



**INTEGRA LIFESCIENCES ITALY S.R.L.**

**Model of Organization, Management and Control**  
*(pursuant Italian Legislative Decree 231/2001)*

*[TRANSLATED FROM THE ORIGINAL ITALIAN VERSION]*

Special Part A

**Business Activities Management**

## 1. Special Part Aim

This Special Part aims to define do's-and-don'ts as well as control activities that are required to adhere to and execute whenever operating within activities and process for interactions with sales agents, dealers, healthcare professionals, and our customers. These controls are for the purpose of *i)* preventing the risk of specific "231" relevant crimes commission as well as of *ii)* assuring correctness and transparency in conducting business activities.

In addition, this Special Part aims to provide Supervisory Body and all other control bodies with relevant information to perform their control activities.

Addressees should adhere to each of the extent applicable:

- Model of Organization, Management and Control, General Part;
- Standard of Business Conduct and Ethics;
- Delegation of Authorities in place;
- Each and all other Company and Group documents addressing activities relevant for the Italian Legislative Decree 231/2001 compliance.

In general, all actions and behaviors in violation of existing and valid laws are forbidden.

## 2. Special Part Scope

This Special Part and, specifically, do's-and-don'ts as well as control activities apply to all Integra managers, employees, and other professionals involved in the below listed processes:

- business activities management;
- sales agents management;
- dealers management;
- clinical trials management.

The last-mentioned area, although not related to Business functions (Sales), is included in the present Special Part to consider do's-and-don'ts applied to business personnel (Sales).

## 3. Applicable 231 crimes

231 crimes theoretically applicable to Integra Lifesciences Italy S.r.l. are the following:

- offences against the Public Administration (art. 24 and 25 Leg. D. 231/2001);
- offences connected with organized crime (art. 24-ter Leg. D. 231/2001);
- crimes against industry and trade (art. 25-bis 1 Leg. D. 231/2001);
- corporate offences (including corruption between private parties) (art. 25-ter Leg. D. 231/2001);

- receiving, laundering and using money, goods or benefits of unlawful origin, as well as self laundering (art. 25-octies Leg. D. 231/2001);
- tax crimes (art. 25-quinquiesdecies Leg. D. 231/2001);
- smuggling offences (art. 25-sexiesdecies Leg. D. 231/2001).

#### **4. Do's-and-don'ts**

The company must:

- comply with the laws and principles set out in the Code of Ethics and in this Model;
- operate in compliance with antitrust and competition protection laws;
- use written form for goods and services sales;
- ensure that prices definition and application is carried out according to principles of fairness, transparency and impartiality;
- respect honesty, courtesy, transparency and collaboration criteria providing adequate and complete information, avoiding elusive or corrupt practices or threats and violence aimed at influencing customers' (and in general counterparts') behavior;
- ensure that customers are selected by the competent functions in order to guarantee the respect of integrity, honesty and reliability, as well as financial and equity, in the business relationships management;
- ensure that every sales transaction is properly authorized, verifiable and legitimate;
- ensure that during commercial activities no services other than those required / desired by the counterparty are provided, or that the latter are not in quality or quantity other than declared;
- ensure that the entire customers invoicing process is managed ensuring consistency, correctness and consistency of the amounts invoiced;
- immediately communicate to management any behavior carried out by personnel operating within counterparty, aimed at obtaining favors, illicit donations of money or other benefits, also towards third parties, as well as any criticality or conflict of interest arising in the context of the relationship with client or potential client;
- report any attempts at undue requests by counterparts' representatives;
- make collections exclusively through banking channel;
- carry out agents' selection and contracting activities based on technical, ethical and attitudinal assessments; activities must be inspired by transparency criteria in evaluating competence, professionalism, capacity and potential requirements;
- verify in advance agents' information available in order to establish relationships only with subjects with good reputation, who are engaged only in legitimate activities and whose ethical culture is in line with Company Policy;

- define levels of commissions and bonuses for agents in line with the market and the commercial policies defined by the Company;
- assign to agents commissions and bonuses in line with the contracts concluded;
- verify, prior to payment of invoices, that the services were actually received in accordance with the contractual arrangements;
- liquidate compensations in a transparent way, always documentable and rebuildable ex post;
- comply with the rules defined into expenses reimbursement management.

It is explicitly forbidden to:

- carry out transactions when unfairness and non-transparency elements are suspected;
- give or receive undue payments, which are not adequately justified in the context of the contractual relationship established and the services performed;
- give or receive undue or unjustified (in whole or in part) payments and similar to create black funds or extra-accounting available funds;
- define relationships with people or entities that intentionally do not adhere to the Company's ethical principles;
- promise or give money or other assets to counterparty's representatives in order to obtain advantages for the Company;
- misleadingly behave in order to influence commercial counterparts on technical-economic evaluation over documentation submitted;
- obtain an unfair advantage through illicit commercial practices;
- omit any due information in order to influence the counterpart's decisions in his favor;
- exhibit false or altered documents, or omit information in order to obtain counterparty's favor;
- issue active invoices for services which are wholly or partly non-existent or for amounts other than those provided for;
- create extra-accounting asset funds against transactions contracted at prices higher than the market price or against in whole or in part non-existent invoices;
- abnormally manage the final statements of revenues from sales transactions;
- fraudulently conceal the amount of revenue from sales transactions in order to indicate, in the tax returns on income or in value added tax declarations, assets for an amount lower than the actual one;
- simulate a negotiating relationship through the use of altered documentation or other fraudulent means in order to achieve undue savings in tax expenditure;
- issue and use fiscal relevant documents in relation to fictitious services (both objectively and subjectively), or services actually rendered but indicated with a consideration or value / quantity which is not true;

- pay, promise or offer, directly or indirectly, improper payments or other undue benefits to public officials, to public service representatives or to any private third party with whom the Company relates (or to people close to them), with the aim of promoting or favoring the interests of the Company or benefitting it;
- offer, or just promise, money or other benefits as remuneration for an illegal intermediation activity carried out by a third party that has existing or even alleged relationships with a public official;
- give or promise money or other benefits, directly or indirectly, also in competition with others, to Public Administration Officers (e.g. responsible for administrative proceedings), or to medical personnel, in order to obtain awarding of the tender;
- submit to the Public Administration modified documents (altered, forged, omissive of relevant data and information) in order to participate in tenders for which the Company does not possess the requisites required by the tender invitation;
- agree with subjects belonging to a mafia criminal organization in order to use intimidation power and illegitimately gain a tender;
- select agents that are close to or suggested by Public Administration Officers or other counterparts with whom Company has commercial relations, or pay them a higher fee, in order to obtain favorable treatment for the Company or create income availability to be used for corruptive purposes;
- promise collaboration or increases in fee / bonuses as an award to activities not in line with law and internal rules and regulations;
- make payments to agents that are not based on adequate justification or use agents in order to pay, promise or offer, directly or indirectly, improper payments or other undue benefits to third parties, with the aim of promoting or favoring the interests of the Company or benefitting it;
- bribe a co-promoter company employee, who concludes corrupt agreements with doctors during visits, aimed at manipulating the documentation related to the tender preparation or management;
- select or use dealers close to or suggested by Public Administration Officers or other counterparties with which the Company has commercial relations; apply to the latter unjustifiably higher prices, in order to create income availability to be used for corruption purposes;
- have any conduct aimed at facilitating the avoidance of payment of due border duties.

With reference to behavioral principles to be adopted in the management of relations with Public Administration Officers, in relation to the registration and reimbursement of local formulary or during institutional events, please refer to the Special Part "Public Administration Relations Management".

In addition to the above, the principles of behavior and the provisions on the matter listed in the Confindustria Medical Devices Code of Ethics and MedTech Europe Code of Ethics, as well as laws, regulations (e.g.: ECM Regulation) must be observed.

## 5. Business Activities Management

Here follows control activities to be put in place within Business Activities process. It should be noted that with specific reference to commercial offers, some of the control activities below may not be applicable.

### Tenders and Commercial Offers Management

- Tenders and other commercial opportunities monitoring are carried out by Tender Function and sales force headed by (Regional / National) Division Sales Managers/Directors;
  - tenders are submitted for review and approve by the appropriate individuals including customer service;
- Annually, price lists are reviewed and updated.
- Discounts are required to be documented, reviewed and approved prior to being offered to customers;
- technical offer is prepared by the Product Specialist, Marketing Function and Regulatory Function for what concerns their competence or (if not present for the Division) by the competent Division personnel (Sales);
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- all tenders and supporting documentation are stored on a shared folder in which access is restricted to authorized individuals.

### Contracts Management

- Commercial relationships and sales conditions are formalized with the Commercial Offer Acceptance;
- the contract is signed and approved by the parties, in line with delegated authorities and powers of attorney;
- contracts / commercial offers are provided with clauses on Italian Legislative Decree 231/2001 knowledge and compliance (or other similar regulations applicable to the counterpart) including the knowledge of the Code of Ethics and Organizational Model adopted by the Company, as well as the consequences in case of violation of the statement;
- all relevant documentation, highlighting process and critical decision, must be duly digitally archived in the shared folder.

### Customer Master file

- With reference to new customers' first registration, or in case of subsequent changes, the Head of Administration / Division Assistant is responsible for sending the "New Customer Form" module to the customer, who is responsible for providing the requested information (e.g. personal data, VAT number, contacts, payment terms, currency, address of shipment, etc.);

### Order management

- Global Business Services (GBS) Organization: Customer Service Function processes the customer order within Integra's management information system- ER;
- with reference to the request for delivery of equipment in loan of use, the staff of GBS checks the order of consumable material as well as the loan for use agreement countersigned by the customer;
- sales orders are documented in Oracle and orders can only be placed once a customer purchase order is received;
- delivery and consequent movements within the system are managed by warehouse department and by the competent Group Functions;
- all relevant documentation, highlighting process and critical decision, must be duly archived by the competent function.

## **6. Sales agents management**

This section summarizes the processes and controls in place for selecting and onboarding new sales Agents.

- Agents' selection is under competent (Regional / National) Division Sales Manager responsibility;
- Regional / National Division Sales Manager is responsible for filling out the "Intake Form" with the selected agent's data;
- all agents are subject to due diligence (e.g. checks on identification data, judicial and financial information such as balance sheet and credit risk, etc.). Agents are required to complete a Due Diligence Questionnaire through Securimate;
- the sales agent is not considered to be approved until Compliance approves the due diligence questionnaire.
- Compliance investigates any potential conflicts and red flags that may be identified through the screening process and in the Due Diligence Questionnaire.
- Once the due diligence is approved, the sales managers fill out the template of contract and obtain the appropriate approvals of the contract in accordance with the related process;
- Corporate Sales Operations staff, following the preparation of a specific form for suppliers by the sales intermediary, records into the Agent Master Data new agent data, in line with information made available by (Regional / National) Division Sales Manager, after Legal Function information verification;
- Sales agents cannot place sales orders until they are approved and have a fully executed contract agreement.

### Contracts drafting

- Agents relations are managed with regular contracts signed off by personnel in line with delegation of authorities and powers of attorney;
- agency contracts are drawn up based on standard templates;

- agency contracts expressly specify that agents may not have any power of representation in the name and on behalf of the Company and therefore cannot directly negotiate sales contracts;
- agency contracts provide an express declaration by the agent to be aware of and comply with the legislation pursuant to Legislative Decree 231/2001, of never having been involved in legal proceedings relating to offenses contemplated in it and to commit to compliance with the Code of Ethics adopted by the Company, as well as the consequences in case of violation of the statement.

#### Commissions / fees calculation and management

- Commissions / fees are calculated based on the revenue provided;
- commissions are calculated automatically by the Group's management information system;
- commissions check is managed by Corporate Sales Operations Department;
- approval is given by the competent (Regional / National) Division Sales Manager;
- all relevant documentation, highlighting process and critical decision, must be duly archived by the competent function.

## **7. Distributors and sub-distributors management**

Below is a summary of the process and controls for engaging with intermediaries (i.e. distributors, sub-distributors, etc.):

- The Company appoints distributors who operate as partners responsible for the purchase of Integra products and their subsequent resale to hospitals and clinics through contract or tender process;
- distributors are selected on the basis of knowledge and curriculum vitae;
- all distributors are subject to internal due diligence to verify their reliability;
- Compliance and Trade Compliance review and approve all due diligence with intermediaries;
- If red flags are identified, the flags are reviewed by Compliance. If they cannot be cleared during the review process, Compliance will work with sales management to determine next steps (i.e. rejection, termination of services with distributor, monitoring, etc.);
- relations with distributors are managed by means of regular contracts (DAL) usually regulating the minimum purchase quantities, the products allocated and the area / hospitals of reference for distribution;
- contracts with distributors are provided, where possible, with contractual clauses that bind the distributor to the knowledge and compliance with the regulations referred to in Legislative Decree 231/2001 (or other similar regulations applicable to the counterparty), the Code of Ethics and the Model adopted by the Company; the clause also provides for the consequences in case of violation;
- sales to distributors should be conducted in accordance with the terms outlined in the DAL and should not occur if the distributors does not have an active DAL;



- the purchase of goods by distributors and their invoicing is carried out in accordance with the principles of control provided for the process of Business Management and General Accounting Management.

Moreover, control measures that must be put in place in dealers management process are the same as those mentioned in the previous paragraph “sales agents management”.

With reference to other aspects (e.g. pricing, contracts, orders) management, please refer to the paragraph dedicated to the “management of business activities”.

## 8. Clinical Trials management

In Integra Lifesciences Group, sponsored clinical trials (including the *Investigator Initiated Study*) are centrally managed, through a dedicated platform (IIS), by the Corporate Clinical Affairs Department, in compliance with Headquarter procedures. Sales and marketing are prohibited from being involved in the IIS reviews. All IIS's are reviewed and approved by the IIS committee, which is comprised of Medical Affairs and Research and Development.

If an institution intends to carry out a clinical study with Integra, it submits the research protocol via the IIS platform and attaches the detailed budget including costs. The protocol is sent to the IIS Committee for analysis and validation. If Integra decides to activate the clinical study project, this will be exclusively managed by the Corporate Clinical and Medical Affairs teams.