

## **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 C** 

**Market Access Management** 



## 1. Special Part Aim

This Special Part aims to define do's-and-don'ts as well as control activities that all Addressees are required to adhere to and execute whenever operating within activities and process listed in subsequent chapter 2, 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 its 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 detailed in subsequent chapters, apply to all Integra managers, employees and other professionals involved with the processes related to "Market Access Management", and particularly to "Reimbursement and local formulary recording management".

#### 3. Applicable 231 crime

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

- offences against the Public Administration (artt. 24 and 25 Leg. D. 231/2001);
- corporate offences (including corruption between private parties) (art. 25-ter Leg. D. 231/2001);
- violation of copyright and other related rights (art. 25-novies Leg. D. 231/2001);
- tax crimes (art. 25-quinquiesdecies Leg. D. 231/2001).

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

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

In addition to the above, the behavior principles and the regulation listed in the Confindustria Medical Devices Code of Ethics and the MedTech European Code of Ethics must be observed.



#### 5. Healthcare Economics and Reimbursement

Here follow the control activities to be put in place within Healthcare Economics and Reimbursement.

- The activity related to the registration and reimbursement submission of Integra Lifesciences medical devices in local formulary is coordinated by the Market Access Department;
- Market Access Department prepares the necessary documentation for request submission by using *i*) clinical evidence, *ii*) hospital observational studies results and similar and *iii*) dissemination material and other relevant documentation prepared at central level and in compliance with the procedures of Group (e.g.: economic evaluation data);
- any translations, modifications, elaborations or integrations of such material are carried out by the
  Market Access Department, with the support of certified consultants and translators;
- consultants selection is carried out by the Market Access Department, in compliance with the provisions of the Special Part "Procurement management"; for the selection of HCPs, please refer to the Special Part B "Marketing and Scientific Dissemination Management";
- costs recognition and invoices management is under the responsibility of the Corporate Finance Function or, for the share of local costs, of the local Finance and Administration Function;
- Division Sales staff supports the Market Access Department in carrying out the abovementioned activities;
- all the relevant documentation, highlighting process and critical decision, must be duly archived by the competent function.