

ORGANISATION, MANAGEMENT AND CONTROL SYSTEM D.LGS. 231/2001

Legislative Decree 8th June 2001, nr. 231

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0. INTRODUCTION

Roelmi HPC S.r.l., property of Roelmi Holding, was born by the fusion of 4 Companies expert and active in the Cosmetic, Nutraceutical and Pharmaceutical (Medical Device) fields. They put together their knowledge and synergies to satisfy all the national and international customers' needs.

- **Brasca:** it is active in the market since 1946, produces Functional Ingredients for the Cosmetic field and is specialized in the production of waxes, acrylates (rheology modifiers), natural origin ingredients and performance products.
- **Principium:** it was born in 2010 as R&D Company of Active Ingredients from bio fermentation, conjugation and ultrafiltration for the Cosmetic market. In 2012, it enlarges its offer with nutraceutical and food ingredients, proposing to its customers IN and OUT solutions. Principium main goal is the guarantee of ingredients with high efficacy title.
- **Bioscontrol:** was born as Brasca' spin off in order to support the customers in the protection of their formulations with the use of tailor made combinations and unconventional synergies. Bioscontrol guarantees technical and formulator support in the launch of their products on the market.
- **Elementi:** known in the market since several years as Formulation Company of cosmetic products. Great competence and knowledge of the market allow Elementi to be the ideal partner of all those companies without internal R&D or that needs small productions. Its competences make it fundamental in ROELMI process of growth, as it is the first customer for all the ingredients.

The purpose of the fusion is to take advantage of the synergies and competences of the previous single companies, offering innovative technologies and "tailor made" solutions. The aim is to provide the highest level of quality, respecting the safety of the end users.

The union of the competences and synergies allows accessing Multinationals that see in Roelmi the ideal partner to support their projects.

Roelmi HPC decided to organize its sales in "vertical", creating Business Unites and maintaining the existing brands of the previous companies, as already strong on the market. The union and synergies of the four companies allow covering the production and formulation needs of the customers.

Roelmi HPC decided to take charge of the engagement of environment and people safety, creating the NIP brand (No Impact in Progress) that means the daily effort of improving the Supply Chain by using non-edible sources, soft processes and renewable resources.

1. AIM AND FIELD OF APPLICATION

This document describes the Organization and control Model to prevent violations of the principals Corporate Administrative liability (D. Lgs. 231/01 adopted by the Company).

The Company adopted this Model to reach the fundamental goal to put in place the principals, processes, policies, procedures and behavior rules in order to respect the Decree to prevent any violation.

2. RELEVANT LEGISLATION

The model of Organization and control adopted by Roelmi HPC has below reference points:

- D.Lgs. 8/06/2001, n. 231.
- ISO 9000:2015 *“Quality management systems – Fundamentals and vocabulary”*.
- *“E.R.M.. – Enterprise Risk Management”*.
- D.Lgs. 81/08.
- ISO 9001:2015 Quality System.
- D.Lgs. 196/2003.
- UNI ISO 31000 *“Risk Management – Principles and Guidelines”*.
- ISO 19600 *“Compliance management systems – Guidelines”*.
- Any other normative reference cited in this document.

3. TERMINI E DEFINIZIONI

For the purposes of this document, apply the terms and definitions of ISO 9000:2015 and ISO 31000, In addition to those mentioned below.

TERM	DEFINITION
CODE OF ETHICS	Set of rights, duties and responsibilities of the Organization towards third parties interested, and to promote, recommend or prohibit certain behaviors beyond and independent of regulatory provisions.
D.LGS. 231/01	Legislative Decree 8 June 2001, no. 231 and subsequent modifications and integrations.
DISCIPLINARY SYSTEM	Disciplinary system referred to in article 6, paragraph 2, point e) of Legislative Decree 231/2001.
SENIOR MANAGERS	The entities referred to in article 5, subparagraph a) of Legislative Decree 231/2001.
PERSONS SUBJECT TO THE DIRECTION OF OTHERS	The entities referred to in article 5, subparagraph b) of Legislative Decree 231/2001.
CORRECTIVE ACTION	Set of coordinated activities aimed at eliminating the causes of non-compliance detected.
RISK ANALYSIS	Organization-specific analysis tasks aimed at detecting the activities which can be committed crimes.
ORGANIZATIONAL MODEL	Structures, responsibilities, of how to carry out activities and protocols/procedures adopted and implemented through which you carry out the characteristic activities of the organization.
NON-COMPLIANCE	Failure to meet specified requirements.
ORGANIZATION	Group, company, Corporation, firm, Enterprise, authority or institution, or parts thereof, or combinations, in a partnership or not, public or private, that has its own administrative and functional structure.
SUPERVISORY BODY	The body referred to in article 6, paragraph 1, point b) of Legislative Decree 231/2001.
DOCUMENTED PROCEDURE	Document describing the responsibilities, tasks and how they should be conducted. Such a document should be prepared, approved, implemented and updated.
PROCESS	Set of related tasks or interacting which transform input into output.

PROTOCOL	Specific method, and used to perform a task or process.
REVIEW	Activities carried out to encounter the suitability, adequacy and effectiveness to achieve the objectives set.
RISK	Effect of uncertainty on objectives.
LEVEL OF RISK	Size of a risk, expressed in terms of the combination of consequences and likelihood.
RISK ASSESSMENT	Process which includes the identification, analysis and the risk weighting.
RISK TREATMENT	Risk modification process.
RESIDUAL RISK	Risk that remains after treatment.

4. ORGANIZATION CONTEXT OF THE COMPANY

4.1 UNDERSTANDING THE STRUCTURE AND ITS CONTEXT

The Company evaluated the analysis of the risks and implemented the Model of organization and control considering the internal and external problems that are relevant for its purpose and that act on its capacity to reach the goals of efficiency and operative efficacy, as well as reliability of the administrative and financial information compared to the Laws and Regulations.

In details, the factors that have been taken in consideration are:

- The dimensions, the structure and the system of proxy.
- The places and fields in which the company acts or expects to act.
- The nature, dimensions and complexity of the activities and Company's operations.
- The business model of the Company.
- The Parties on which the Company have control.
- The applicable Laws and any other normative and contractual obligation or duty.

4.2 UNDERSTANDING OF THE NEEDS AND EXPECTATIONS OF THE PARTIES

The Company identified and periodically analyzes the relationships with the "Stakeholders", represented by individuals or groups that influence or are influenced by all the activities carried out by the Company.

The periodical analysis of the relationships with the "Stakeholders" is essential to evaluate the risk exposure areas and the risk of committing a violation within Legislative Decree 231/01.

4.3 PURPOSE AND FIELD OF APPLICATION OF THE MODEL

The Company defined the borders and the field of application of the Model, by considering:

- The internal and external matters, as per point 4.1.
- The requirements of the involved Parties, as per point 4.2.
- The results of risks evaluation.

4.4 THE MODEL

The company is sensible to the need of ensuring the accuracy and transparency conditions of its own activities and business activities, as well as ensuring its position, image and expectations and therefore decided to apply the Model of Leg. D. 231/01.

This venture is linked to the Model as optional and not compulsory tool of consciousness towards to those who act in the name of and on behalf of the Company, with the purpose of carrying out their own activities with correct and linear behaviors that may prevent the risk of committing violations or offences.

The Board of Directors have entrusted the task of monitoring the principals of operation and efficacy of the Model to the Surveillance Body, as per Leg. D. 231/01.

5. LEADERSHIP

5.1 LEADERSHIP E ENGAGEMENT

The Board of Directors and the Top Management showed leadership and commitment as per the Model in order to:

- Make all the workers trained, informed and aware to conduct their activities with conformity to the Model, and to undertake their responsibilities in case of violations.
- Be constantly and positively ready to improve and prevent any violations.
- Provide the Human Resources and tools necessary for the efficient operation of the Model.
- Make the whole Company structure active, according to everyone's proper competences, to reach the objectives and goals under below requirements:
 - a) The methods and organization aspects are put in place to prevent any violation in the activities in which the Company acts.
 - b) All the workers are informed, aware and constantly updated on the risks, upon everyone's role.
 - c) Action and reaction during working activities must be quick, efficient and meticulous.
 - d) Cooperation, participation and consultation between the Workers must be encouraged.
 - e) All the applied Laws and Rules, as well as the Company' standards, must be respected.

- Make the Model alive and in continuous improvement, as it is not a result but a starting point.
- Put the Model in place in a reliable and complete manner, according to a constant monitoring program.
- Each Worker needs to be well identified according to the Company's policy and objective, with a clear idea of everyone's role and individual responsibility.
- Strengthen the trainings and awareness of the employees with the purpose of carrying out their tasks in compliance with the Model.
- Put in place the measures necessary to prevent the situations of risk and prevent any violation.
- Keep an open relationship with the suppliers, making them aware of the importance of keeping ethically correct behaviors.
- Organize controls, inspections and Audits in order to prevent any non-conformity situation according to the Model.
- Develop and keep open relationships with Local authorities and all the involved parties.

5.2 ETHICAL CODE

The company composed, and keep updated and propagate the "**Ethical Code**", formalizing rights, duties and responsibilities of the Structure towards to internal and external relationships and to the pursued goals.

The Ethical Code is integral part of the Model, and is one of the elements used by the Company to ensure an efficient activity of prevention of violations.

The Company ensure that the Ethical Code:

- Is appropriate according to the Structure.
- Is given and well understood within and outside the Structure.
- Is re-examined to ensure the continuous eligibility.
- Is approved by the Board of Directors.

5.3 ROLES, RESPONSIBILITIES AND AUTHORITIES OF THE COMPANY

The Company enlighten and formalized the responsibilities and the roles of the actors involved in the Model.

The Board of Directors defined powers of attorney, authorities, responsibilities and tasks within the Company, ensuring the coherency and adequacy to the Model. In particular, the Company arranged Organigrams, Job Descriptions, Processes Descriptions, in order to provide the following information:

- Hierarchical and functional relationships between the different roles in the Structure.
- Process objectives.
- Processes in which the mansion is performed.
- Activities and tasks typical of the mansion within the process.
- Control Chains.

- Representative and authorized powers (powers of attorneys, authorities, responsibilities).

The Applied general criteria put in place is linked to a separation of the functions and division of the roles, in order to have as much as possible different actors that “do”, “evaluate” and “approve” within each process and department.

5.3.1 SURVEILLANCE ENTITY

Legislative Decree 231/01, article 6, paragraph 1, point b), requires that the task of supervising the operation of and compliance with the organizational, management and control model as well as its updating is entrusted to a body of the company, equipped with autonomous powers of initiative and control. Roelmi Hpc has identified as the most suitable entity to perform the functions of OdV: Dott.ssa. Daniela Bruno, *Camosci Guareschi Piantanida & Associati*, Corso Magenta, 85, Milan, odv231@roelmihpc.com.

5.3.1.1 REQUIREMENTS AND POWERS OF THE SURVEILLANCE BODY

The Surveillance Entity must:

- Have its own Statute.
- Be autonomous and independent.
- Be adequately professional.
- Have adequate resources.
- Do continuative action.
- Be in the position to report directly to the Board of Directors without hierarchical binds that may affect an autonomous judgement.
- Be able to get information from and to each level and division of the Structure.
- Be able to propose eventual sanctions for those actors that haven't respected the regulations of the Model.
- Be addressee of compulsory information channels.
- Be able to plan and pursue compulsory information channels.
- Be in the position to plan and put in place Audits focused on the Model.

5.3.1.2 THE SURVEILLANCE BODY TASKS

The activities of the Surveillance Entity are based on Leg. D 231/2001, art. 6 and 7, and are:

- Surveillance on the efficiency of the Model and the coherence of the related behaviors.
- Put under scrutiny the Model and its real capacity of prevent inadequate behaviors.
- Analysis of the continuative maintenance of the parameters of solidity and functionality of the Model.

- Continuative renewal of the Model, in case of the performed analysis reveal the necessity of corrections and modifications.

The operative instructions of above points are listed in a “**Guideline of Surveillance Entity**”.

5.3.1.3 THE STATUTE OF THE SURVEILLANCE BODY

The Board of Directors of the Company approved the “Statute of the Surveillance Entity” that establishes:

- The mandate of the Surveillance Entity and the rules for the eventual re-election, plus the hypothesis of revocation.
- The possibility to get external actors or consultants, in case the Surveillance Entity needs them.
- In relation to potential conflict of interest with the Organization, which may be a member of the Supervisory Board, reporting to the Board of Directors and any other control authorities of the situation of potential or actual conflict of interest, with respect to an operation at risk or category of business at risk.
- The Surveillance Entity statement that declares:
 - Relative, conjugal or kin relationship within the 4th grade with the members of the Board of Directors, auditors or revisers, plus apical actors in the Structure.
 - Direct or indirect titles ownership of the Entity that may represent a dominant influence on the Structure, as per article 2359 c.c.
 - Administrative functions with powers of attorney within the Structure.
 - Previous working experiences in the Public institutions within 3 years before the nominee of membership in the Surveillance Entity.
 - Legal sentences of any responsibility in Italy or abroad for crimes listed in the Leg. D. 231/2001, or similar.
 - Legal sentences or legal responsibilities that implicate a ban, even temporary, from Public Institutions, Legal Entities and Endeavors.

6. PLANIFICATION

6.1 ACTIONS TO FACE RISKS AND OPPORTUNITIES

The ability to preserve and create value without compromising the Company reputation depends on the inclination of the Companies to identify, evaluate, handle and monitor the risks related to the strategies and activities put in place.

For this reason, the Company established, implemented and keeps updated the “**Map of the high risk Areas**”, in order to punctually and continuously identify the risks and evaluate the best measures of control.

The procedures for the identification and evaluation of the risks have taken in consideration:

- The processes and activities that influence the Model.
- The highlighted risks that originated outside the Structure, with the high potential of causing situation of danger for the put in place of the Model.
- Infrastructures, plants and materials in the working areas.
- Changes in the Structure.
- Modifications, even temporary, and their impact on the operations, processes and activities.
- The active Legislation and any other legal obligation linked to the evaluation of the risks and the implementation of the necessary measures of control.

The company keeps the “**Map of the high risk Areas**” updated with the results of the risks identification, evaluation and controls.

6.2 CHANGES HANDLING

Every change in the Company is pre-emptively evaluated, re-considering the “**Map of the high risk Areas**” as well.

The change is handled when refers to:

- Technological introduction and/or modifications, including software, tools, activities guidelines and general standards.
- Introduction of sensible changes in the Structure and/or in Suppliers’.
- Introduction of new legislative dispositions and/or prescriptive requirements.
- Episodes of serious violations of the Model.
- Results after investigations on the violations of the Model.

7. SUPPORT

7.1 RESOURCES

The Company identified and provides the necessary resources for:

- The put in place, maintenance and continuous improvement of the Model.
- Guarantee the activities of the Surveillance Entity.

7.2 COMPETENCY

Roelmi Hpc:

- Determined the competences of the employees, necessary to work under its control and that may influence the Company performances.
- Guarantees that the employees are competent thanks to a proper education, training or experience.
- If necessary, acts to get and maintain the necessary competences, and evaluates the efficiency of these actions.
- Maintains appropriate documentation proving such competences.

7.3 AWARENESS

The company regularly provides adequate and appropriate awareness and training on MOG 231 to staff. This training addresses the following issues, depending on the case, taking into account the results of the risk assessment pursuant to Legislative Decree 231/01:

- Ethical code, procedures of the company and the MOG 231 and the obligation to respect them.
- The risks related to their function and damage caused to the organization.
- The circumstances where risks may occur in relation to their tasks, and how to recognize such conditions.
- The contribution that each one can give to the effectiveness of the MODEL 231.
- The implications and the potential consequences of non-compliance with the requirements of MOG231.
- How and to whom to communicate any issues.
- Information on training activities and other resources available.

Staff awareness and training activities are provided on a regular basis and at scheduled intervals depending on the roles, risks related to the function and all reasonably foreseeable circumstances. Awareness and training programs are periodically updated as necessary to reflect any relevant updates.

The company maintains documented information on the procedures for the formation and content thereof.

7.4 COMMUNICATION

The Company, fixed appropriate communication channels, based on the Surveillance Entity, in order to:

- Ensure internal communications between different levels and different functions of the Structure about the Model, to ease the understanding of the critical situations of some operations by the relevant employee.
- Receive, register, reply to the requests and signalization related to the requirements of the Model, coming from the parties outside the Company.
- Define how the Structure communicates to its suppliers, its consultants and any other third party, the way to handle the requirements of the Model and the way to register any decision on the topic.

7.5 DOCUMENTED INFORMATION

7.5.1 GENERALITY

The Model concretize a pyramidal system of principals, described as below:

- The present “**Model**” and the **Ethical Code**: these documents resume the main principals inspiring the daily activities.
- The protocols and procedures to regularize the activities of the Governance Entities and Employees, introduce specific rules in order to avoid situations of violation risk, as per Leg. D. 231/2001.
- The **System of Internal Control (SCI)** for the Operative Units: is the set of tools that guarantee to reach efficiency and efficacy of Financial and Managing information compared to laws and regulations, plus safeguard of the Company assets and properties against eventual frauds.
The SCI bases on some general principals, clearly defined with a link to the applicative field and then it extends athwart all the other levels.
- The **Disciplinary System**, fundamental aspect of the Model, reports adequate sanctions against violation of the rules and models defined to prevent the violations.

7.5.2 CREATION AND UPDATING

When creating and updating the recorded information, the company guarantees appropriate parameters for:

- Identification and description.
- Format and support.
- Revision and approval.

The Surveillance Body is in charge of promoting the updates and adjustments of the Organization and Control Model (as well as the Code of Ethics), by recommending to the administrative authority, or to the involved corporate departments, the necessary and appropriate amendments.

The Board of Directors, together with the involved corporate departments, is responsible for the update and adjustment of the Model in case of changes in the corporate structure or operative processes, significant violations of the Model, legislative integrations.

Such updates and adjustments (also involving the related Protocols) are conveyed to the Surveillance Body via email and, if necessary, through informative sessions.

7.5.3 CONTROL OF THE RECORDED INFORMATION

The recorded information significant for the Organization and Control Model are controlled in order to let them:

- Be available and suitable for usage, where and when necessary.
- Be adequately safeguarded (from privacy and integrity loss, improper usage)

In order to control such information, the company has to take into consideration the following activities:

- Distribution, access, usage and retrieval.
- Storage and conservation (in particular, conservation of readability).
- Change control.
- Recording and disposal.

The recorded information coming from an external source, that the company considers as essential for the planning and functioning of the Organization and Control Model, must be identified as appropriate to the purpose and managed in a controlled way.

8. OPERATIONAL ACTIVITIES

8.1 OPERATIONAL PLANNING AND CONTROL

The company plans and develops processes, their related activities and the associated operations in order to identify dangers for which it is necessary to apply control measures for risk control.

For these operations and activities, the Organization implements and maintains active the operational controls, to the extent applicable to the Organization and to its activities. For this purpose, verified protocols have been arranged (procedures, instructions or check-lists) for every process considered as sensible for the purposes envisaged by the Organization, Control and Management Model, in order to manage situations in which their absence could cause discrepancies with respect to the Ethical Code and to the Model itself.

All the Addressees of the Organization, Control and Management Model must comply with the controls defined by the Company and any failure to comply with it is reported to the attention of the Supervisory Board. In particular, the Company has mapped and planned the operational processes which are more

sensitive to the offence cases referred to in D.Lgs 231/01 and to the related processes having the functions of monitoring and control.

Therefore, during the mapping and the analysis of the process flows, for every process and activity, as far as possible, the following elements are identified:

- Responsibility: who is the “Process Manager” and which are the involved figures, at different responsibility levels, in the single activities of the process.
- Input elements.
- Output Elements.
- Eventual “best-practice” or “warnings” related to particular behaviors to avoid.
- Performance indicators of the process and of the related objectives.
- Typology and modality of information to transmit to the Supervisory Board under Article 6 comma 1, let. B, ex D.Lgs 231/01.

The output elements of this planning, included the necessary registration to provide evidence, are adequate according to the operating way of the Organization. 9. VALUTAZIONE DELLE PRESTAZIONI

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

The Company plans and implements processes of monitoring, measurement, analysis and improvement in order to ensure compliance to the current Organization, Control and Management Model and constantly improve its efficacy.

The Company has determined:

- What must be monitored and measured.
- The methods for the monitoring, measuring, analyze and the evaluation as the case may be, in order guarantee valid results.
- When monitoring and measurement must be performed.
- When the results of the monitoring and measurement must be analyzed and evaluated.

The Organization, therefore, evaluates the performances and the efficiency of the Organization, Control and Management Model and the compliance with the applicable regulation.

This process ensures the systematic and timely verification of the compliance of the company with the mandatory requirements, with a particular reference to the cases of which at the D.Lgs 231/01.

9.2 INTERNAL AUDITS

The Society, through Surveillance Body and the support of qualified third parties, periodically carries out internal audits to determine if Organization, Management and Control Model is efficaciously employed and kept in compliance with what has been planned.

Management of audit process refers to the standard **UN EN ISO 19011:2012** “Guidelines for Management system audits” and includes procedures of scheduling, planning, execution and reporting of audit.

An “Annual program of internal audit” is organized and it takes into account the status and importance of the processes and the areas to be examined, as well as results of previous audits.

9.3 RE-EXAMINATION BY BOARD OF DIRECTORS

Society carries out a specific procedure for management of re-examination and update of its own Organization, Management and Control Model. Such procedure applies to Surveillance Body too, limited to its tasks, with particular attention to the compliance of the Model itself, upon re-examination of its adequacy and efficacy.

Re-examination and update of Organization, Management and Control Model takes into account:

- Results of audits carried out on Organization, Management and Control Model
- Cases of accidents and non-conformities, including violations of Code of Ethics and offences, as provided by D.Lgs 231/01
- Evolution of regulatory framework, starting from categories of offences provided by D.Lgs. 231/01, of relevant case law and applicable guidelines.
- Significant changes in company structure (ownership, organization, economic and financial aspects, administration, infrastructure).

Accordingly, Surveillance Body makes an overall evaluation on the outstanding adequacy of MOG 231 and relative proposal of update with particular attention to:

- Code of ethics.
- Risk evaluation.
- Management procedures and relevant process of monitoring.
- Disciplinary system.
- Organizational Structure.

The Company commits to proceed with prompt adjustment of the Model in case:

- New significant offences for the Company would be introduced in D.Lgs. 231/01
- Significant variations to the organization and/or to system of delegations and powers

- Company starts new activities that may lead to commit offences from what provided by D.Lgs. 231/01 and subsequent modifications.
- Deficiencies of Model 231 emerge, such as to suggest immediate adjustment 10. CONTINUOUS IMPROVE

10.1 NON-CONFORMITY AND CORRECTIVE ACTIONS

The Company puts in place a specific process to handle all those events that may entail violations as per Leg. D. 231/01, Ethical Code violations included.

Furthermore, the Company has planned and put in place a specific process to handle the non-conformities coming from the inobservance of the applicable requirements to the control measures, including Company Policies, procedures, and operative instructions.

All the non-conformities are reported punctually and immediately to the Surveillance Body, who investigates and finds out the problems. By this way, the Surveillance Body may propose corrective actions and eliminate the source of the non-conformity.

Thus, in case of non-conformity, the Company:

- Promptly reacts to the non-conformity.
- Eliminates the source to avoid reiteration, if approved by the Surveillance Body.
- Puts in place every necessary action under supervision of the Surveillance Body.
- If necessary, modifies the Model.

The corrective actions put in place to eliminate the existing causes of non-conformity (external sources included), and any other undesirable situation that needs to be prevented from reiteration have to be appropriate. The Company keeps the documented proves:

- Of the nature of the non-conformity and following actions put in place.
- Of the corrective actions results.

The corrective actions are based on an activity plan, responsibilities and timings, beyond an impacts evaluation on the other Company processes.

10.2 CONTINUOUS IMPROVE

The Company continuously improves the suitability, adequacy and efficacy of the Model, using the Ethical Code, the Audits results, the analysis of the data, the corrective actions, the re-examination of the Board of Directors defining the most suitable and measurable objectives.