structure for health and safety at work, clearly and formally identifying the persons responsible for health and safety at work.

8. CERTIFICATIONS ISSUED TO THE COMPANY

The Company has decided to adopt management systems developed in accordance with its own organisational structure, taking into account the specific activities carried out and the peculiarities of the market concerned, with the specific intention of implementing and maintaining an effective management of internal processes, in order to guarantee services and performances capable of satisfying both customer expectations and the applicable mandatory law provisions requirements.

The Company and its management system are reviewed annually to ensure that they comply with plans and the requirements of relevant legislation.

In detail, TIT is a certified company according to the UNI EN ISO13485:2016 standard "*Medical devices - Quality management systems - Requirements for regulatory purposes*" relating to the quality management system specific to companies in the medical sector, which includes aspects of the ISO 9001 standard and requirements specific to the medical device sector.

The requirements of the above-mentioned standard ensure a good degree of consistency between the Management System and the 231 Model. In this sense, the identification and analysis of the "risk", as well as the consequent definition of actions aimed at its prevention, which constitute one of the most important elements of the above-mentioned standards and which, at the same time, is also an element of particular relevance for the purposes of the precautionary approach envisaged in the context of prevention of the risks of commission of offences pursuant to Legislative Decree no. 231/2001.

Following this approach, it can therefore be stated that a Management System effectively designed, implemented and, above all, conceived by the organisation that applies it as an actual support to operational management, is already able, to a large extent, to meet many of the requirements of Legislative Decree no. 231/2001.

Moreover, the standards followed in the design and implementation of the System adopted by the Company can be considered to all intents and purposes "best available techniques" in the organisational field for the management of Quality aspects in the specific sector in which it operates.

9. THE SYSTEM OF DELEGATIONS AND POWERS OF ATTORNEY

9.1 General principles

The Board of Directors is the body responsible for formally allocating and approving delegated and signatory powers.

The power to represent the Company is granted to both members of the Board of Directors.

However, where appropriate, special powers of attorney may be granted to the heads of certain functions in close relation to the tasks and activities carried out by each of them.

Powers of attorney, where granted, are always formalised through notarial deeds and communicated to the addressee for his full knowledge and acceptance. In addition, powers of attorney with external relevance are then registered with the competent Office of the Companies Registry. Each of these acts of delegation or power of attorney therefore provides the following information:

- ✓ delegating party and the source of its power of delegation or power of attorney;
- ✓ the delegated person, with explicit reference to the function assigned to him/her and the link between the delegations and powers of attorney granted and the organisational position held by the delegated person;
- ✓ object, consisting of a list of the types of activities and acts for which the delegation/power of attorney is granted. These activities and acts are always functional and/or closely related to the competences and functions of the delegated person;

- ✓ value limits within which the delegate is entitled to exercise the power he/she is granted. This value limit is determined according to the role and position held by the delegate within the company organisation.

In allocating the powers granted by the power of attorney, account is normally taken of the criterion according to which, in relation to the same transaction, the same delegate may not alone:

- ✓ authorise a commitment and give authorisation for payment;
- ✓ commit and authorise payment;
- ✓ commit and pay/cash;
- ✓ give authorisation for payment and pay/cash.

In addition, in accordance with internal control principles:

- ✓ the Delegates, whatever their delegated powers, may neither authorise a commitment, nor grant a payment voucher on their behalf, nor exercise a power if they have a personal interest, direct or indirect, in the resulting transaction;
- ✓ the acts of requesting a commitment and of committing for the same transaction are distinct and are normally exercised by different and independent persons;
- ✓ there must always be at least two people in the commitment process (from the preparation of the commitment - the initial request - to the commitment itself). If the applicant and the holder of the commitment authorisation power are the same person, his request must be formally approved by the higher level hierarchical authority or other delegated person, even if the amount in question is within the commitment authorisation threshold of this person.

10. J-SOX CONTROLS AND PROCEDURAL SYSTEM

TIT, as a member of the TERUMO Group listed on the Tokyo Stock Exchange and subject to regulation under the Financial Instruments and Exchange Act ("J-SOX"), complies with the Group's Control Principles.

Each corporate function is subject to a series of procedures, rules of conduct, ethical standards and control criteria (adopted on the basis of J-SOX) which already limit, within areas of reasonable discretion, the modus operandi of the corporate Bodies as well as the relevant senior functions and the persons subordinated to them.

Therefore, with reference to the Company's organisational and procedural system and its suitability to mitigate operational risks, it cannot be disregarded the current organisational rules and guidelines already in place at TERUMO Group and the companies belonging to the same, which are considered reasonably suitable to reduce to acceptable levels the risks that the crime may be committed also for the benefit and to the advantage of the Company itself.

The procedures prepared by the Company and/or TERUMO Group, both manual and IT, constitute the rules to be abided by within the company processes concerned.

In general, the internal procedures, operating instructions and practices adopted by the Company and/or TERUMO Group are based on the following principles:

- ✓ the formation and implementation of the entity's decisions must be based on the utmost transparency and sharing among different persons;
- ✓ technical and operational functions must be kept separate from accounting and control functions;
- ✓ internal procedures, where possible, must also be characterised by the segregation of roles, with particular reference to the exercise of control functions, which must remain separate from decision-making and operational functions;
- ✓ traceability of processes must be ensured;
- ✓ the principle of transparency must be implemented, consisting both in the visibility of procedures within the company and the completeness of the rules governing them, and in the duty of communication and information on relevant decisions between the various company departments.

As specifically regards IT procedures, the main management systems of the administrative and control area are supported by high quality IT applications. In particular, the company's IT systems guarantee the traceability of individual steps and the identification of the operator by whom data is entered or modified in the system.

They are in themselves the "guide" to how carrying out certain transactions and ensure a high level of standardisation and compliance, as the processes managed by these applications are validated before the software is released.

In this context, therefore, the Company ensures compliance with the following principles:

- ✓ facilitate the involvement of several persons, in order to achieve an appropriate segregation of tasks through the opposition of functions;
- ✓ take steps to ensure that every operation, transaction and action is verifiable, documented, consistent and appropriate;
- ✓ require measures to be taken to document the controls carried out in respect of the operations and/or actions performed.

11. MANAGEMENT CONTROL AND FINANCIAL FLOWS

TIT's management control system (hereinafter also referred to as "**Management Control**") is managed on the basis of the indications provided by the Group, also providing for periodic reporting and sharing with the competent functions at Group level and the mechanisms for verifying the management of resources, which must ensure, in addition to the verifiability and traceability of expenses, the efficiency and cost-effectiveness of business activities, aiming at the following objectives:

- ✓ defining in a clear, systematic and comprehensible manner the resources (monetary and non-monetary) available to individual functions and the perimeter within which these resources can be used, through planning and budgeting;
- ✓ detect, through a constant flow of information between the corporate functions concerned, any deviations from what was predefined in the budget on the basis of weekly "*actual*" situations, analyse the causes and report the results of evaluations to the appropriate hierarchical levels for the necessary adjustments;
- ✓ revision of the initial planning defined in the budget on the basis of the deviations detected in the actual-budget analysis.

11.1 Planning and budgeting phase

In order to achieve the above objectives, the existing strategic budgeting processes ensure:

- ✓ the participation of different responsible persons in the definition of available resources and expenditure areas, with the aim of guaranteeing the constant presence of controls and cross-checks on the same process/activity, in order to ensure adequate segregation of duties and constant monitoring of any deviations;
- ✓ the provision of specific authorisation procedures in the event of requests to supplement the budget initially allocated;
- ✓ the adoption of any mutually agreed corrective actions in order to identify the best corrective strategy.

11.2 Final balance phase

In this phase, there is constant verification of the coherence between the expenditure actually incurred and the commitments made in the planning.

The monitoring of deviations, in terms of costs, with respect to the planned budget is carried out through a specific internal consultation that allows to evaluate/explain possible positive and negative variations of the forecast. Formal evidence of this activity is provided.

12. CODES OF CONDUCT

12.1 Relationship between the Organisation, Management and Control Model and the Codes of Conduct

An essential element of the preventive control system is represented by the adoption, also at Group level, of a series of principles and rules of ethics and conduct contained in the following documents (together the "Codes of Conduct"), which the Recipients must scrupulously comply with in the performance of their activities:

- "TERUMO Group Code of Conduct" - this document, prepared and approved by the Board of Directors of TERUMO Corporation, provides the guidelines and standard of business conduct to which each member of the Group (starting with the members of the Board of Directors) shall adhere in the conduct of their daily business activities and is intended to assist all TERUMO Group members in the event of uncertainties in their conduct of business activities.
- "TERUMO EMEA Code of Business Compliance" - this document supplements the above-mentioned TERUMO Group Code of Conduct, providing principles and rules to be followed in order to comply with applicable laws and regulations and the required standards of conduct (inter alia, with regard to safety and environment, anti-money laundering and anti-corruption, and more generally with regard to compliance).
- "TERUMO Europe Supplier Code of Conduct" - this document sets out the principles of the Pharmaceutical Supply Chain Initiative ("PSCI"), which TERUMO Group supports, regarding ethics, workers' rights, health and safety, environment and management system, which TERUMO Group's suppliers and sub-contractors must adhere to in the performance of their business.

- "MedTech Europe Code of Ethical Business Practice" - TERUMO adheres to the European MedTech Association, which has adopted its own code of ethics (most recently updated in the year 2018), in order to regulate relations between member companies, Professionals and Healthcare Organisations, with the specific purpose of ensuring that support actions by member companies do not lend themselves to doubts regarding impartiality and good faith in the relationship between the latter, operators and healthcare structures. In detail, the new MedTech Code intervenes in redefining the way in which the industry and Healthcare Professionals interact, introducing a new model of financial support to Healthcare Professionals and Organisations for participation in Educational Events Organised by Third Parties.

The Codes of Conduct, as referred to above, represent a general instrument establishing the conduct that the Company - in compliance with the Group's rules - intends to promote, disseminate, comply with and enforce in carrying out its business activities to protect its reputation and image in the market. They contain the fundamental principles of the Company and the guidelines on the conduct to be adopted in the relations within and outside the Company itself; they also contain the codes of conduct in relation to any areas of ethical risk. It should be noted, therefore, that these principles aim to avoid the commission of offences - whether or not provided for in the Decree - as well as conduct not in line with the ethical expectations of the Company and the Group.

The Model and the Codes of Conduct are closely related and must be understood as the expression of a single set of rules adopted by the Company in order to promote the high moral principles of fairness, honesty and transparency in which TIT believes and intends to standardise its activities.

The Model meets the need to prevent, through the implementation of specific rules, processes and procedures, the commission of the offences provided for by the Decree and in general by the law.

The Codes of Conduct, to which reference is made for the sake of brevity, express the company's ideal social contract with its stakeholders and define the ethical criteria adopted in balancing the expectations and interests of the various stakeholders.

13. DISCIPLINARY SYSTEM

13.1 Purpose of the Disciplinary System

TIT considers compliance with the Model to be essential. Therefore, in compliance with article 6, paragraph 2, letter e) of the Decree, the Company has adopted an adequate system of sanctions ("**Disciplinary System**") which will also apply in the event of non-compliance with the rules set out in the Model, since the violation of these rules and measures, imposed by TIT for the purpose of preventing the offences set out in the Decree, damages the relationship of trust established with the Company.

For the purposes of TIT's application of the disciplinary sanctions provided for therein, the commencement of any criminal proceedings, if the case may be, and outcome thereof are not necessary, as the rules and measures provided for in the Model are adopted by the Company in full autonomy, regardless of the offence which any conduct may determine.

Attempts and, in particular, acts or omissions unambiguously aimed at violating the rules and regulations laid down by the Company shall also be sanctioned, even if the action is not carried out or the event does not occur for any reason whatsoever.

While reference is made to the relevant document for details, the following is a brief description of the sanctions system adopted by the Company.

13.2 Sanctioning system against employees

The violation by an employee of the provisions, principles and rules contained in the Model prepared by TIT in order to prevent the commission of offences under the Decree constitutes a disciplinary offence, punishable according to the procedures for notifying violations and the imposition of the consequent sanctions provided for in the National Collective Labour Agreement applicable to employees working for the Company.

The disciplinary system relating to the Model has been outlined in strict compliance with all the labour law provisions. No procedures and sanctions other than those already codified and set out in collective agreements and trade union agreements have been set forth. The National Collective Agreements referred to provide for a variety of sanctions capable of modulating, on the basis of the seriousness of the infringement, the sanction to be imposed.

It represents a disciplinary offence, in relation to activities identified as being at risk of offence:

- ✓ failure to comply with the principles contained in the Codes of Conduct or the adoption of behaviour that does not in any case comply with the rules laid down therein;
- ✓ failure to comply with the standards, rules and procedures set out in the Model;
- ✓ the lack of, incomplete or untruthful documentation or the inadequate storage of the same necessary to ensure the transparency and verifiability of the activities carried out in accordance with the procedural rules set out in the Model;
- ✓ violation and circumvention of the control system, carried out by removing, destroying or altering the documentation required by the above procedures;
- ✓ obstructing controls and/or unjustifiably preventing access to information and documentation by the persons in charge of such controls, including the Supervisory Board.

The above disciplinary offences may be punished, depending on the seriousness of the offence, by the following sanctions:

- ✓ verbal warning;
- ✓ written warning;
- ✓ a fine not exceeding three hours' pay calculated on the minimum wage scale;
- ✓ suspension from work and wage up to three days;
- ✓ dismissal.

In compliance with the provisions of article 6, paragraph 2 *bis*, letter d) of the Decree, the Disciplinary System provides (inter alia) for specific sanctions against those who violate the protection measures put in place by the Company in favour of persons who submit, in order to protect the integrity of the Entity, detailed reports of unlawful conduct, relevant under the Decree, as well as against those who make reports in bad faith or false and ungrounded reports, with malice or gross negligence, for the sole purpose of harming or otherwise causing damage to one or more employees of the Company or the Group.

The sanctions shall be imposed having regard to the seriousness of the infringements: in view of the extreme importance of the principles of transparency and traceability, as well as the relevance of the monitoring and control activities, the Company shall apply the sanctions with the greatest impact to those infringements which by their nature breach the very principles on which this Model is based.

The Supervisory Board is entrusted with the task of verifying and assessing the suitability of the disciplinary system in relation to the Decree. The Supervisory Board shall also indicate in its periodic report possible areas for improvement and development of this disciplinary system, especially in the light of developments in the relevant legislation.

13.3 Sanctions against executives

In the event of violation of the Model by executives, the Company shall impose the most appropriate disciplinary measures. Moreover, in the light of the deeper relationship of trust which, by its very nature, binds the Company to its executives, and in view of the latter's greater experience, violations of the provisions of the Model committed by executives shall above all entail dismissal from office measures, since these are considered more appropriate.

13.4 Measures against persons holding corporate offices

Upon receiving notice of violation of the principles, provisions and rules laid down in the Model by members of the Board of Directors, the Supervisory Board is required to promptly inform the entire Board of Directors, for the adoption of the appropriate measures, including, for example, convening the Shareholders' Meeting in order to adopt the most suitable measures.

The Supervisory Board, in its reporting activity, shall not only report on the details of the breach, but also indicate and suggest the appropriate further investigations to be carried out.

13.5 Measures against Third Parties

Compliance by third parties with the rules of the Model (limited to the aspects applicable from time to time) and with the principles of the Codes of Conduct is guaranteed through the provision of specific contractual clauses.

Any violation by Third Parties of the above referred rules, or the possible commission by such persons of the offences provided for in the Decree, shall not only be sanctioned in accordance with the provisions of the contracts entered into with them, but shall also be subject to appropriate legal action to protect the Company.

14. TRAINING, COMMUNICATION AND DISSEMINATION OF THE MODEL

14.1 Communication and involvement on the Model and related Protocols

The Company promotes the widest possible dissemination, inside and outside the structure, of the principles and provisions contained in the Model and in the Protocols connected to it.

The Model is formally communicated to all Senior Management (including Directors and Statutory Auditors) and to the Company's Personnel by delivery of a full copy, in electronic form or via telematic

means, and by posting it in a place accessible to all, as provided for in Article 7, paragraph 1, of Law no. 300/1970, as well as by publication on the Company's intranet.

The involvement and compliance with the Model by Third Parties, to whom the Model will have been made available, is guaranteed by means of a specific contractual agreement in order to guarantee and formalise the commitment to compliance with the principles of the Model by such Third Parties. The clauses provide for specific contractual sanctions in the event of violation of the Company's Model (e.g. warning of compliance with the Model, application of a penalty, termination of the contract, etc.).

The Supervisory Board keeps a documentary record of the fact that the Model has been communicated and of the relevant declarations of commitment.

14.2 Training on the Model and related Protocols

In addition to the activities related to informing the recipients, the Company must ensure periodic and constant training of its personnel.

In turn, the SB shall promote and monitor the implementation by the Company of initiatives aimed at fostering adequate knowledge and awareness of the Model and of the Protocols connected to it, in order to increase the culture of ethics and control within the Company.

In particular, the principles of the Model shall be illustrated to corporate resources by means of appropriate training activities (e.g. courses, seminars, questionnaires, etc.), which must be attended and whose implementation methods are planned through the preparation of specific Training Plans, implemented by the Company.

The courses and other training initiatives on the principles of the Model must be differentiated according to the role and responsibility of the resources concerned, i.e. by providing more intensive training characterised by a higher degree of detail for persons qualifying as "senior management" in accordance with the Decree, as well as for those operating in areas qualifying as "at direct risk" under the Model.

In particular, the contents of the training sessions must include a part relating to the Decree and the administrative liability of entities (law sources, offences, sanctions against individuals and companies and exemptions) and a specific part on the Model adopted by the Company.

Evidence must be kept of successful participation in training courses.

15. THE SUPERVISORY BOARD

15.1 Composition and appointment

Account taken of the purposes pursued by the law and the size and organisation of the Company, TIT has opted for a mixed collegial composition of the Supervisory Board, which is therefore composed of both external and internal members.

The Supervisory Board is appointed by the Board of Directors and remains in office for the duration of 3 financial years or for the shorter period of time established at the time of appointment, but in any case not less than 1 financial year.

The Board of Directors may provide that the Supervisory Board remains in office until the expiry of the term of office of the Board of Directors which appointed it, in compliance with the minimum term of office provided for above.

At the time of appointment, the Board of Directors establishes the remuneration, if any, due to the members of the Supervisory Board. During the making of the company budget, the Board of Directors decides on the approval of an adequate allocation of financial resources to the Supervisory Board, on the basis of a proposal received from the Supervisory Board itself.

The Supervisory Board may use the budget allocated to it for any requirement necessary for the proper performance of its tasks (e.g. specialist consultancy, travel, etc.), abiding by, in any event, company procedures.

15.2 The Regulations

The Supervisory Board is responsible for drawing up its own internal document aimed at regulating the concrete aspects and methods of the exercise of its action, including its organisational and operating system.

In particular, the following profiles, among others, are governed by these internal regulations:

- the type of control and supervisory activities carried out by the Supervisory Board;
- the type of activities connected with updating of the Model;
- the activity related to the fulfilment of the tasks of information and training of the Recipients of the Model;
- the management of information flows to and from the Supervisory Board;
- information flows to the Board of Directors;
- the functioning and internal organisation of the SB (e.g. convening and resolutions of the Supervisory Board, etc.).

In addition, it is appropriate to provide that each activity of the Supervisory Board is documented in writing and that each meeting or inspection in which it takes part is duly recorded.

15.3 Termination of office

Termination of office due to expiry of the term takes effect as of the date in which the Supervisory Board is re-established.

The termination of office may also occur through resignation, forfeiture, revocation or death.

Members of the Supervisory Board who resign from office are required to notify the Board of Directors and the Supervisory Board in writing, so that they can be promptly replaced.

The members of the Supervisory Board forfeit the office in the event of a supervening lack of the requirements for holding office (for example, disqualification, incapacity, bankruptcy, conviction to a penalty entailing disqualification from public office or in the event of being found guilty of the offences provided for in the Decree and, in general, in the event of incapacity and incompatibility, conflict of interests, etc.).

Members of the Supervisory Board may be dismissed for just cause by the Board of Directors, after consulting the Board of Statutory Auditors. By way of example, just cause exists in the event of non-compliance with the obligations laid down for each member of the Supervisory Board, unjustified absence from three or more meetings of the Supervisory Board, the existence of a conflict of interest, the impossibility of carrying out the activities of a member of the Supervisory Board, etc. Moreover, any termination of the employment relationship between the internal member of the Supervisory Board and the Company normally entails the revocation of the resigning person's appointment. The revocation of office of a member of the Supervisory Board may be requested to the Board of Directors by the Supervisory Board itself, upon grounded request.

In the event of resignation, forfeiture, revocation or death, the Board of Directors shall replace the member of the Supervisory Board who has ceased to hold office. The members thus appointed shall remain in office for the remainder of the term of office of the Supervisory Board.

15.4 Requirements

In accordance with the provisions of Article 6, paragraph 1, of the Decree, the Supervisory Board has the task of supervising the functioning of and compliance with the Organisation, Management and Control Model, of ensuring the updating thereof, and is entrusted with autonomous powers of initiative and control. The requirements to be met by the control body for the effective performance of these functions are:

- autonomy and independence, as:
  - the control activities carried out by the Supervisory Board are not subject to any form of interference and/or conditioning by persons internal to the Company;
  - it reports directly to the top management, i.e. the Board of Directors, with the possibility of reporting directly to Shareholders and Statutory Auditors;
  - it has not been assigned operational tasks, nor is it involved in operational decisions and activities in order to protect and ensure the objectivity of its judgment;
  - is entrusted with adequate financial resources necessary for the proper performance of its activities;
  - the internal operating rules of the Supervisory Board are defined and adopted by the same body;
- professionalism, in that the professional skills present within the Supervisory Board enable it to rely on a fund of expertise both in terms of inspection activities and analysis of the control system, and in terms of legal skills; to this end, the Supervisory Board is also entitled to make use of company departments and internal resources, as well as external consultants;
- continuity of action, since the Supervisory Board constitutes an ad hoc body dedicated exclusively to the activities of supervision of the functioning and compliance with the Model;
- honourability and absence of conflicts of interest, to be meant in the same terms as those laid down by law for directors and members of the Board of Statutory Auditors.

The Board of Directors assesses the permanence of the above referred requirements and conditions of operation of the Supervisory Board, that the members of the Supervisory Board meet the subjective requirements of honourability and competence and are not in situations of conflict of interest, in order to further guarantee the autonomy and independence of the Supervisory Board.

15.5 Functions, activities and powers of the Supervisory Board

In accordance with the provisions of Article 6, paragraph 1, of the Decree, the Supervisory Board is entrusted with the task of supervising the functioning of and compliance with the Model and taking care of the updating thereof.

In general, therefore, the Supervisory Board has the following tasks:

- control and supervision of the Model, namely:
  - verify the adequacy of the Model, in order to prevent the occurrence of unlawful conducts, as well as to highlight its commission, if the case may be;
  - verify the effectiveness of the Model, i.e. the correspondence between the concrete behaviours and those formally provided for by the Model itself;
  - carry out analyses concerning the maintenance over time of the requirements of validity and functionality of the Model;
- updating the Model, namely:
  - take steps to ensure that the Company updates the Model, proposing, if necessary, to the Board of Directors or any competent company departments, the adjustment of the same, in order to improve its adequacy and effectiveness;
- information and training on the Model, namely:
  - promote and monitor initiatives aimed at fostering the dissemination of the Model among all persons required to comply with its provisions;
  - promote and monitor initiatives, including courses and communications, aimed at fostering adequate knowledge of the Model on the part of all persons required to comply with its provisions;
  - assessing requests for clarification and/or advice from corporate functions or resources or from administrative and control bodies, if connected and/or related to the Model;
- management of information flows to and from the SB, namely:
  - ensure the timely performance by the relevant persons of all reporting activities relating to compliance with the Model;
  - examine and evaluate all information and/or reports received and related to compliance with the Model, including with regard to any violations thereof;
  - inform the competent bodies, specified below, of the activity carried out, the results thereof and planned activities;
  - report to the competent bodies, for the appropriate decisions, any violations of the Model and the persons responsible, proposing the sanction deemed most appropriate in the specific case;
  - in case of controls by institutional subjects, including the Public Authority, provide the necessary information support to the inspection bodies;
- follow-up activities, i.e. verifying the implementation and actual functionality of the proposed solutions.

In order to perform the tasks assigned to it, the Supervisory Board is granted all the powers necessary to ensure prompt and efficient supervision of the functioning of and compliance with the Model.

The Supervisory Board, also by means of the resources at its disposal, has the power, by way of example:

- to carry out, including on spot basis, all checks and inspections deemed appropriate for the proper performance of its tasks;
- arrange, where necessary, for the interview of resources that can provide useful indications or information on the performance of the company's activities or on any dysfunctions or violations of the Model;
- to avail itself, under its direct supervision and responsibility, of the assistance of all the structures of the Company or of external consultants, basing its relations with them on company guidelines and procedures and having them sign appropriate confidentiality clauses;
- to have at its disposal, for any requirement necessary for the proper performance of its tasks, the financial resources allocated by the Board of Directors.

In any case, the Supervisory Board, when carrying out its tasks, shall:

- arrange the Monitoring Plan, which contains the objectives and priorities of the controls, the activities to be carried out, the budgets for expenditure and resources, and the estimated timeframe. The Monitoring Plan must be brought to the attention of the Board of Directors;
- inform the Board of Directors of any conflicts and limitations encountered during the performance of their duties;
- operate in accordance with company policies and procedures.

The Supervisory Board is required to report the results of its activities to the Board of Directors.

In particular, the Supervisory Board reports on the violations of the Model detected with a view to the adoption of the relevant sanctions and, in the event of cases highlighting serious critical aspects of the Model, it submits proposals for amendments or supplements.

The Supervisory Board shall prepare, for the managing body, an informative report, on an annual basis, on the supervisory activity carried out and the outcome of such activity and on the implementation of the Model within the Company; such report shall be forwarded to the Board of Statutory Auditors.

The activities of the Supervisory Board are unquestionable by any body, structure and function of the company, without prejudice, however, to the obligation of supervision by the Board of Directors on the adequacy of the Supervisory Board and its intervention, the Board of Directors being in any case responsible for the functioning and effectiveness of the Model.

In order to carry out the supervisory functions assigned to the Supervisory Board, the latter has adequate financial resources and is entitled to make use - under its direct supervision and responsibility - of the assistance of the internal company structures and, if necessary, of the support of external consultants in accordance with the applicable company procedures.

The internal functioning of the Supervisory Board is regulated by the Supervisory Board itself, which defines - by means of specific regulations - the aspects relating to the performance of its supervisory functions,

including the determination of the controls frequency, the identification of the analysis criteria and procedures, the recording of the meetings, the regulation of information flows, etc.

15.6 Information flows to the Supervisory Board

The Supervisory Board must be promptly informed by all company people, as well as by third parties required to comply with the provisions of the Model, of any news concerning the existence of possible violations thereof.

In any case, information that may be related to violations, even potential ones, of the Model, including, but not limited to, the following, must be compulsorily and immediately transmitted to the SB:

- any orders received from the superior and considered to be contrary to the law, internal rules, or the Model;
- any requests for or offers of money, gifts (in breach of company rules and procedures) or other benefits from, or intended for, public officials or persons in charge of a public service;
- any omission, neglect or forgery in the keeping of accounts or in the retention of the documents on which the accounting records are based;
- measures and/or news coming from the judicial police or any other authority from which it can be inferred that investigations are being carried out concerning, even indirectly, the Company, its employees or members of the corporate bodies;
- requests for legal assistance made to the company by employees in accordance with the CCNL, in the event of criminal proceedings against them;
- information on ongoing disciplinary proceedings and any sanctions imposed or the reasons for their dismissal;
- any reports, not promptly acknowledged by the competent functions, concerning both shortcomings or inadequacies of the premises, of the work equipment, or of the protection devices made available to the Company, and any other dangerous situation connected with health and safety at work.

Without prejudice to what is specified in the Special Section in relation to information flows to the Supervisory Board, information relating to the Company's activities, which may be relevant in terms of the performance by the Supervisory Board of its assigned tasks, includes, but is not limited to, the following:

- news of changes in the organisation or in existing company procedures;
- updates of the system of powers and delegations;
- any disclosures in the accounts auditing concerning matters that may indicate a deficiency in internal controls;
- decisions relating to the application for, granting and use of public funds;
- statements summarising the public or public-relevant tenders at national/local level in which the Company has participated and has been awarded the order; as well as statements summarising any orders obtained by negotiated contracts;
- periodic reporting on health and safety at work, and in particular the minutes of the periodic meeting pursuant to Article 35 of Legislative Decree no. 81/2008, as well as all data on accidents at work occurred on Company sites;

- the annual balance sheet, alongside the explanatory notes;
- assignments regarding accounts auditing;
- communications from the Board of Statutory Auditors concerning any critical issues that have emerged, even if solved;
- results of any internal audit activities aimed at verifying effective compliance with the Codes of Conduct.

Personnel and all those working in the name and on behalf of TIT who come into possession of information relating to the commission of offences within the Company or to practices which are not in line with the rules of conduct and the principles of the Codes of Conduct are required to inform the Supervisory Board without delay.

These reports, the confidentiality of which must be guaranteed, may be sent by mail addressed to the Supervisory Board c/o the Company, or by e-mail to the following address: odvtit@libero.it.

The SB, in the course of the investigation following the report, must act in such a way as to ensure that the persons involved are not subject to retaliation, discrimination or, in any case, penalisation, thus ensuring the confidentiality of the person submitting the report (unless there are legal obligations that impose otherwise).

The information provided to the Supervisory Board is intended to facilitate and improve its control planning activities and does not impose on it a systematic and punctual checking of all the phenomena represented: it is, therefore, left to the discretion and responsibility of the Supervisory Board to determine in which cases to take action.

As regards the SB's reporting to the corporate bodies, the SB:

- at any time, in the presence of particular needs or in cases of urgency, reports to the Board of Directors, which takes the most appropriate decisions;
- reports in writing to the Board of Directors and the Board of Statutory Auditors on the activities carried out and their outcome, also providing an advance indication of the general lines of action for the following period, highlighting, in particular, the objectives and priorities of the controls, the activities to be carried out, the budgets for expenditure and resources, and the estimated timing.

The reporting activity will focus in particular on:

- the activities, in general, carried out by the Supervisory Board;
- any problems or critical issues arisen in the course of supervisory activities;
- the necessary or possible corrections to be made in order to ensure the effectiveness and efficiency of the Model;
- the assessment of conduct not in line with the Model;
- the detection of organisational or procedural shortcomings able to expose the Company to the risk of offences under the Decree being committed;
- any failure to cooperate or lack of cooperation by the corporate functions in the performance of its control and/or investigation tasks;

- in any case, any information deemed useful for the purposes of the adoption of urgent decisions by the competent bodies.

Meetings with the Board of Directors and the Board of Statutory Auditors must be minuted and copies of the relevant minutes (if necessary, also those of the Board of Directors and the Board of Statutory Auditors limited to the relevant item on the agenda) must be kept in the SB archives.

In any case, the Supervisory Board may report to the Board of Directors and/or its Chairman and the Board of Statutory Auditors at any time it deems appropriate. Minutes are always taken in the event of a meeting.

16. COMMUNICATION CHANNELS AND PROTECTION OF REPORTING PARTY

In order to allow both Senior Management and Subordinates to address reports and information flows to the SB, the Company has activated the following communication channels (so-called whistleblowing):

- E-mail: odvtit@libero.it
- Postal address: Terumo Italia S.r.l.
  Attention of Supervisory Board
  Via Paolo di Dono, 73
  00142 Rome

In addition to the above-mentioned communication channel, the Group has made the "Terumo Integrity Helpline" available to its employees, collaborators and business partners at the international web page www.terumointegrity.com, which allows - in full protection of the identity of the reporting party and its protection from possible retaliatory acts, in line with the provisions of the Decree and the "Group Compliance Violations Reporting and Anti-Retaliation Policy" - to report facts or circumstances that could potentially constitute violations of the ethical principles set out in the Codes of Conduct and/or internal procedures and applicable laws and regulations (so-called whistleblowing).

All the reporting systems mentioned and described above - without prejudice to any legal obligations, the protection of the rights of the Company and of persons wrongly accused or in bad faith - guarantee:

- **the protection of the confidentiality of the identity of the reporting party and the alleged perpetrator of the violations**. To this end, the SB and/or any other persons involved in the management of reports are required to:
  - disclose the identity of the reporting party only with the latter's prior written consent or when knowledge of the reporting party's identity is indispensable for the defence of the person subject of the reporting;
  - separate the identification data of the reporting party from the content of the report, so that the report can be processed anonymously, and the report can then be linked to the identity of the reporting party only where strictly necessary.
- **the protection of the reporting party against retaliatory, discriminatory or otherwise unfair conduct as a result of the report**. To this end, retaliatory or discriminatory acts, whether direct or indirect, including the change of duties pursuant to Article 2103 of the Civil Code, against the reporting party for reasons directly or indirectly linked to the report are prohibited. Moreover, the adoption of discriminatory measures against persons making the above-mentioned reports may be reported to the National Labour Inspectorate, for measures falling within its competence.

In view of the function assigned to the Supervisory Board by the law and the potential relevance, for the purposes of the liability provided for in the Decree, of any reports received through the above referred reporting systems implemented at Group level, adequate information flows are provided for coordination between the different parties responsible for receiving and managing reports.

17. UPDATING THE MODEL

One of the Supervisory Board's tasks is to inform the Board of Directors of the need to update the Model. Updating is required, purely by way of example, as a result of changes in organisational structures or operational processes, significant violations of the Model itself, or legislative supplements.

Communication and training on Model updates must follow the same procedures as approval.