



ORGANISATION, MANAGEMENT AND CONTROL MODEL

pursuant to Italian Legislative Decree No. 231 of 8 June 2001, as subsequently amended and supplemented

Version	Date	Approved by
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CONTENTS

General Part

INTRODUCTION.....	5
1. ITALIAN LEGISLATIVE DECREE NO. 231 OF 8 JUNE 2001	5
1.1. Principle of legality	5
1.2. Objective criteria for attributing liability	5
1.3. Subjective criterion for attributing liability.....	6
1.4. Types of offences covered	6
1.5. Offences committed abroad	12
1.6. Sanctions	13
1.7. Grounds for exemption from administrative liability	14
2. COMPANY HISTORY	15
3. PURPOSE.....	15
4. SCOPE OF APPLICATION.....	15
5. RISK ASSESSMENT AT MEDICA S.P.A.	16
5.1. Summary of the project for the preparation and development of the Organisation, Management and Control Model pursuant to Italian Legislative Decree 231/2001 for MEDICA S.p.A.....	16
5.2. Phase 1: Project launch and Macro Risk Assessment	17
5.3. Phase 2: Micro Risk Assessment	17
5.4. Phase 3: Gap Analysis and definition of the implementation plan.....	18
5.5. Phase 4: Implementation of the Organisation, Management and Control Model for MEDICA S.p.A... ..	18
5.6. Phase 5: Continuous updating and adaptation of the Model	18
6. STRUCTURE AND ORGANISATION OF THE MODEL	20
6.1. Reference models	20
6.2. Structure and rules for approval of the Model and its updates	25
6.3. Code of Ethics	27
6.4. Reporting Procedure (Whistleblowing)	27
6.5. Sensitive activity areas, instrumental processes and decision-making process	28
6.5.1. Filing of documentation relating to sensitive activities and instrumental processes.....	32
6.5.2. Information systems and software applications	32
6.6. Management systems and Company procedures	32
6.6.1. Request to create a procedure	32
6.6.2. Amendments and revisions to procedures	33
6.7. System of delegations and powers	33
6.8. Information and training	33
6.8.1. Information	33
6.8.2. Information to external collaborators and partners	34
6.8.3. Information to Group companies.....	34
6.8.4. Training	34
6.8.5. Training for personnel in so-called “senior positions”	34
6.8.6. Training for other personnel	35
6.8.7. Training of the Supervisory Body	36
6.9. Sanctions System	36
6.10. Information flows to the Supervisory Body	37
6.11. Reporting to the Corporate Bodies	38

MEDICA



Special Part

Special Part A - Code of Ethics
Special Part B - Sanctions System
Special Part C - Structure and Organisation
Special Part D - Supervisory Body Rules
Special Part E - Offences against the Public Administration and to the detriment of the State
Special Part F - Offences involving counterfeiting of currency and public credit instruments
Special Part G - Corporate offences
Special Part H - Offences against the individual
Special Part I - Workplace health and safety offences
Special Part J - Offences of receiving stolen goods, money laundering, use of money, assets or benefits of unlawful origin, and self-laundering
Special Part K - Transnational offences referred to in Law No. 146 of 16 March 2006
Special Part L - Cybercrime offences
Special Part M - Offences against industry and trade
Special Part N - Copyright infringement offences
Special Part O - Organised crime offences
Special Part P - Offence of inducing a person not to make statements, or to make false statements, to the judicial authorities
Special Part Q - Environmental offences
Special Part R - Offence of employing third-country nationals whose stay is irregular
Special Part S - Tax offences
Special Part T - Smuggling offences
Special Part U - Offences relating to payment instruments other than cash
Criminal Law Manual
Preventive Protocols Manual
Reporting Procedure - Whistleblowing



INTRODUCTION

This document, adopted by the Board of Directors of Medica S.p.A., sets out, pursuant to Italian Legislative Decree No. 231 of 8 June 2001, the prevention rules and related responsibilities aimed at preventing the offences referred to in the Decree.

The Model consists of a General Part and several Special Parts.

The General Part describes:

- the operating principles of Italian Legislative Decree 231/01;
- the procedures for its adoption and dissemination within the Company;
- the duties of the Supervisory Body and the related information flows;
- the disciplinary system.

The Special Parts, including the Preventive Protocols Manual, describe:

- the detailed mapping of sensitive areas;
- examples of how the offences may be committed;
- the conduct required of, and prohibitions applicable to, the Recipients.

Among the Special Parts, the Code of Ethics establishes standards of conduct for managers and employees. Compliance with the Code of Ethics is of particular importance both for the proper operation and reliability of the Company and for protecting its standing and reputation in day-to-day activities.

1. ITALIAN LEGISLATIVE DECREE NO. 231 OF 8 JUNE 2001

Italian Legislative Decree No. 231 of 8 June 2001, entitled “Regulation of the administrative liability of legal persons, companies and associations, including those without legal personality, pursuant to Article 11 of Law No. 300 of 29 September 2000” (hereinafter, the “Decree”), entered into force on 4 July 2001. Its purpose was to align Italian rules on the liability of legal persons with international conventions that Italy had already signed.

The Decree introduced into the Italian legal system a regime of administrative liability for legal persons (hereinafter, “companies”) which is, in practical terms, comparable to criminal liability. This liability is additional to that of the natural person who actually committed certain unlawful acts and is intended to involve in the sanctions those companies in whose interest or to whose advantage the offences were committed.

Liability under the Decree may also arise in connection with offences committed abroad, provided that the State in whose territory the offence was committed does not prosecute the same offence.

The entity may be held liable even where the perpetrator of the offence has not been identified and even where the offence has ceased to be punishable in respect of the offender for a reason other than amnesty or limitation.

1.1. Principle of legality

An entity may incur liability only within the limits provided by law: it “may not be held liable for an act constituting an offence unless its [criminal] liability in relation to that offence, and the relevant sanctions, are expressly provided for by a law that entered into force before the act was committed” (Article 2 of the Decree).

1.2. Objective criteria for attributing liability



There are three types of objective criteria for attributing liability:

- a) Commission of an offence included within the scope of the Decree, from Article 24 to Article 25-duodecies.
- b) The offence must have been committed “in the interest or to the advantage of the entity”.

Interest and/or advantage

A further constituent element of the liability in question is that the alleged unlawful conduct must have been carried out in the interest or to the advantage of the Entity.

The Entity's interest or advantage may establish liability even where the perpetrator of the offence or third parties also have an interest or derive an advantage, except where the interest in committing the offence on the part of the person holding a qualified position within the entity is exclusively that of the perpetrator or of third parties.

Since no exemption is recognised where only the “advantage” belongs exclusively to the perpetrator or to third parties, but only, as stated above, where the interest is exclusively theirs, the Entity may also be held liable where it obtains no advantage or where the advantage is exclusively that of the perpetrator or third parties, provided that the Entity has an interest, possibly concurrent with that of third parties, in the commission of the offence by persons holding a qualified position within its organisation.

Interest and/or advantage in negligent offences

The rules on entities' liability are generally based on intentional predicate offences.

The introduction of negligent offences concerning workplace health and safety by Law No. 123 of 3 August 2007 (the “new” Article 25-septies, subsequently repealed and replaced by Article 300 of Italian Legislative Decree No. 81 of 9 April 2008), together with certain environmental misdemeanours (Article 25-undecies), has nevertheless brought renewed focus to the subjective basis of the attribution criteria.

In this context, it may therefore be argued that failure to adopt conduct required by precautionary rules intended to prevent workplace accidents could lead to lower business costs and could therefore be characterised, ex post, as an “advantage” (for example, failure to provide protective equipment or to service equipment for cost-saving reasons).

1.3. Subjective criterion for attributing liability

The subjective criterion for attributing liability is met where the offence reflects a policy or direction characteristic of the Company, or at least results from an organisational fault.

The Decree excludes an entity's liability where, before the offence was committed, the entity had adopted and effectively implemented an “organisation and management model” (hereinafter, the “Model”) suitable for preventing offences of the type that occurred.

From this perspective, the entity's liability is attributable to the “failure to adopt or comply with mandatory standards” concerning the entity's organisation and activities, a deficiency that may stem from corporate policy or from structural and procedural shortcomings within the organisation.

1.4. Types of offences covered

The scope of Italian Legislative Decree 231/01 includes the following offences.

- offences against the Public Administration or to the detriment of the State (Articles 24 and 25 of the Decree), most recently updated by Law No. 137/2023 and amended by Law No. 90/2024 and, most recently, by Law No. 112/2024 and Law No. 114/2024:

- Misappropriation of public funds to the detriment of the State (Article 316-bis of the Italian Criminal Code);
- Undue receipt of public funds to the detriment of the State (Article 316-ter of the Italian Criminal Code);

MEDICA

Fraud to the detriment of the State or another public body, or under the pretext of securing exemption from military service (Article 640(2)(1) of the Italian Criminal Code);
Aggravated fraud for the purpose of obtaining public funds (Article 640-bis of the Italian Criminal Code);
Computer fraud (Article 640-ter of the Italian Criminal Code);
Bribery in connection with an official act (Article 321 of the Italian Criminal Code);
Bribery in the exercise of public functions (Article 318 of the Italian Criminal Code);
Incitement to bribery (Article 322 of the Italian Criminal Code);
Extortion by a public official (concussione) (Article 317 of the Italian Criminal Code);
Bribery in connection with an act contrary to official duties (Articles 319, 319-bis and 321 of the Italian Criminal Code);
Bribery in judicial proceedings (Articles 319-ter(2) and 321 of the Italian Criminal Code);
Undue inducement to give or promise benefits (Article 319-quater of the Italian Criminal Code);
Bribery of a person in charge of a public service (Article 320 of the Italian Criminal Code);
Embezzlement, extortion by a public official, bribery and incitement to bribery involving members of European Community bodies, officials of the European Communities and officials of foreign States (Article 322-bis of the Italian Criminal Code);
Trading in unlawful influence (Article 346-bis of the Italian Criminal Code);
Fraud in public supply contracts (Article 356 of the Italian Criminal Code);
Fraud involving agricultural funding (Article 2 of Law No. 898 of 23 December 1986);
Embezzlement by a public official (Article 314 of the Italian Criminal Code);
Embezzlement by taking advantage of another person's error (Article 316 of the Italian Criminal Code);
Disruption of public tenders (Article 353 of the Italian Criminal Code);
Interference with the freedom to select a contracting party (Article 353-bis of the Italian Criminal Code);
Misuse of money or movable property (Article 314-bis of the Italian Criminal Code);

- following the enactment and entry into force of Decree-Law No. 350 of 25 September 2001, converted with amendments into Law No. 409 of 23 November 2001, and the additions introduced by Law No. 99 of 2009, the offences referred to in Article 25-bis of the Decree, namely offences involving counterfeiting of currency, public credit instruments, revenue stamps and instruments or signs of identification:

Counterfeiting currency, circulating and introducing counterfeit currency into the State by prior agreement (Article 453 of the Italian Criminal Code);
Alteration of currency (Article 454 of the Italian Criminal Code);
Circulating and introducing counterfeit currency into the State without prior agreement (Article 455 of the Italian Criminal Code);
Circulating counterfeit currency received in good faith (Article 457 of the Italian Criminal Code);
Counterfeiting revenue stamps; introducing into the State, purchasing, possessing or circulating counterfeit revenue stamps (Article 459 of the Italian Criminal Code);
Counterfeiting watermarked paper used to manufacture public credit instruments or revenue stamps (Article 460 of the Italian Criminal Code);
Manufacturing or possessing watermarks or instruments intended for counterfeiting currency, revenue stamps or watermarked paper (Article 461 of the Italian Criminal Code);
Use of counterfeit or altered revenue stamps (Article 464 of the Italian Criminal Code);
Counterfeiting, altering or using trademarks or distinctive signs, patents, models or designs (Article 473 of the Italian Criminal Code);
Introducing into the State and trading in products bearing counterfeit signs (Article 474 of the Italian Criminal Code).

MEDICA

- following the enactment and entry into force of Italian Legislative Decree No. 61 of 11 April 2002, as amended by Law No. 262 of 28 December 2005, and the amendments introduced by Law No. 69 of 27 May 2015 and Italian Legislative Decree No. 38/2017, the offences referred to in Article 25-ter of the Decree, namely corporate offences:

False corporate communications (Article 2621 of the Italian Civil Code);

Minor cases (Article 2621-bis of the Italian Civil Code);

False corporate communications by listed companies (Article 2622 of the Italian Civil Code);

False statements in a prospectus (Article 2623 of the Italian Civil Code – Article 173-bis of Law No. 58 of 24 February 1998);

False statements in reports or communications of audit firms (Article 2624 of the Italian Civil Code – repealed by Article 37(34) of Italian Legislative Decree No. 39/2010 and replaced by Article 27 of the same Decree, entitled “False statements in reports or communications by statutory auditors”);

Obstruction of control activities (Article 2625 of the Italian Civil Code – paragraph 1 amended by Article 37(35) of Italian Legislative Decree No. 39/2010 and referred to by Article 29 of the same Decree);

Unlawful return of contributions (Article 2626 of the Italian Civil Code);

Unlawful distribution of profits and reserves (Article 2627 of the Italian Civil Code);

Unlawful transactions involving shares or quotas of the company or its parent company (Article 2628 of the Italian Civil Code);

Transactions prejudicial to creditors (Article 2629 of the Italian Civil Code);

Fictitious formation of share capital (Article 2632 of the Italian Civil Code);

Unlawful distribution of company assets by liquidators (Article 2633 of the Italian Civil Code);

Private-to-private bribery (Article 2635 of the Italian Civil Code);

Incitement to private-to-private bribery (Article 2635-bis of the Italian Civil Code);

Unlawful influence over the shareholders’ meeting (Article 2636 of the Italian Civil Code);

Market manipulation (Article 2637 of the Italian Civil Code);

Obstruction of the functions of public supervisory authorities (Article 2638 of the Italian Civil Code).

- following the enactment and entry into force of Law No. 7 of 14 January 2003, the offences referred to in Article 25-quater of the Decree, namely offences for purposes of terrorism or subversion of the democratic order provided for by the Italian Criminal Code and special laws.

- following the enactment and entry into force of Law No. 7 of 9 January 2006, the offences referred to in Article 25-quater.1 of the Decree, namely offences involving practices of female genital mutilation.

- following the enactment and entry into force of Law No. 228 of 11 August 2003, as amended by Law No. 38 of 6 February 2006, Italian Legislative Decree No. 39 of 4 March 2014 and Law No. 199/2016, the offences referred to in Article 25-quinquies of the Decree, namely offences against the individual governed by Section I, Chapter III, Title XII, Book II of the Italian Criminal Code.

- following the enactment and entry into force of Law No. 62 of 18 April 2005, the offences referred to in Article 25-sexies of the Decree, namely, among the offences provided for in Part V, Title I-bis, Chapter II of the Consolidated Law under Italian Legislative Decree No. 58 of 24 February 1998, those relating to market abuse:

insider dealing (Article 184 of Italian Legislative Decree No. 58 of 24 February 1998);

market manipulation (Article 185 of Italian Legislative Decree No. 58 of 24 February 1998).

- following the enactment and entry into force of the law ratifying and implementing the United Nations Convention and Protocols against Transnational Organized Crime adopted by the General Assembly on 15 November 2000 and 31 May 2001, finally approved and published in the Official Gazette on 11 April 2006, the transnational offences referred to in Law No. 146 of 16 March 2006, namely:

Criminal association (Article 416 of the Italian Criminal Code);

MEDICA

Mafia-type association (Article 416-bis of the Italian Criminal Code);

Criminal association for the purpose of smuggling foreign manufactured tobacco (Article 291-quater of Presidential Decree No. 43 of 23 January 1973);

Association for the illicit trafficking of narcotic or psychotropic substances (Article 74 of Presidential Decree No. 309 of 9 October 1990);

Money laundering (Article 648-bis of the Italian Criminal Code);

Use of money, assets or benefits of unlawful origin (Article 648-ter of the Italian Criminal Code);

Offences concerning migrant smuggling under Article 12(3), (3-bis), (3-ter) and (5) of Italian Legislative Decree No. 286 of 25 July 1998;

Obstruction of justice: inducing a person not to make statements, or to make false statements, to the judicial authorities (Article 377-bis of the Italian Criminal Code);

Obstruction of justice: personal assistance to an offender (Article 378 of the Italian Criminal Code).

- following the enactment and entry into force of Law No. 123 of 3 August 2007, the offences under Article 25-septies committed in breach of accident-prevention and workplace health and safety rules, namely:

Negligent homicide committed in breach of accident-prevention and workplace health and safety rules (Article 589 of the Italian Criminal Code);

Serious or very serious negligent personal injury committed in breach of accident-prevention and workplace health and safety rules (Article 590 of the Italian Criminal Code).

- following the enactment and entry into force of Italian Legislative Decree No. 231 of 21 November 2007, as amended by Law No. 186 of 15 December 2014 and Italian Legislative Decree No. 195/2021, the offences under Article 25-octies (Receiving stolen goods, money laundering, use of money, assets or benefits of unlawful origin, and self-laundering), namely:

Receiving stolen goods (Article 648 of the Italian Criminal Code);

Money laundering (Article 648-bis of the Italian Criminal Code);

Use of money, assets or benefits of unlawful origin (Article 648-ter of the Italian Criminal Code).

Self-laundering (Article 648-ter.1 of the Italian Criminal Code).

- following the enactment and entry into force of Law No. 48 of 18 March 2008, the offences under Article 24-bis, namely cybercrime and unlawful data-processing offences, as amended by Law No. 90/2024:

Unauthorised access to a computer or telecommunications system (Article 615-ter of the Italian Criminal Code);

Unauthorised possession, dissemination and installation of equipment, codes and other means of access to computer or telecommunications systems (Article 615-quater of the Italian Criminal Code);

Unlawful interception, prevention or interruption of computer or telecommunications communications (Article 617-quater of the Italian Criminal Code);

Installation of equipment designed to intercept, prevent or interrupt computer or telecommunications communications (Article 617-quinquies of the Italian Criminal Code);

Damage to computer or telecommunications systems (Article 635-bis of the Italian Criminal Code);

Damage to information, data and computer programs used by the State or another public body or otherwise of public utility (Article 635-ter of the Italian Criminal Code);

Damage to computer or telecommunications systems (Article 635-quater of the Italian Criminal Code); unauthorised possession, dissemination and installation of equipment, devices or computer programs intended to damage or interrupt a computer or telecommunications system (Article 635-quater.1 of the Italian Criminal Code);

Damage to computer or telecommunications systems of public utility (Article 635-quinquies of the Italian Criminal Code);

Computer documents (Article 491-bis of the Italian Criminal Code);

MEDICA

Computer fraud committed by a provider of electronic signature certification services (Article 640-quinquies of the Italian Criminal Code).

Breach of rules concerning the national cybersecurity perimeter

Extortion (Article 629 of the Italian Criminal Code)

- following the enactment and entry into force of Law No. 94 of 2009, the offences under Article 24-ter, namely organised crime offences:

Criminal association (Article 416 of the Italian Criminal Code);

Criminal association aimed at committing one of the offences under Articles 600, 601 and 602 of the Italian Criminal Code (Article 416(6) of the Italian Criminal Code);

Mafia-type association (Article 416-bis of the Italian Criminal Code);

Political-mafia electoral exchange (Article 416-ter of the Italian Criminal Code);

Kidnapping for the purpose of extortion (Article 630 of the Italian Criminal Code);

Association for the illicit trafficking of narcotic or psychotropic substances (Article 74 of Presidential Decree No. 309 of 9 October 1990).

- following the enactment and entry into force of Law No. 99 of 2009, the offences under Article 25-bis.1, namely offences against industry and trade:

Interference with freedom of industry and trade (Article 513 of the Italian Criminal Code);

Unlawful competition involving threats or violence (Article 513-bis of the Italian Criminal Code);

Fraud against domestic industries (Article 514 of the Italian Criminal Code);

Fraud in the conduct of trade (Article 515 of the Italian Criminal Code);

Sale of non-genuine food products as genuine (Article 516 of the Italian Criminal Code);

Sale of industrial products bearing misleading signs (Article 517 of the Italian Criminal Code);

Manufacture and sale of goods infringing industrial property rights (Article 517-ter of the Italian Criminal Code);

Counterfeiting geographical indications or designations of origin for agri-food products (Article 517-quater of the Italian Criminal Code).

- following the enactment and entry into force of Law No. 99 of 2009, the offences under Article 25-novies, namely copyright infringement offences:

Article 171(1)(a-bis) and (3) of Law No. 633 of 22 April 1941, Protection of copyright and related rights;

Article 171-bis of Law No. 633 of 22 April 1941;

Article 171-ter of Law No. 633 of 22 April 1941;

Article 171-septies of Law No. 633 of 22 April 1941;

Article 171-octies of Law No. 633 of 22 April 1941.

- following the enactment of Law No. 116 of 3 August 2009, the offence under Article 25-decies, namely inducing a person not to make statements or to make false statements to the judicial authorities (Article 377-bis of the Italian Criminal Code), in the domestic context.

- following the enactment of Italian Legislative Decree No. 121 of 7 July 2011 and the amendments introduced by Law No. 68 of 22 May 2015, the offences under Article 25-undecies, namely environmental offences:

Environmental pollution (Article 452-bis of the Italian Criminal Code);

Environmental disaster (Article 452-quater of the Italian Criminal Code);

Negligent offences against the environment (Article 452-quinquies of the Italian Criminal Code);

Trafficking in and abandonment of highly radioactive material (Article 452-sexies of the Italian Criminal Code);

Killing, destruction, capture, taking or possession of specimens of protected wild animal or plant species (Article 727-bis of the Italian Criminal Code);

Destruction or deterioration of habitats within a protected site (Article 733-bis of the Italian Criminal Code);

MEDICA

Articles 137, 256, 257, 258, 259, 260, 260-bis and 279 of Italian Legislative Decree No. 152 of 3 April 2006, Environmental Regulations;

Articles 1, 2 and 3-bis of Law No. 150 of 7 February 1992, regulating offences relating to the application in Italy of the Convention on International Trade in Endangered Species of Wild Fauna and Flora, signed in Washington on 3 March 1973, implemented by Law No. 874 of 19 December 1975, and EEC Regulation No. 3626/82, as subsequently amended, as well as rules governing the sale and possession of live specimens of mammals and reptiles that may pose a danger to public health and safety;

Article 3 of Law No. 549 of 28 December 1993, Measures for the protection of the stratospheric ozone layer and the environment;

Articles 8 and 9 of Italian Legislative Decree No. 202 of 6 November 2007, implementing Directive 2005/35/EC on ship-source pollution and related penalties.

- following the enactment of Italian Legislative Decree No. 109 of 16 July 2012 and the amendments introduced by Italian Legislative Decree No. 161 of 17 October 2017, the offences under Article 25-duodecies, namely offences concerning the employment of third-country nationals whose stay is irregular:

Article 22(12-bis) of Italian Legislative Decree No. 286 of 25 July 1998;

Article 12(3), (3-bis), (3-ter) and (5) of Italian Legislative Decree No. 286 of 25 July 1998.

- following the enactment of the so-called European Law No. 167 of 20 November 2017, the offences under Article 25-terdecies, namely racism and xenophobia offences:

Article 3(3-bis) of Law No. 654 of 13 October 1975.

- following the enactment of Law No. 39 of 3 May 2019, the offences under Article 25-quaterdecies, namely fraud in sporting competitions, unlawful gaming or betting and gambling conducted through prohibited devices:

Articles 1-4 of Law No. 401 of 13 December 1989.

- following the enactment of Decree-Law No. 124 of 26 October 2019, subsequently supplemented by Italian Legislative Decree No. 75 of 14 July 2020, the offences under Article 25-quinquiesdecies, namely tax offences:

fraudulent tax return using invoices or other documents for non-existent transactions under Article 2(1) of Italian Legislative Decree No. 74/2000;

fraudulent tax return using invoices or other documents for non-existent transactions under Article 2(2-bis) of Italian Legislative Decree No. 74/2000;

fraudulent tax return by means of other artifices under Article 3 of Italian Legislative Decree No. 74/2000;

issuing invoices or other documents for non-existent transactions under Article 8(1) of Italian Legislative Decree No. 74/2000;

issuing invoices or other documents for non-existent transactions under Article 8(2-bis) of Italian Legislative Decree No. 74/2000;

concealment or destruction of accounting documents under Article 10 of Italian Legislative Decree No. 74/2000;

fraudulent avoidance of tax payments under Article 11 of Italian Legislative Decree No. 74/2000;

inaccurate tax return (Article 4 of Italian Legislative Decree No. 74/2000);

failure to file a tax return (Article 5 of Italian Legislative Decree No. 74/2000);

undue tax offsetting (Article 10-quater of Italian Legislative Decree No. 74/2000).

- following the enactment of Italian Legislative Decree No. 75 of 14 July 2020, the offences under Article 25-sexiesdecies, namely smuggling offences:

smuggling in the movement of goods across land borders and customs areas (Article 282 of Presidential Decree No. 43/1973);

smuggling in the movement of goods on border lakes (Article 283 of Presidential Decree No. 43/1973);

MEDICA

smuggling in the maritime movement of goods (Article 284 of Presidential Decree No. 43/1973);
smuggling in the movement of goods by air (Article 285 of Presidential Decree No. 43/1973);
smuggling in extra-customs zones (Article 286 of Presidential Decree No. 43/1973);
smuggling through improper use of goods imported under customs concessions (Article 287 of Presidential Decree No. 43/1973);
smuggling in customs warehouses (Article 288 of Presidential Decree No. 43/1973);
smuggling in cabotage and circulation (Article 289 of Presidential Decree No. 43/1973);
smuggling in the export of goods eligible for repayment of duties (Article 290 of Presidential Decree No. 43/1973);
smuggling in temporary import or export operations (Article 291 of Presidential Decree No. 43/1973);
smuggling of foreign manufactured tobacco (Article 291-bis of Presidential Decree No. 43/1973);
aggravating circumstances in the offence of smuggling foreign manufactured tobacco (Article 291-ter of Presidential Decree No. 43/1973);
criminal association for the purpose of smuggling foreign manufactured tobacco (Article 291-quater of Presidential Decree No. 43/1973);
other cases of smuggling (Article 292 of Presidential Decree No. 43/1973);
aggravating circumstances of smuggling (Article 295 of Presidential Decree No. 43/1973).

- following the enactment of Italian Legislative Decree No. 184 of 18 November 2021 and the amendments introduced by Italian Legislative Decree No. 195 of 18 November 2021, Law No. 137/2023 and Decree-Law No. 19/2024, the offences under Article 25-octies.1, namely offences relating to payment instruments other than cash:

unlawful use and counterfeiting of credit cards and payment instruments other than cash (Article 493-ter of the Italian Criminal Code);
possession and dissemination of equipment, devices or computer programs intended to commit offences involving payment instruments other than cash (Article 493-quater of the Italian Criminal Code);
computer fraud (Article 640-ter of the Italian Criminal Code);
fraudulent transfer of assets (Article 512-bis of the Italian Criminal Code).

- following Law No. 22 of 9 March 2022, containing provisions on offences against cultural heritage referred to in Article 25-septiesdecies of Italian Legislative Decree No. 231/2001, namely:

Article 518-bis of the Italian Criminal Code, "Theft of cultural property"
Article 518-ter of the Italian Criminal Code, "Misappropriation of cultural property"
Article 518-quater of the Italian Criminal Code, "Receiving stolen cultural property"
Article 518-octies of the Italian Criminal Code, "Forgery of private documents relating to cultural property"
Article 518-novies of the Italian Criminal Code, "Violations concerning the disposal of cultural property"
Article 518-decies of the Italian Criminal Code, "Unlawful import of cultural property"
Article 518-undecies of the Italian Criminal Code, "Unlawful removal or export of cultural property"
Article 518-duodecies of the Italian Criminal Code, "Destruction, dispersal, deterioration, defacement, soiling and unlawful use of cultural and landscape heritage"
Article 518-quaterdecies of the Italian Criminal Code, "Counterfeiting of works of art".

- following Law No. 22 of 9 March 2022, containing provisions on offences against cultural heritage referred to in Article 25-duodevicies of Italian Legislative Decree No. 231/2001, namely:

Article 518-sexies of the Italian Criminal Code, "Laundering of cultural property"
Article 518-terdecies of the Italian Criminal Code, "Devastation and looting of cultural and landscape heritage".

1.5. Offences committed abroad

Under Article 4 of the Decree, an entity may be held liable in Italy in relation to certain offences committed abroad. The conditions on which such liability is based are as follows:



- a) the offence must be committed abroad by a person functionally linked to the Company;
- b) the Company must have its registered head office in Italy;
- c) the Company may be held liable only in the cases and under the conditions set out in Articles 7, 8, 9 and 10 of the Italian Criminal Code and, where the law provides that the natural person who committed the offence may be prosecuted only at the request of the Minister of Justice, proceedings may be brought against the Company only if that request also concerns the Company;
- d) where the cases and conditions set out in the above-mentioned provisions of the Italian Criminal Code apply, the Company is liable provided that the State in which the offence was committed does not prosecute the Company for the same offence.

1.6. Sanctions

The administrative sanctions applicable to administrative offences arising from criminal offences are:

- financial penalties;
- disqualification sanctions;
- confiscation of assets;
- publication of the judgment.

A financial penalty is always imposed for an administrative offence arising from a criminal offence. In setting the amount, the court takes into account the seriousness of the offence, the degree of the Company's liability and the measures taken by the Company to eliminate or mitigate the consequences of the offence or to prevent further offences.

The financial penalty is reduced where:

- the perpetrator committed the offence primarily in his or her own interest or in the interest of third parties and the Company obtained no advantage or only a minimal advantage;
- the financial damage caused is particularly minor;
- the Company has fully compensated the damage and eliminated the harmful or dangerous consequences of the offence, or has in any event taken effective action to that end;
- the Company has adopted and implemented an organisational model suitable for preventing offences of the type that occurred.

Disqualification sanctions apply where at least one of the following conditions is met:

- the Company derived a substantial profit from an offence committed by one of its employees or by a person in a senior position, and the offence was caused or facilitated by serious organisational deficiencies;
- the offences have been repeated.

In particular, the main disqualification sanctions are:

- (i) prohibition from carrying on business activities;
- (ii) suspension or revocation of authorisations, licences or concessions instrumental to the commission of the offence;
- (iii) prohibition from entering into contracts with the Public Administration, except to obtain the provision of a public service;
- (iv) exclusion from benefits, funding, grants and subsidies, and revocation of any already granted;
- (v) prohibition from advertising goods or services.

Where necessary, disqualification sanctions may also be applied jointly.



Upon conviction, confiscation of the price or proceeds of the offence is always ordered against the entity, except for the portion that may be returned to the injured party. Rights acquired by third parties in good faith are preserved. Confiscation may also be ordered “by equivalent value”; where the price or proceeds of the offence cannot be confiscated directly, sums of money, assets or other benefits of equivalent value may be confiscated instead.

Publication of the judgment may be ordered where a disqualification sanction is imposed on the Company.

As an interim measure in proceedings against the Company, a disqualification sanction may be imposed or preventive or conservatory seizure may be ordered.

1.7. Grounds for exemption from administrative liability

Article 6(1) of the Decree provides a specific exemption from administrative liability where the offence was committed by persons in so-called “senior positions” and the Company proves that:
before the unlawful act was committed, the governing body adopted and effectively implemented a model suitable for preventing offences of the type that occurred;
it entrusted an internal body, the Supervisory Body, vested with autonomous powers of initiative and control, with the task of supervising the operation of and effective compliance with the Model and keeping it up to date;
the persons in so-called “senior positions” committed the offence by fraudulently circumventing the Model;
there was no omission or insufficient supervision by the Supervisory Body.

Article 6(2) of the Decree further provides that the Model must meet the following requirements:

- identify business risks, namely the activities within which offences may be committed;
- ensure that no person operating within the Company can justify his or her conduct by claiming ignorance of Company rules, and prevent, in ordinary circumstances, the offence from being caused by an error, including one due to negligence or lack of expertise, in assessing Company instructions;
- introduce a disciplinary system capable of sanctioning failure to comply with the measures set out in the Model;
- identify methods of managing financial resources suitable for preventing the commission of such offences;
- provide for a system of preventive controls that can only be circumvented intentionally;
- provide for information obligations towards the Supervisory Body responsible for monitoring the operation of and compliance with the Model.

In practical terms, in order to qualify for exemption from administrative liability, the Company must:

- adopt a Code of Ethics setting out principles of conduct in relation to the relevant offences;
- define an organisational structure capable of ensuring a clear and coherent allocation of duties, implementing segregation of duties, and promoting and monitoring proper conduct;
- formalise manual and IT-based Company procedures governing the performance of activities (the control measure consisting of “segregation of duties” among persons involved in critical stages of a risk process is particularly effective as a preventive measure);
- assign authorisation and signature powers consistently with the defined organisational and management responsibilities;
- communicate the Code of Ethics, Company procedures, the sanctions system, authorisation and signature powers and all other measures designed to prevent unlawful acts to personnel in a widespread, effective, clear and detailed manner;
- provide for an appropriate sanctions system;
- establish a Supervisory Body with substantial autonomy and independence, whose members possess the professional expertise required to perform the assigned duties;
- provide for a Supervisory Body capable of assessing the adequacy of the Model, monitoring its operation, keeping it up to date and acting continuously and in close coordination with the Company functions.



2. COMPANY HISTORY

Medica S.p.A. has been operating in the Mirandola biomedical district since 1985. Innovation and the development of new blood purification products have always been the Company's core business. Over the years, R&D activities have been integrated with highly automated manufacturing capabilities. Medica provides end-to-end design and development of disposable medical devices and electromedical equipment.

In recent years, the drive to identify new products and high-margin markets led Medica to launch the Medica Water Division for the development and marketing of microbiological water filtration devices and to begin developing products for bioregenerative medicine.

Today, the Company's activities are divided into three Business Units:

- Medical
- Water Purification
- Turnkey Solutions.

Medica therefore positions itself as an ideal provider of comprehensive solutions for companies operating in the healthcare and water purification sectors.

3. PURPOSE

In order to ensure fairness and transparency in the conduct of business and Company activities, the Company has deemed it necessary to adopt the Model in accordance with the requirements of Italian Legislative Decree No. 231 of 2001.

The Model is intended to describe the operating methods adopted and the responsibilities assigned within MEDICA S.p.A.

The Company believes that, beyond legal requirements, adoption of the Model is a valuable means of raising awareness and providing information to all employees and other stakeholders (consultants, partners, etc.).

The purposes of the Model are therefore to:

- prevent and reasonably limit potential risks connected with the Company's activities, with particular regard to risks associated with unlawful conduct;
- ensure that all persons acting in the name and on behalf of MEDICA S.p.A. in risk-sensitive areas are aware that, if they breach the provisions of the Model, they may commit an offence punishable by criminal and/or administrative sanctions not only against themselves but also against MEDICA S.p.A.;
- reaffirm that MEDICA S.p.A. does not tolerate unlawful conduct;
- provide information on the serious consequences that the Company, and therefore indirectly all stakeholders, could face as a result of the financial and disqualification sanctions provided for by the Decree, including the possibility that such sanctions may be imposed on an interim basis;
- enable the Company to maintain constant control and careful supervision over its activities, so that it can intervene promptly where risk factors arise and, where appropriate, apply the disciplinary measures provided for by the Model.

4. SCOPE OF APPLICATION



The rules contained in the Model apply to persons who, even de facto, perform management, administration, executive or control functions within the Company, to shareholders and employees, and to persons who, although not belonging to the Company, act on its behalf or are contractually linked to it.

Accordingly, the Recipients of the Model include, among persons in senior positions: 1) the Chair of the Board of Directors; 2) directors; 3) executives; 4) members of the Board of Statutory Auditors; 5) members of the Supervisory Body; and, among persons subject to the direction of others: 1) employees; 2) interns.

By virtue of specific contractual clauses, and limited to the sensitive activities in which they may participate, the following external parties may be subject to specific obligations designed to ensure proper implementation of the internal control activities provided for in this General Part:

- collaborators, agents and representatives, consultants and, more generally, self-employed persons, insofar as they operate within sensitive areas on behalf or in the interest of the Company;
- suppliers and business partners (including temporary business associations and joint ventures) that operate to a significant and/or continuous extent within so-called sensitive areas on behalf or in the interest of the Company.

The so-called external parties also include persons who, although contractually linked to another Group company, in practice operate to a significant and/or continuous extent within sensitive areas on behalf or in the interest of the Company.

MEDICA S.p.A. disseminates this Model through methods designed to ensure that all relevant persons have effective knowledge of it.

The persons to whom the Model is addressed are required to comply fully with all its provisions, also in fulfilment of the duties of loyalty, fairness and diligence arising from their legal relationships with the Company.

MEDICA S.p.A. condemns any conduct that is inconsistent not only with the law but, in particular for the purposes of this document, with the Model and the Code of Ethics, even where the unlawful conduct was carried out in the Company's interest or with the intention of providing it with an advantage.

5. RISK ASSESSMENT AT MEDICA S.P.A.

5.1. Summary of the project for the preparation and development of the Organisation, Management and Control Model pursuant to Italian Legislative Decree 231/2001 for MEDICA S.p.A.

The 231 Working Group presented to the Company's senior management the launch of the project aimed at developing the Company's Organisation, Management and Control Model (hereinafter, the "MOG"), pursuant to Article 6(2)(a) of Italian Legislative Decree 231/01.

The MOG was prepared for MEDICA S.p.A., with registered office in Medolla (MO), Via Degli Artigiani 7.

During the project, the 231 Working Group involved the relevant Company functions extensively in understanding, analysing, evaluating and discussing the various topics, through meetings and interviews aimed at collecting information about the Company, carrying out detailed analysis and assessment of risk areas, and providing periodic updates on project progress and any issues identified.

MEDICA

Figure 1: MEDICA S.p.A. Organisation, Management and Control Model pursuant to Italian Legislative Decree 231/2001



5.2. Phase 1: Project launch and Macro Risk Assessment

This phase involved the following activities:

- Organisation, planning, communication and launch of the project for the preparation and development of the MOG;
- Collection of preliminary documentation/information;
- Analysis of the Company and identification of risk areas under Italian Legislative Decree 231/01 (“macro areas” of sensitive activities) and the relevant managers/company roles involved;
- Analysis and assessment of MEDICA S.p.A.’s control environment to identify any gaps in relation to the key components of the MOG.

This phase produced specific documentation concerning the planning, organisation, communication and launch of the project for the preparation and development of the MOG.

5.3. Phase 2: Micro Risk Assessment

This phase involved the following activities:

- Detailed analysis of the risk areas identified through interviews;
- Identification of the specific processes/activities sensitive to the offences under Italian Legislative Decree 231/01 emerging from the detailed analysis of the areas (“macro areas” of sensitive activities);
- Risk assessment by mapping sensitive processes in terms of:
 - potential offences to which each process may theoretically be exposed;
 - potential methods by which the offence could be committed in each process;
 - organisational functions/company roles involved in the process;
 - level of coverage through preventive protocols, in terms of the system of powers, information systems, documented procedures and reporting;
 - description of the process flow.



The process mapping is set out in this “General Part” and in the individual “Special Parts” of the Organisation, Management and Control Model.

5.4. Phase 3: Gap Analysis and definition of the implementation plan

This phase involved the following activities:

- Identification of the framework of preventive protocols (system-level and specific) to be applied to each sensitive process (“macro areas” of sensitive activities) in order to prevent the offences under Italian Legislative Decree 231/01, as subsequently supplemented;
- Assessment of the mapping of sensitive processes carried out in Phase 2 in order to identify gaps in those processes against the identified framework of preventive protocols (Gap Analysis);
- Definition of the action plan for developing the MOG within the Company, taking into account the process gaps identified through the Micro Risk Assessment and the recommendations made in Phase 1 regarding the control environment and the Model’s macro-level components (Macro Risk Assessment).

The results of these activities are set out in the “General Part”, the “Preventive Protocols Manual” and the individual “Special Parts” of the Organisation, Management and Control Model.

5.5. Phase 4: Implementation of the Organisation, Management and Control Model for MEDICA S.p.A.

This phase involved the following activities:

- Implementation of the improvement action plan defined in Phase 3, resulting in the definition, sharing and formalisation of:
 - the macro components of the MOG: Code of Ethics, Organisational Structure, System of Delegations and Powers, Sanctions System, Supervisory Body Rules;
 - system-level and specific preventive protocols and instrumental processes for each “macro area” of sensitive activities, analysed in detail in the Preventive Protocols Manual and the relevant “Special Parts”.
- Formalisation of the Organisation, Management and Control Model pursuant to Italian Legislative Decree 231/01, reproduced in full as an annex to this document.

The Organisation, Management and Control Model pursuant to Italian Legislative Decree 231/01 was presented to senior management and subsequently submitted to the Company’s Board of Directors and approved, in its first version, by resolution of the Board of Directors.

5.6. Phase 5: Ongoing updating and adaptation of the MOG

Risk analysis must therefore be regarded as a dynamic activity, enabling the Supervisory Body and the Company as a whole to maintain an up-to-date understanding of the risk factors associated with its operations.

This requires repeating the entire analysis cycle across all Company activities, incorporating where necessary legislative changes since the previous update (for example, new offences or new approaches to risk management) and process changes resulting from organisational measures and the Company’s development.

Ultimately, the risk profile must be recalculated by applying the Model and identifying both inherent risk and residual risk.

In this updating process, an overall comparison between the current and previous risk profiles is not significant, since



the two situations may relate to organisational and legislative contexts that are not necessarily comparable. Accordingly, improvement or corrective actions are defined not so much on the basis of a difference between different risk profiles, but on the evidence emerging from the updated risk analysis.

The Organisation, Management and Control Model pursuant to Italian Legislative Decree 231/01 was presented to senior management and subsequently submitted to the Company's Board of Directors and approved, in its successive versions updated and adapted to organisational and regulatory changes, by resolutions of the Board of Directors.

6. STRUCTURE AND ORGANISATION OF THE MODEL

6.1. Reference models

This Model is based on the “Guidelines for the preparation of organisation, management and control models pursuant to Italian Legislative Decree No. 231/2001” approved by Assobiomedica, now Confindustria Medical Devices, and updated in 2013, and on the “Guidelines for the preparation of organisation, management and control models pursuant to Italian Legislative Decree 231/01” approved by Confindustria on 7 March 2002 and updated in 2021.

With regard to whistleblowing rules, the updated Model draws on Confindustria’s explanatory note of January 2018 and the Assonime circular of 28 June 2018. It also draws on the ANAC Guidelines of July 2023 and Confindustria’s Operational Guide of October 2023.

The key stages identified by the Guidelines for preparing Models may be summarised as follows:

- the first stage consists of identifying risks, namely analysing the Company context to determine where (in which area/sector of activity) and how events that could undermine the objectives of the Decree may occur;
- the second stage consists of designing the control system (i.e. protocols for planning the formation and implementation of the entity’s decisions), namely assessing the system already in place within the entity and, where necessary, adapting it so that it is capable of effectively countering, and therefore reducing to an acceptable level, the identified risks.

Conceptually, risk reduction requires action on two determining factors: 1) the likelihood of the event occurring; 2) the impact of the event itself.

To operate effectively, however, the system cannot be limited to occasional activity; it must become an ongoing process, repeated with particular attention at times of organisational change.

It should also be noted that defining “acceptable risk” is a prerequisite for building an adequate preventive control system.

With regard to the preventive control system to be developed in relation to the risk of committing the offences covered by Italian Legislative Decree No. 231 of 2001, the conceptual threshold of acceptability, for intentional offences, is represented by a prevention system that cannot be circumvented except fraudulently. This solution is consistent with the concept of “fraudulent circumvention” of the organisational Model as an express ground for exemption from the entity’s administrative liability under the Decree (Article 6(1)(c): “the persons committed the offence by fraudulently circumventing the organisation and management models”).

Following the approach outlined above, the operational steps that the Company must take to implement a risk management system consistent with the requirements of Italian Legislative Decree No. 231 of 2001 are described below. In describing this process, particular emphasis is placed on the material results of the self-assessment activities carried out for the purpose of implementing the system.

Inventory of Company business areas

This phase may be carried out using different approaches, including by activity, function or process. In particular, it requires a comprehensive periodic review of the Company’s operations in order to identify the areas potentially affected by the relevant offences. For example, with regard to offences against the Public Administration, the aim is to identify areas that, by their nature, have direct or indirect dealings with Italian or foreign Public Administrations. Certain types of processes/functions will necessarily be involved, such as sales to the Public Administration or management of concessions granted by local Public Administrations, while others may not be involved or may be affected only marginally. By contrast, for negligent homicide and serious or very serious negligent injury committed in breach of workplace health and safety rules, no area of activity can be excluded in advance because such offences may potentially involve all parts of the Company.

MEDICA

As part of this review of at-risk processes/functions, it is appropriate to identify the persons subject to monitoring. With regard to intentional offences, in certain particular and exceptional circumstances these may also include persons linked to the Company through quasi-subordinate relationships, such as agents, or through other forms of collaboration, such as business partners, as well as their employees and collaborators.

For negligent offences of homicide and personal injury committed in breach of workplace health and safety rules, all workers subject to those rules are subject to monitoring.

In the same context, due diligence exercises should also be carried out whenever the risk assessment identifies “red flags” relating to a particular business transaction, such as negotiations in countries with high levels of corruption, particularly complex procedures, or the involvement of new personnel not previously known to the entity.

Finally, it should be stressed that each company/sector has its own specific risk areas, which can only be identified through detailed internal analysis. Financial-area processes are nevertheless of particular significance for the purposes of applying Italian Legislative Decree No. 231 of 2001.

Analysis of potential risks

The analysis of potential risks must consider the possible ways in which offences may be committed in the various Company areas identified through the process described above. This analysis, which is a prerequisite for properly designing preventive measures, must provide a comprehensive representation of how each type of offence could be committed in the internal and external operating context in which the Company operates.

In this regard, it is useful to consider both the entity's history, including past events, and the characteristics of other entities operating in the same sector, particularly any unlawful acts committed by them in the same field of activity.

In particular, analysis of the possible methods of committing negligent homicide and serious or very serious negligent injury in breach of workplace health and safety obligations corresponds to the occupational risk assessment carried out in accordance with Article 28 of Italian Legislative Decree No. 81 of 2008.

Assessment/development/adaptation of the preventive control system

The activities described above are completed by assessing any existing preventive control system and adapting it where necessary, or creating such a system where none exists. The preventive control system must ensure that the risks of offences being committed in the ways identified and documented in the previous phase are reduced to an “acceptable level”, as defined above. In essence, this means designing what Italian Legislative Decree No. 231 of 2001 calls “specific protocols aimed at planning the formation and implementation of the entity's decisions in relation to the offences to be prevented”. There are numerous components of an internal preventive control system for which established methodological references exist.

It should nevertheless be reiterated that, for all entities, the preventive control system must be such that:

- in the case of intentional offences, it cannot be circumvented except intentionally;
- in the case of negligent offences, which by their nature are incompatible with fraudulent intent, the system may nevertheless be breached despite proper fulfilment of supervisory duties by the relevant Supervisory Body.

In accordance with the above, the components (protocols) generally regarded as forming a preventive control system, and which should be implemented at Company level to ensure the effectiveness of the Model, are listed below separately for intentional and negligent offences under Italian Legislative Decree No. 231 of 2001.

A) Preventive control systems for intentional offences

According to the Confindustria Guidelines, the most significant components of the control system are:

MEDICA

- the Code of Ethics, with reference to the offences concerned;
- a formalised and clear organisational system, particularly with regard to the allocation of responsibilities;
- manual and IT procedures (information systems) governing the performance of activities and providing appropriate control points; in this context, the segregation of duties among persons carrying out crucial stages (activities) of a risk-sensitive process is a particularly effective preventive control measure;
- authorisation and signature powers assigned consistently with the defined organisational and management responsibilities;
- a management control system capable of providing timely warning of existing or emerging general and/or specific critical situations;
- communication to personnel and related training.

B) Preventive control systems for negligent homicide and negligent personal injury committed in breach of workplace health and safety rules

Without prejudice to the points already made in relation to intentional offences, the most significant components of the control system in this area are:

- the Code of Ethics (or Code of Conduct), with reference to the offences concerned;
- an organisational structure in which workplace health and safety duties and responsibilities are formally defined in a manner consistent with the Company's organisational and functional structure, from the employer through to each individual worker. Particular attention must be paid to the specific roles operating in this area. In practical terms, this means that:
 - a) when defining the organisational and operational duties of Company management, executives, supervisors and workers, their respective health and safety duties and the responsibilities connected with those duties must also be expressly defined;
 - b) the duties of the Head of the Prevention and Protection Service (RSPP), any Prevention and Protection Service Officers (ASPP), the Workers' Safety Representative, emergency management personnel and the occupational physician must, in particular, be documented;
- education and training: duties that may affect workplace health and safety require adequate competence, which must be verified and maintained through education and training designed to ensure that all personnel, at every level, understand the importance of ensuring that their actions comply with the organisational Model and the potential consequences of conduct that departs from the Model's rules. In practical terms, each worker/company operator must receive sufficient and appropriate training, with particular reference to his or her workplace and duties. Training must be provided upon hiring, transfer or change of duties, or when new work equipment, technologies, hazardous substances or preparations are introduced. The Company should organise education and training on the basis of needs identified periodically;
- **communication and involvement: the circulation of information within the Company is important in promoting the involvement of all relevant persons and ensuring appropriate awareness and commitment at every level. Involvement should be achieved through:**
 - a) prior consultation regarding the identification and assessment of risks and the definition of preventive measures;

MEDICA

b) periodic meetings that take account, at a minimum, of the requirements laid down by applicable legislation, also making use of meetings already planned for Company management purposes.

- Operational management: with regard to workplace health and safety risks, the control system should be integrated and consistent with the overall management of Company processes. Analysis of Company processes and their interrelationships, together with the results of the risk assessment, should lead to the definition of methods for safely performing activities that have a significant impact on workplace health and safety. Having identified the areas requiring action in relation to health and safety matters, the Company should ensure that they are subject to regulated operational management.

In this regard, particular attention should be paid to:

- a) recruitment and qualification of personnel;
- b) work organisation and workplace layout;
- c) procurement of goods and services used by the Company and communication of appropriate information to suppliers and contractors;
- d) routine and extraordinary maintenance;
- e) qualification and selection of suppliers and contractors;
- f) emergency management;
- g) procedures for dealing with deviations from established objectives and the rules of the control system;

- Safety monitoring system: workplace health and safety management should include a verification phase aimed at confirming that the adopted prevention and protection measures continue to be suitable and effective. The technical, organisational and procedural prevention and protection measures implemented by the Company should be subject to planned monitoring.

A monitoring plan should be developed by defining:

- a) the timing and frequency of checks;
- b) the allocation of duties and implementation responsibilities;
- c) the methods to be followed;
- d) the procedures for reporting any non-compliant situations.

Systematic monitoring should therefore be provided for, with methods and responsibilities established at the same time as the methods and responsibilities for operational management are defined.

This first-level monitoring is generally carried out by internal resources, either through self-monitoring by the operator or by the supervisor/manager; for specialist matters, such as instrumental measurements, other internal or external resources may be used. It is also appropriate for checks on organisational and procedural health and safety measures to be carried out by the persons already designated when responsibilities are assigned, generally managers and supervisors. Of particular importance among these is the Prevention and Protection Service, which is required, within its remit, to develop systems for checking the measures adopted.

The Company must also periodically conduct second-level monitoring of the effectiveness of the preventive system adopted. Such effectiveness monitoring should support strategic decision-making and be carried out by competent personnel who ensure objectivity and impartiality and are independent of the work area being audited.

According to the Confindustria Guidelines, the components described above must be organically integrated into a system architecture that complies with a number of control principles, including:

- every operation, transaction and action must be verifiable, documented, consistent and appropriate: each operation must be supported by adequate documentation enabling checks to be carried out at any time to

MEDICA

verify the characteristics and reasons for the operation and to identify who authorised, performed, recorded and checked it;

- no one may independently manage an entire process: the system must ensure application of the segregation-of-duties principle, whereby responsibility for authorising an operation must rest with a person other than the person who records, operationally performs or controls the operation;
- documentation of controls: the control system must document the performance of controls, including supervisory controls, where appropriate through the preparation of minutes or records;

It should be noted that failure to comply with specific points of the Confindustria Guidelines does not, in itself, invalidate the Model. Since each Model must be prepared with reference to the actual circumstances of the company concerned, it may depart from the Guidelines, which are by nature general, on specific points where this is necessary to provide greater protection for the interests safeguarded by the Decree.

The illustrative observations contained in the appendix to the Guidelines (the so-called case studies), as well as the summary list of control tools contained therein, should also be assessed in light of the above observation.

C) Preventive control systems for environmental offences

Without prejudice to the points already made in relation to intentional offences, the most significant components of the control system in this area are:

- the Code of Ethics (or Code of Conduct), with reference to the offences concerned;
- an organisational structure in which environmental duties and responsibilities are formally defined in a manner consistent with the Company's organisational and functional structure, from the legal representative through to each individual worker. Particular attention must be paid to the specific roles operating in this area.
In practical terms, this means that:
 - a) when defining the organisational and operational duties of Company management, executives, supervisors and workers, the environmental activities falling within their respective areas of responsibility and the responsibilities connected with carrying out those activities must also be expressly defined;
 - b) the duties of the Environmental Management System Manager (RSGA) must, in particular, be documented;
- information, education and training: duties that may affect environmental matters require adequate competence, which must be verified and maintained through education and training designed to ensure that all personnel, at every level, understand the importance of ensuring that their actions comply with the organisational Model and the potential consequences of conduct that departs from the Model's rules. In practical terms, all persons involved must receive sufficient and appropriate training, with particular reference to their workplace and duties. Training must be provided upon hiring, transfer or change of duties, or when new work equipment, technologies, hazardous substances or preparations are introduced. The Company must organise education and training on the basis of needs identified periodically and must document such activities, retaining records from which the course content, mandatory attendance requirements and attendance checks can be established;
- communication and involvement: the circulation of information within the Company is important in promoting the involvement of all relevant persons and ensuring appropriate awareness and commitment at every level. Involvement should be achieved through:
 - a) prior consultation regarding the identification and assessment of risks and the definition of preventive measures;
 - b) periodic meetings that take account, at a minimum, of the requirements laid down by applicable legislation, also making use of meetings already planned for Company management purposes;

MEDICA

- operational management: with regard to environmental risks, the control system should be integrated and consistent with the overall management of Company processes.

In this regard, particular attention should be paid to:

- a) recruitment and qualification of personnel;
- b) work organisation and workplace layout;
- c) procurement of goods and services used by the Company and communication of appropriate information to suppliers and contractors;
- d) routine and extraordinary maintenance;
- e) qualification and selection of suppliers and contractors;
- f) procedures for dealing with deviations from established objectives and the rules of the control system.

- Environmental monitoring system: environmental management should include a verification phase aimed at confirming that the adopted risk prevention and protection measures continue to be suitable and effective. The technical, organisational and procedural prevention and protection measures implemented by the Company should be subject to planned monitoring.

A monitoring plan should be developed by defining:

- a) the timing and frequency of checks;
- b) the allocation of duties and implementation responsibilities;
- c) the methods to be followed;
- d) the procedures for reporting any non-compliant situations.

Systematic monitoring should therefore be provided for, with methods and responsibilities established at the same time as the methods and responsibilities for operational management are defined.

This first-level monitoring is generally carried out by internal resources, either through self-monitoring by the operator or by the supervisor/manager; for specialist matters, such as instrumental measurements, other internal or external resources may be used. It is also appropriate for checks on organisational and procedural environmental protection measures to be carried out by the persons already designated when responsibilities are assigned.

The Company must also periodically conduct second-level monitoring of the effectiveness of the preventive system adopted. Such effectiveness monitoring should support strategic decision-making and be carried out by competent personnel who ensure objectivity and impartiality and are independent of the work area being audited.

The components described above must be organically integrated into a system architecture that complies with a number of control principles, including:

- every operation, transaction and action must be verifiable, documented, consistent and appropriate: each operation must be supported by adequate documentation enabling checks to be carried out at any time to verify its characteristics and rationale and to identify who authorised, performed, recorded and checked the operation;
- no one may independently manage an entire process: the system must ensure application of the segregation-of-duties principle, whereby responsibility for authorising an operation must rest with a person other than the person who records, operationally performs or controls it;
- documentation of controls: the control system must document the performance of controls, including supervisory controls, where appropriate through the preparation of minutes or records.

6.2. Structure and rules for approval of the Model and its updates

For the purpose of preparing the Model, and in methodological consistency with the Confindustria Guidelines, the Company therefore proceeded to:

MEDICA

- identify the so-called sensitive activities through a preliminary review of Company documentation (articles of association, regulations, organisation charts, powers of attorney, job descriptions, organisational provisions and communications) and a series of interviews with persons responsible for the various areas of Company operations (i.e. heads of the different functions). The analysis was aimed at identifying and assessing the actual performance of activities in which unlawful conduct potentially giving rise to predicate offences could occur. At the same time, the existing control measures, including preventive controls, and any areas requiring subsequent improvement were assessed;

- design and implement the actions necessary to improve the control system and align it with the objectives pursued by the Decree, taking into account the Confindustria Guidelines and the fundamental principles of segregation of duties and authorisation powers consistent with assigned responsibilities. During this phase, particular attention was paid to identifying and regulating financial management and control processes in risk-sensitive activities;

- define control protocols where a risk scenario was identified. Decision-making and implementation protocols were therefore defined, setting out the rules and discipline which the persons with operational responsibility for those activities helped identify as most suitable for managing the relevant risk profile. The principle adopted in designing the control system is that the conceptual threshold of acceptability is represented by a prevention system that cannot be circumvented except fraudulently, as already indicated in the Confindustria Guidelines. The protocols are based on the principle that the various stages of the decision-making process must be documented and verifiable so that the reasons underlying each decision can be reconstructed.

The key elements of the Model are therefore:

- mapping the Company's risk-sensitive activities, namely those activities within which the offences provided for by the Decree may be committed;
- establishing appropriate control measures to prevent the offences provided for by the Decree;
- ex post review of Company conduct and the operation of the Model, followed by periodic updating;
- dissemination of, and involvement of all Company levels in, the implementation of the established rules of conduct and procedures;
- assigning the Supervisory Body specific duties for monitoring the effective and proper operation of the Model;
- adopting a Code of Ethics.
- establishing a specific whistleblowing procedure for reports by persons in senior positions and persons subject to their direction (Article 5(1)(a) and (b));

Without prejudice to the specific purposes described above concerning the exemption from liability provided for by the Decree, the Model forms part of the broader control system already in place, which is designed to provide reasonable assurance that Company objectives are achieved in compliance with laws and regulations, that financial information is reliable and that assets are safeguarded, including against possible fraud.

In particular, with reference to the so-called sensitive areas of activity, the Company has identified the following core principles of its Model. By governing those activities, these principles are direct tools for planning the formation and implementation of the Company's decisions and for ensuring appropriate control over them, including in relation to the offences to be prevented:

- segregation of duties through proper allocation of responsibilities and appropriate authorisation levels, in order to avoid functional overlaps or operational arrangements that concentrate critical activities in a single person;
- clear and formal assignment of powers and responsibilities, expressly indicating the limits on their exercise and ensuring consistency with assigned duties and positions within the organisational structure;
- no material operation may be undertaken without authorisation;
- the existence of rules of conduct suitable for ensuring that Company activities are carried out in compliance with laws and regulations and with due protection of Company assets;



- adequate procedural regulation of the so-called sensitive Company activities so that: operating processes are defined and supported by adequate documentation, allowing them to be verified at all times in terms of appropriateness, consistency and responsibility; decisions and operational choices are always traceable in terms of their characteristics and rationale and the persons who authorised, carried out and checked individual activities can always be identified; financial resources are managed in ways suitable for preventing the commission of offences; control and supervisory activities relating to Company transactions are carried out and documented; security mechanisms ensure adequate protection of physical and logical access to data and Company assets; and information exchanged between adjacent stages or processes preserves the integrity and completeness of the data managed.

The principles described above are consistent with the Confindustria Guidelines and are considered by the Company to be reasonably suitable for preventing the offences referred to in the Decree.

For this reason, the Company considers it essential to ensure the proper and effective application of the above control principles in all so-called sensitive Company activity areas identified and described in the Special Parts of this Model.

6.3. Code of Ethics

The Code of Ethics is the document independently prepared and adopted by MEDICA S.p.A. to communicate to all stakeholders the principles of business ethics, ethical commitments and responsibilities in conducting business and Company activities with which the Company intends to comply. Compliance is required of all persons working at MEDICA S.p.A. and all persons having contractual relationships with it.

The principles and rules of conduct contained in this Model complement those set out in the Code of Ethics adopted by the Company, although the Model has a different scope from the Code in view of the specific purposes it pursues in implementing the provisions of the Decree. Both documents are, however, inspired, insofar as compatible, by the MedTech Europe Code of Ethical Business Practice (December 2016 version) and the Confindustria Medical Devices Code of Ethics (September 2020 version).

It should be clarified that the Code of Ethics is an independently adopted instrument of general application within the Company, intended to express a set of business ethics principles that the Company recognises as its own and with which it requires all employees and all persons who cooperate in pursuing Company objectives, including suppliers and customers, to comply. The Model, by contrast, responds to specific requirements of the Decree aimed at preventing particular types of offences which, if apparently committed in the interest or to the advantage of the Company, may give rise to administrative liability under the Decree. However, because the Code of Ethics sets out principles of conduct that are also suitable for preventing the unlawful conduct covered by the Decree, it is relevant for the purposes of the Model and formally constitutes an integral part of the Model.

The Company's Code of Ethics is set out in "Special Part A: Code of Ethics".

6.4. Reporting Procedure (Whistleblowing)

Law No. 179 containing "Provisions for the protection of persons reporting offences or irregularities of which they have become aware in the context of a public or private employment relationship" entered into force on 29 December 2017. The law is intended to encourage employee cooperation in order to facilitate the detection of corruption within public and private entities.

As regards the private sector, Article 2 of Law No. 179/17 amended Italian Legislative Decree 231 and introduced into Article 6 ("Persons in senior positions and organisational models of the entity") a new provision bringing measures relating to the submission and management of reports within the scope of the 231 Model.

MEDICA

Accordingly, companies that adopt the Model are also required to implement these new measures.

In particular, in order to be considered adequate and effective, the 231 Model must provide for the following additional measures:

- one or more channels enabling the persons referred to in Article 5(1)(a) and (b), for the purpose of protecting the integrity of the entity, to submit detailed reports of unlawful conduct relevant under the Decree and based on precise and consistent factual elements, or of breaches of the entity's organisation and management Model, of which they became aware by reason of the functions performed; such channels must ensure the confidentiality of the reporting person's identity throughout the management of the report;
- at least one alternative reporting channel capable of ensuring, through IT-based methods, the confidentiality of the reporting person's identity.
- a prohibition on direct or indirect retaliatory or discriminatory acts against the reporting person for reasons directly or indirectly connected with the report.
- within the disciplinary system adopted pursuant to paragraph 2(e), sanctions against persons who breach the measures protecting the reporting person and against persons who intentionally or with gross negligence submit reports that prove to be unfounded.

In light of the legislative changes described above, and on the basis of the guidance contained in Confindustria's explanatory note of January 2018 and the Assonime circular of 28 June 2018, the 231 Model must include a specific Whistleblowing Procedure establishing dedicated channels through which reports based on precise and consistent factual elements can be submitted while ensuring the confidentiality of the reporting person's identity.

The procedure must also take the following measures into account:

- the identification of a system for managing violation reports that makes it possible to ensure the anonymity of the so-called whistleblower;
- specific training for persons in senior positions and persons subject to their direction;
- integration of the disciplinary system established by the 231 Model to include sanctions against persons who breach the measures protecting the reporting person and against persons who intentionally or with gross negligence submit reports that prove to be unfounded.

Subsequently, Italian Legislative Decree No. 24 entered into force on 10 March 2023 with the aim of extending whistleblowing rules by broadening both their subjective and objective scope and the internal channels that the Company must implement.

In light of the legislative changes described above, and on the basis of the guidance provided by the ANAC Guidelines adopted by resolution of 12 July 2023 and Confindustria's Operational Guide of October 2023, the 231 Model must include a specific Whistleblowing Procedure establishing dedicated channels through which reports based on precise and consistent factual elements can be submitted while ensuring the confidentiality of the reporting person's identity.

The procedure must also take the following measures into account:

- the identification of a system for managing violation reports that ensures the confidentiality of the so-called whistleblower;
- specific training for persons in senior positions and persons subject to their direction;
- integration of the disciplinary system established by the 231 Model to include sanctions against persons who breach the measures protecting the reporting person and against persons who intentionally or with gross negligence submit reports that prove to be unfounded.

The Reporting Procedure ("Whistleblowing") is set out in the "Reporting Procedure" document, which describes all available reporting methods.

6.5. Sensitive activity areas, instrumental processes and decision-making process

The decision-making process relating to sensitive activity areas must comply with the following criteria:

- every decision concerning operations within the sensitive activity areas identified below must be documented in writing;

MEDICA

- the person who decides how a process within a sensitive activity area is to be carried out must never be the same person who actually performs and completes that process;
- the persons who decide upon and carry out a process within a sensitive area must never be the same persons who have the authority to allocate the necessary economic and financial resources to that process.

The main sensitive activities and instrumental processes are listed below and are analysed in detail in the Preventive Protocols Manual and the relevant Special Parts.

For offences against the Public Administration and to the detriment of the State (Special Part E):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For offences involving counterfeiting of currency, public credit instruments, revenue stamps and instruments or signs of identification (Special Part F):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For corporate offences (Special Part G):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For offences of receiving stolen goods, money laundering, use of money, assets or benefits of unlawful origin, and self-laundering (Special Part J):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For offences against industry and trade (Special Part M)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)



For transnational offences under Law No. 146/2006 (Special Part K)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For workplace health and safety offences (Special Part I):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For offences against the individual (Special Part H):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For cybercrime and unlawful data-processing offences (Special Part L)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For copyright infringement offences (Special Part N)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For organised crime offences (Special Part O)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For the offence under Article 377-bis of the Italian Criminal Code (Special Part P)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

MEDICA

For offences against the individual (Special Part O):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For the offence of employing third-country nationals whose stay is irregular (Special Part R):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For environmental offences (Special Part Q)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For tax offences (Special Part S):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For smuggling offences (Special Part T):

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)

For offences relating to payment instruments other than cash (Special Part U)

Sensitive macro-activities

(Omitted)

Instrumental processes

(Omitted)



With regard to the other “families” of offences not expressly covered by the individual Special Parts, it has been considered that the specific activities carried out by the Company do not present risk profiles that would make it reasonably likely that such offences could be committed in its interest or to its advantage.

In this respect, reference to the principles contained in this General Part of the Model and in the Code of Ethics is therefore considered sufficient, as these bind the Recipients of the Model to comply with the values of solidarity, ethical conduct, compliance with the law and fairness.

6.5.1. Filing of documentation relating to sensitive activities and instrumental processes

Activities carried out within sensitive activities and instrumental processes are appropriately formalised, with particular reference to the documentation prepared in connection with their performance.

The documentation described above, produced and/or available in paper or electronic form, is filed in an orderly and systematic manner by the functions involved or by the functions specifically identified in detailed procedures or work instructions.

Appropriate security measures are in place to safeguard the Company’s documentary and information assets against risks of loss and/or alteration of documentation relating to sensitive activities and instrumental processes, or unauthorised access to data/documents.

6.5.2. Information systems and software applications

In order to safeguard data integrity and the effectiveness of information systems and/or software applications used to perform operational or control activities within sensitive activities or instrumental processes, or in support of them, the presence and operation of the following are ensured:

(Omitted)

6.6. Management systems and Company procedures

The Company has adopted a formalised set of procedures governing its principal activities, which are available to all employees on the Company intranet.

As a rule, the procedures form an integral part of the management systems adopted by the Company and already described above.

The Company is ISO 9001 certified for quality management.

The Company is ISO 13485 certified for medical device quality management.

For each procedure, the function responsible for drafting, reviewing and approving it has been clearly identified.

The authorisation process to which procedures must be subject before they can be officially issued has also been defined.

6.6.1. Request to create a procedure

A request to issue a procedure may be submitted to Management or, depending on the subject matter of the procedure, by any member of the Company organisation. The appropriateness of issuing a document is assessed by Management together with the manager responsible for the area concerned.

Once the feasibility of the request has been assessed, a negative outcome results in the request being filed or discarded. If the outcome is positive, the person responsible for drafting the document and the person responsible for review/approval are identified and preparation of the document begins.

Once the document has been prepared, the person responsible for drafting it signs a copy and submits it to the person responsible for review/approval. If the latter assesses the document negatively, it is returned to the drafter for the necessary corrections. The process is then repeated until the reviewer/approver gives approval, after which distribution may begin.

6.6.2. Amendments and revisions to procedures

Amendments and revisions to procedures follow the same process as the initial issue of the document. Revision is entrusted to the department that issued the original document.

6.7. System of delegations and powers

The authorisation system, expressed through a structured and consistent system of delegations of functions and powers of attorney, must comply with the following requirements:

- delegations must link each management power to the corresponding responsibility and to an appropriate position in the organisation chart, and must be updated following organisational changes;
- each delegation must specifically and unambiguously define and describe the management powers of the delegate and the person to whom the delegate reports hierarchically;
- the management powers assigned through delegations and their exercise must be consistent with Company objectives;
- the delegate must have spending powers appropriate to the functions assigned;
- powers of attorney may be granted only to persons who have an internal functional delegation or specific appointment and must specify the scope of representative powers and, where applicable, numerical spending limits;
- only persons vested with specific and formal powers may assume obligations towards third parties in the name and on behalf of the Company;
- all persons who have dealings with the Public Administration must hold an appropriate delegation or power of attorney;
- the Articles of Association define the requirements and procedures for appointing the manager responsible for preparing accounting and corporate documents.

MEDICA S.p.A.'s System of Delegations and Powers forms an integral and substantive part of the Model.

All powers assigned by delegation or otherwise exercised correspond exactly to the duties and responsibilities set out in the Company's organisation chart.

6.8. Information and training

6.8.1. Information

To ensure the effectiveness of the Model, MEDICA S.p.A. aims to ensure that all Recipients have an appropriate understanding of it, taking into account their different levels of involvement in sensitive processes.

To this end, MEDICA S.p.A. will disseminate the Model through the following general methods:

- creation of dedicated, continuously updated pages on the Company website, whose content will primarily cover:
 - 1) general information on the Decree and the guidelines adopted in preparing the Model;
 - 2) the structure and main operating provisions of the Model adopted by MEDICA S.p.A.;
 - 3) the reporting procedure to the Supervisory Body and the standard form for persons in senior positions and employees to report any conduct by other employees or third parties that is considered potentially inconsistent with the contents of the Model.

When the Model is adopted, all current employees will receive a communication from the designated Company bodies (e.g. the Chair) informing them that MEDICA S.p.A. has adopted an Organisation, Management and Control Model pursuant to the Decree and referring them to the Company website for further details. The communication will be



accompanied by an acknowledgement of receipt and acceptance to be signed by employees and sent to the Supervisory Body.

New employees will receive specific information on the adopted Model, including a note in the employment letter concerning the Decree and the characteristics of the Model adopted.

6.8.2. Information to external collaborators and partners

All parties external to the Company (consultants, partners, suppliers, etc.) will be appropriately informed that MEDICA S.p.A. has adopted a Model that includes a Code of Ethics. For this purpose, MEDICA S.p.A. will inform all such parties of the website address at which the Model and Code of Ethics can be consulted.

They will also be required to formally undertake to comply with the provisions contained in those documents.

With regard to external consultants who work with MEDICA S.p.A. on an ongoing basis, MEDICA S.p.A. will contact them and, through detailed checks, ensure that they are familiar with the Company's Model and are willing to comply with it.

6.8.3. Information to Group companies

Group companies must be informed of the contents of the Model and of MEDICA S.p.A.'s interest in ensuring that the conduct of all Group companies complies with the Decree. Accordingly, they are notified of the adoption of this Model at the time it is adopted.

6.8.4. Training

The content of training programmes must be reviewed and approved by an external consultant to the Company with expertise in corporate administrative liability under Italian Legislative Decree No. 231/2001 or, more generally, in criminal law, who will also work in coordination with the Supervisory Body.

Formal records of training must be maintained.

Training may generally also be delivered online or, for employees who cannot be reached by computer, through paper-based materials.

6.8.5. Training for personnel in so-called "senior positions"

Training for personnel in so-called "senior positions", including members of the Supervisory Body, is provided through training and refresher courses, with mandatory participation and attendance and a final assessment test, which may also be conducted orally, capable of confirming the quality of the training received.

Training and refresher activities must be scheduled at the beginning of the year. For newly co-opted members of the Board of Directors or newly hired persons in so-called "senior positions", training also includes information contained in the relevant appointment or employment letter.

Training for persons in so-called "senior positions" must be divided into two parts: a "general" part and a "specific" part.

The "general" part must cover:

- legislative, case-law and best-practice references;
- administrative liability of the entity: purpose and rationale of the Decree, nature of the liability and regulatory developments;
- persons to whom the Decree applies;
- conditions for attributing liability;
- description of predicate offences;



- types of sanctions applicable to the entity;
- conditions for excluding or limiting liability.
- Whistleblowing rules and reporting procedure

The following activities will also be carried out during training:

- participants will be made aware of the importance MEDICA S.p.A. attaches to adopting a governance and risk-control system;
- the structure and contents of the adopted Model will be described, together with the methodological approach followed in preparing and updating it.

The “specific” part of the training will focus on:

- a detailed description of each individual offence;
- identification of the possible perpetrators of the offences;
- examples of the ways in which offences may be committed;
- analysis of the applicable sanctions;
- matching each type of offence to the specific risk areas identified;
- the specific preventive protocols identified by the Company to avoid exposure to the identified risk areas;
- conduct to be followed in communicating with and training direct reports, particularly personnel working in Company areas considered sensitive;
- conduct to be followed in dealings with the Supervisory Body concerning communications, reports and cooperation in monitoring activities and updates to the Model;
- raising awareness among managers of Company functions potentially exposed to offence risk and their direct reports regarding the conduct required, the consequences of non-compliance and, more generally, the Model adopted by MEDICA S.p.A.

6.8.6. Training for other personnel

Training for all other personnel begins with an internal information notice which, for new hires, will be provided at the time of recruitment.

Training for persons other than those in so-called “senior positions” must be divided into two parts: a “general” part and a “specific” part, the latter provided where applicable and/or only in part.

The “general” part must cover:

- legislative, case-law and best-practice references;
- administrative liability of the entity: purpose and rationale of the Decree, nature of the liability and regulatory developments;
- persons to whom the Decree applies;
- conditions for attributing liability;
- description of predicate offences;
- types of sanctions applicable to the entity;
- conditions for excluding or limiting liability.
- whistleblowing rules and reporting procedure

The following activities will also be carried out during training:

- participants will be made aware of the importance MEDICA S.p.A. attaches to adopting a governance and risk-control system;
- the structure and contents of the adopted Model will be described, together with the methodological approach followed in preparing and updating it.



The “specific” part of the training will focus on:

- a detailed description of each individual offence;
- identification of the possible perpetrators of the offences;
- examples of the ways in which offences may be committed;
- analysis of the applicable sanctions;
- matching each type of offence to the specific risk areas identified;
- the specific preventive protocols identified by the Company to avoid exposure to the identified risk areas;
- conduct to be followed in communicating with and training direct reports, particularly personnel working in Company areas considered sensitive;
- conduct to be followed in dealings with the Supervisory Body concerning communications, reports and cooperation in monitoring activities and updates to the Model;
- raising awareness among managers of Company functions potentially exposed to offence risk and their direct reports regarding the conduct required, the consequences of non-compliance and, more generally, the Model adopted by MEDICA S.p.A.

With regard to the “specific” part of the training, this will be provided only to persons who are genuinely exposed to the risk of carrying out activities falling within the scope of Italian Legislative Decree No. 231 of 2001, and only in relation to the risk areas with which they may come into contact.

6.8.7. Training of the Supervisory Body

Training of the Supervisory Body is agreed together with an external consultant to the Company with expertise in corporate administrative liability under Italian Legislative Decree No. 231/2001 or, more generally, in criminal law.

This training is intended to provide the Supervisory Body both with a high level of technical understanding of the organisational Model and the specific preventive protocols identified by the Company, and with the tools needed to properly perform its supervisory duties.

This mandatory and monitored training may generally be provided through participation in: 1) conferences or seminars on Italian Legislative Decree No. 231 of 2001; 2) meetings with experts in corporate administrative liability under Italian Legislative Decree No. 231 of 2001 or in criminal law; and, specifically for understanding the organisational Model and the specific preventive protocols identified by the Company, through participation in the training and refresher courses organised for persons in so-called “senior positions”.

Training for the Supervisory Body must include the “general” and “specific” content already described, together with in-depth coverage of:

- independence;
- autonomy;
- continuity of action;
- professional expertise;
- relationships with the corporate bodies;
- relationships with the other bodies responsible for internal control;
- the relationship between implementation of the Model and the other control systems in place within the Company;
- whistleblowing and the management of reports in order to protect the confidentiality of reporting persons;
- reporting on the activities of the Supervisory Body (inspection records, meeting reports, etc.);
- examples of checklists for inspection activities;
- examples of mapping sensitive activities and instrumental processes.

6.9. Sanctions System



The establishment of an effective sanctions system for breaches of the provisions contained in the Model is an essential condition for ensuring the Model's effectiveness.

In this regard, Article 6(2)(e) and Article 7(4)(b) of the Decree provide that the Model must "introduce a disciplinary system suitable for sanctioning failure to comply with the measures indicated in the Model".

Application of disciplinary sanctions determined pursuant to the Decree is independent of the outcome of any criminal proceedings, since MEDICA S.p.A. adopts the rules imposed by the Model and the Code of Ethics autonomously, irrespective of the type of offence to which a breach of the Model or Code may give rise.

In particular, MEDICA S.p.A. uses a sanctions system that:

- is structured differently according to the category of Recipient: persons in so-called "senior positions"; employees; external collaborators and partners;
- precisely identifies the disciplinary sanctions to be applied to persons who commit breaches, infringements, circumventions, or imperfect or partial application of the provisions contained in the Model, in compliance with the relevant National Collective Labour Agreements (CCNL) and applicable legal requirements;
- provides for a specific procedure for imposing such sanctions, identifying the person responsible for imposing them and, more generally, for monitoring compliance with, application of and updates to the sanctions system;
- introduces appropriate methods for publication and dissemination;
- includes sanctions against persons who breach the protective measures applicable to a person who makes a report under the Reporting Procedure ("Whistleblowing"), as well as against persons who intentionally or with gross negligence submit reports that prove to be unfounded.

MEDICA S.p.A. has prepared and implemented the sanctions system in accordance with the above principles. It forms an integral and substantive part of the Model as "Special Part B".

6.10. Information flows to the Supervisory Body

In order for the Supervisory Body to properly perform its functions and duties, adequate information flows to and from the Body must be ensured.

A specific procedure identifies the information that must be communicated to the Supervisory Body; in any event, the following must be transmitted:

- measures and/or information from the Judicial Police or any other authority indicating that investigations are being conducted, including against unknown persons, in relation to offences under the Decree;
- requests for legal assistance submitted by Company executives and/or employees where judicial proceedings are initiated for offences referred to in the Decree;
- evidence of disciplinary proceedings for failure to comply with the provisions of the Model and the related outcomes;
- information concerning judicial and out-of-court disputes relating to offences referred to in the Decree;
- the organisation chart and system of delegations;
- reports prepared by Control and Supervisory Functions/Bodies from which facts, acts, events or omissions may emerge that present critical issues in relation to compliance with the rules of the Decree or the provisions of the Organisation and Management Model.

The same procedure governs:

- the methods for reporting any actual or suspected breach of the Code of Ethics, the Model or the procedures established to implement it;



- the tools available for communications to the Supervisory Body.

The Supervisory Body will also examine communications received anonymously.

The Company adopts appropriate measures to ensure that the identity of persons providing information remains confidential at all times; any form of retaliation, discrimination or penalty against persons who make reports or communications in good faith is prohibited.

Medica reserves the right to take any appropriate action against persons who knowingly make false reports in bad faith.

A breach of the information obligations towards the Supervisory Body set out in this section constitutes a breach of the Model and is therefore subject to the provisions of the sanctions system.

6.11. Reporting to the Corporate Bodies

The Supervisory Body reports annually to the Board of Directors, by means of a written report, on the activities carried out, their outcomes and the preventive effectiveness of the Model.

The Supervisory Body liaises with the Independent Auditors and the Board of Statutory Auditors to examine matters concerning the Model's prevention rules in relation to the control activities performed by those two bodies.

The Supervisory Body may request meetings with the Board of Directors and the Board of Statutory Auditors to report on specific situations concerning implementation and/or effectiveness of the Model or to discuss specific aspects of the Model and its effectiveness.

The Supervisory Body may be convened at any time by the Board of Directors or the Board of Statutory Auditors to report on the operation of the Model or on specific situations.