

# INTEGRATED MANAGEMENT SYSTEM POLICY

MQI\_5.2.A1 - Rev. 3 - 12/10/2021

## **Dedalus Italia S.p.A. con Socio Unico Dedalus Finance GmbH**

**Sede Legale:**  
Via di Collodi 6/c  
50141 Firenze

**Tel.** +39 055 42471  
**Fax** +39 055 451660  
reception@dedalus.eu

**Capitale sociale:**  
€ 11.634.062 i.v.  
R.E.A. Firenze 591564

Codice fiscale, partita IVA  
e registro imprese  
05994810488



## **TABLE OF CONTENTS**

<b>1</b>	<b>GENERAL ELEMENTS ON THE INTEGRATED MANAGEMENT SYSTEM POLICY</b>	<b>3</b>
1.1	Objectives of Dedalus	3
1.2	Contents and parts of the Integrated Management System Policy of Dedalus	3
1.3	Parts of the Integrated Management System Policy of Dedalus	3
<b>2</b>	<b>POLICY FOR OVERALL QUALITY, SERVICE MANAGEMENT AND MEDICAL DEVICE MANAGEMENT</b>	<b>4</b>
2.1	Standards applicable to the section	4
2.2	Applicable principles	4
2.3	What to do to put these principles in practice	4
<b>3</b>	<b>INFORMATION SECURITY MANAGEMENT POLICY</b>	<b>6</b>
3.1	Standards applicable to the section	6
3.2	ISMS key principles	6
3.3	What to do to put these principles in practice	7
<b>4</b>	<b>ENVIRONMENTAL POLICY</b>	<b>7</b>
4.1	Standards applicable to the section	7
4.2	Applicable principles	7
4.3	What to do to put these principles in practice	8
<b>5</b>	<b>OUR CORE VALUES</b>	<b>8</b>



# 1 GENERAL ELEMENTS ON THE INTEGRATED MANAGEMENT SYSTEM POLICY

## 1.1 Objectives of Dedalus

The goal of Dedalus is to consolidate its role as a leader in the global Health Care Systems market.

## 1.2 Contents and parts of the Integrated Management System Policy of Dedalus

To reach this goal, Top Management of Dedalus Group has defined this **Integrated Management System Policy** for the whole organization.

The policy **contains the strategic elements** that are the keys to maintain an effective and efficient:

1. Quality Management System (**QMS**) built on **ISO 9001** standard
2. Service Management System (**SMS**), built on **ISO/IEC 20000-1** standard
3. Information Security Management System (**ISMS**), built on **ISO/IEC 27001**
4. Environmental Management System (**EMS**), built on **ISO 14001** standard
5. Quality Management System for Medical Devices (**MDQMS**) built on **ISO 13485** standard

## 1.3 Parts of the Integrated Management System Policy of Dedalus

Top Management of Dedalus Group ensures that this policy:

- is **appropriate to the purpose and context of the organization** and supports its strategic goals;
- provides a **framework for setting goals** for all applicable management systems;
- includes a **commitment to meet the applicable requirements** of all management systems, including mandatory and contractual requirements, and to continually **improve the management systems and their effectiveness**;
- is **available** as documented information;
- is **communicated, understood, and applied** within the organization;
- is made available to relevant stakeholders;



- is **reviewed** periodically for continued suitability.

## 2 POLICY FOR OVERALL QUALITY, SERVICE MANAGEMENT AND MEDICAL DEVICE MANAGEMENT

### 2.1 Standards applicable to the section

This section of the IMS policy refers specifically to the requirements of **ISO 9001, ISO/IEC 20000-1, and ISO 13485.**

### 2.2 Applicable principles

Top Management strongly believes that the adoption of an IMS results in great benefits in terms of value for our customer and of internal organization improvements, and it has defined the Quality Policy of Dedalus Group, that is built on these **principles**:

- Guarantee and constantly improve **customer satisfaction**, meeting their expectations and complying with **product and service requirements** in order to become a reliable and strategic partner for them;
- Ensure that **customers receive real value through** the delivery of Dedalus Group **services** and the adherence to defined Service Level Agreements;
- Develop **continuous improvement in the quality of our products, services**, and in the Quality System **effectiveness**;
- **Promptly respond to market** developments through a flexible, highly competent and worldwide competitive organization;
- Achieve and constantly maintain the **compliance of our medical devices with all the regulatory requirements** of the markets where we sell;
- **Involve the entire staff** in processes, supporting them to constantly **grow on their skills** and encouraging them to feel and act as a fundamental part for the quality system and for the continuous improvement of the organization, its products and services.

### 2.3 What to do to put these principles in practice

The implementation of this policy involved the activation of the following **actions**:



## MQI\_5.2.A1 INTEGRATED MANAGEMENT SYSTEM POLICY

- defining and specifying the **responsibilities, roles, tasks** for the different phases of the processes;
- developing **internal rules** that have been taken on as organizational, procedural and operational reference standards in the management of activities;
- **prevent** the occurrence of **non-conformities** during the performance of processes;
- identify and record non-conformities, promoting the activation of appropriate **corrective actions** and the consolidation of the solutions adopted;
- Promote the **development** of the **skills of professional resources**, promoting integration and collaboration between internal organizational areas and activating permanent training actions;
- enhance the **value of the know-how** possessed, activating the dissemination of good practices and pursuing their optimization in order to make common heritage, working methods and acquired experiences;
- ensure the promotion of the **focus on the customer** throughout the organization, as well as the integrity of the management system itself.

Dedalus Top Management has established appropriate **internal communication** processes such as, for example, through the company website, e-mail, newsletters, video conferences, physical and virtual meetings/meetings between work groups, tools and instruments for sharing information with the utmost respect for the security of such information.

For **external communication** the following tools are basically used: advertising, production of brochures and informative documentation about the organization, websites, organization of events, press office activities, participation in events, knowledge sharing portals, company areas specifically dedicated to experimentation and involvement of customers and stakeholders in knowledge development processes.



## 3 INFORMATION SECURITY MANAGEMENT POLICY

### 3.1 Standards applicable to the section

This is the part of the IMS policy which is specifically referred to ISMS and to the requirements of **ISO/IEC 27001** standard.

### 3.2 ISMS key principles

In our ISMS information is a strategic asset and it is of vital importance to ensure and preserve confidentiality, integrity and availability of all handled data (the so-called "RID" paradigm), according to the requirements of ISO/IEC 27001.

The main principles for the ISMS of Dedalus Group are:

- the **confidentiality** of the information managed: it has not to be made available or disclosed to unauthorized individuals, entities, or processes;
- the **integrity** of the information managed, e.g., that data and information are protected from unauthorized modifications;
- the **availability** of the managed information assets, so that information is always accessible by authorized users when it is necessary;
- **compliance** with all the applicable mandatory, regulatory and contractual requirements, with particular reference to the ones of **GDPR** (EU Regulation 2016/679), and all the specific privacy regulations applicable to the markets here we work, as Dedalus processes data, including sensitive data;
- the design, realization and maintenance of effective **business continuity plans** for all the processes that are critical for business and for the management of the information security;
- ensure adequate **training of personnel** on information security and on the applicable privacy regulations;
- guarantee the prompt and careful **management of all** information security possible **violations** and of the identifiable weak points, in order to promptly detect, fully investigate and manage them, to improve continuously the ISMS and ensure regulation compliance.



### 3.3 What to do to put these principles in practice

In order to guarantee the concrete application of these key principles, Dedalus Group has defined and keeps up-to-date its **objectives for information security**, as described in its ISMS.

Dedalus Group has defined the criteria for the **evaluation of information security risks**, considering the strategic value for the organization of the application of the ISMS, the expectations and perceptions of the interested parties (stakeholders) and the possible image damage for the company that could result from an incorrect management of this very important area.

Dedalus Group is aware that information security is not just a product/technological system to be purchased, but is a very **complex cultural process** that must involve all of the human and organization resources of the company.

For this reason, Top Management is committed to continuously meet the applicable and relevant information security requirements according to ISO/IEC 27001:2013 and to ensure the **continuous improvement** of the ISMS itself.

## 4 ENVIRONMENTAL POLICY

### 4.1 Standards applicable to the section

This is the part of the IMS policy which is specifically referred to EMS and to the requirements of **ISO 14001** standard.

### 4.2 Applicable principles

The environmental impacts of the work processes and activities of Dedalus Group are very low, as we are a service company; however, the company's management believes it is very important that the **organization's activities** are performed with a focus on protecting and **respecting the environment, preventing pollution and minimizing the environmental impacts due to energy consumption and carbon footprint**, as well as **the importance of commitment to green design of ICT infrastructures.**

To this end, the IMS has also been developed to ensure the continuous reduction of the impact on the environment that the organization's activities may have, in accordance with the requirements of ISO 14001.

The general **goals** of our EMS are:



## MQI\_5.2.A1 INTEGRATED MANAGEMENT SYSTEM POLICY

- Ensure **compliance with** and continued **adherence to applicable legislative** and contractual **requirements** that impact the **environment**;
- **Continuously improve the environmental performances** of the organization's processes in terms of reducing their impact on the environment, lowering the energy consumption, reducing Dedalus carbon footprint, commit to green design of ICT infrastructures, as well as preventing and minimization the pollution directly or indirectly associated to the organization processes.

These general objectives are then detailed from year to year through specific targets, which may include, for example, the following: reducing impacts related to travel for business activities, increasing environmental sustainability in offices and encouraging sustainable purchasing, reuse and recycling, and finally promoting a reduction in the amount of emails sent.

### 4.3 What to do to put these principles in practice

These objectives become concrete through formal **plans** to reduce environmental impacts, **environmental targets** fixed in accordance to them and **periodical checks** on their achievement.

The EMS is first of all targeted on the own organization of Dedalus Group, where the actions taken can have the highest impact, but as far as possible Dedalus Group aims also to promote consistent and environmentally conscious behaviour **of all its suppliers, customers and stakeholders** in general.

## 5 OUR CORE VALUES

We strongly believe that in order to achieve real quality at 360 degrees, each of us must adopt the following principles on a daily basis:

- **act with determination**, because quality and customer satisfaction are obtained only through concrete actions, with a constant commitment and a deep sense of responsibility of everyone of us;
- get it **right the first time**, with the aim of meeting product and service requirements, including applicable regulatori requirements;
- be **prompt in responding** to incidents and react with a **desire to remove** the real **cause** of it;





## MQI\_5.2.A1 INTEGRATED MANAGEMENT SYSTEM POLICY

- act by implementing **careful and continuous prevention**, just as we do when our own interests are at stake;
- **be always aware of the repercussions** that **our actions** and decisions have on the other part of the organization;
- **consider as a "Customers" the colleague who receives the result of our work**: in fact customers are not only the end users, but also our colleagues, other departments in the organization and our external collaborators; we have to do our best to give them the best inputs, because if everyone of us do it this way, the overall result will be excellent and always the very maximum possible
- be aware that **poor adherence to** the product and service **specifications creates a high cost** for the organization, in terms of the need to fix products or **re-deliver services** and in terms of **loss of image in the market**.

We believe that **competitive advantage** is firmly linked to **intellectual capital and** innovative business **organization**: we think that the most interesting minds are those that know how to unleash their imagination, ask new questions and find answers, face challenges and plot a new path for those who follow.

We believe that a successful business organization should be based on the **passion of** its people, on a continuous and effective internal communication, on the **tension to problem solving**, on the goal to produce **value and satisfaction** for its stakeholders and **the customer** in particular: in short, we want to be a strategic and irreplaceable partner and not just a simple supplier for our customers.

### The TOP MANAGEMENT of DEDALUS ITALIA spa