

# CODE OF CONDUCT OF THE DEMETRA GROUP

## Summary

<b>Executive Statement</b> .....	4
<b>Definitions</b> .....	5
<b>Introduction</b> .....	5
What the Code of Conduct is and to whom it applies .....	5
What to do when in doubt? .....	6
<b>Reports</b> .....	6
How to make a report .....	6
Confidentiality of the reporter .....	6
Zero tolerance for retaliation and reports made in bad faith .....	6
<b>Our vision, mission and values</b> .....	7
Mission .....	7
Vision .....	7
Demetra Values .....	7
Sustainability .....	7
Environment .....	7
Human Rights .....	8
<b>Ethical business conduct</b> .....	9
<b>Compliance with applicable laws</b> .....	9
Why it is important .....	9
What we expect from Demetra Representatives and our Third Parties .....	9
<b>Public and private stakeholder interactions</b> .....	9
Why it is important .....	9
What we expect from Demetra Representatives and our Third Parties .....	9
<b>Political contributions</b> .....	9
<b>Anti-corruption policy</b> .....	10
Why it is important .....	10
What we expect from Demetra Representatives and our Third Parties .....	10
<b>Relations with Third Parties</b> .....	10
Why it is important .....	10
What we expect from the Demetra Representatives .....	10
What we require from our Third Parties .....	10
<b>People and working environment</b> .....	11
Why it is important .....	11
The Demetra Commitment .....	11
What we expect from Demetra Representatives and our Third Parties .....	11

<b>Health and Safety</b> .....	12
Why it is important .....	12
Demetra's commitment .....	12
What we expect from Demetra Representatives and our Third Parties .....	12
<b>Data privacy</b> .....	12
Why it is important .....	12
Demetra's commitment .....	12
What we expect from the Demetra Representatives and our Third Parties .....	12
<b>Competition and antitrust policies</b> .....	13
Why it is important .....	13
Demetra's commitment .....	13
What we expect from Demetra Representatives and our Third Parties .....	13
<b>Confidential information, corporate assets and intellectual property</b> .....	13
Why it is important .....	13
Demetra's commitment .....	13
What we expect from Demetra Representatives and our Third Parties .....	13
<b>Intellectual Property</b> .....	14
<b>Product Safety and Quality</b> .....	14
Why it is important .....	14
Demetra's commitment .....	14
What we expect from Demetra Representatives and our Third Parties .....	14
<b>Interactions with Health Professionals, Health Organisations and Patient Associations</b> .....	15
Why it is important .....	15
Demetra's commitment .....	15
<b>Interactions with Health Professionals</b> .....	15
<b>Product Promotion</b> .....	16
<b>Events and conferences</b> .....	16
<b>Meals and hospitality</b> .....	16
<b>Relations with Patient Associations, Expert Patients and Caregivers</b> .....	16
<b>Donations and gifts</b> .....	17
<b>Research and development</b> .....	17

## Executive Statement

Dear all,

**Demetra's** Mission inspires our work every day. Improving the lives of people all over the world is a big commitment because we protect and improve one of people's most cherished assets: health. We are active all over the world and want to make our technology more and more accessible, sustainable and state-of-the-art for doctors and patients alike.

We achieve our ambition through our Values, which, although declined in different ways in the companies of the group, allow us to always act according to the ethical principles that **Demetra** considers fundamental to live up to our Mission.

The **Code of Conduct**, in addition to our Values by which it is in any case inspired, is an important contribution to the making of decisions, large or small, and to the assumption of behaviours that have an impact on the Group. Our **Demetra Code of Conduct** gives concreteness, together with the Values, to our identity and fully expresses the sense of our Mission, helping us to reflect on the choices to be made in the interest of **Demetra** and of the scientific progress that we pursue every day.

Therefore, we read our **Code of Conduct** carefully and disseminate it to all those who work for **Demetra** in any capacity. Knowledge, application and dissemination of our Values and our **Code of Conduct** is how we will make a difference in improving the lives of many people around the world.

Enjoy your reading,

Denis Faccioli

Chairman

Demetra Holding S.p.A.

## Definitions

**Code of Conduct (also the “Code”):** this Code of Conduct adopted by Demetra Holding S.p.A. applies to both Demetra Representatives and Third Parties acting for the companies of the Demetra Group

**Board of Directors (also “BoD”):** the Board of Directors of Demetra Holding S.p.A.

**Customers:** public or private entities that purchase products and services from Demetra Group companies.

**Competitors:** Third Parties offering similar services or goods on the market as those offered by Demetra Group companies.

**Demetra Holding S.p.A. (or also “Demetra Holding” or “the Company”):** Demetra Holding S.p.A. having its registered office in Corso Monforte 16, 20121 - Milan (MI), Italy.

**Demetra Representatives (also Demetra Representative in the singular):** employees, managers, directors and members of the Board of Directors of Demetra Holding S.p.A., as well as of the companies controlled by and affiliated with the Demetra Group.

**Addressees:** the persons to whom the provisions of this Code of Conduct apply, i.e. Demetra Representatives and Third Parties working for companies of the Demetra Group.

**Demetra Group (or also “Group” or “Demetra”):** Multinational group operating in the medical devices sector consisting of Demetra Holding S.p.A. and its subsidiaries or associated companies, to which this Code of Conduct applies.

**Healthcare Organisations (also “HCO” or “Healthcare Organization”):** Any legal person or entity (regardless of legal form or organisation), association or healthcare, medical or scientific organisation through which one or more Healthcare Professionals provide services or which is able to exercise a direct or indirect influence on any prescription, recommendation, purchase, order supply, use, sale or rental of medical technology and related services. Examples: hospitals, central purchasing offices, clinics, laboratories, pharmacies, research institutes, associations, foundations, universities, scientific societies or other educational or professional institutions. Also included in this definition are Patients’ Associations, i.e. organisations representing and advocating for the needs of patients and their supporters (caregivers) within a specific disease or health aspect.

**Healthcare Professionals (also “HCPs”, “Healthcare Professionals” or “Healthcare Workers”):** are those who carry out their professional activity in the healthcare sector (e.g. doctors, nurses, laboratory staff, technicians, administrative staff within healthcare facilities, etc.) in the public and/or private sector, who in the course of their professional activity have the power, directly or indirectly, to purchase, hire, recommend, manage, use, supply, procure or determine the purchase, hire or prescription of medical technologies or related services.

**Stakeholders:** persons interested, directly or indirectly, in the conduct of business activities by the Demetra Group or its companies.

**Third Parties:** Third Parties (by way of example but not limited to suppliers, consultants, agents, distributors, agents and external collaborators) who perform activities in favour of the companies belonging to the Demetra Group.

## Introduction

### What the Code of Conduct is and to whom it applies

The present **Code of Conduct** defines the ethical principles and values considered essential for **Demetra** and to which all Addressees must adhere in the performance of their activities. The Code applies to all Recipients, whether they are **Demetra Representatives** themselves, such as employees (including temporary staff), managers, directors or external parties such as suppliers, consultants, agents, distributors or, more generally, **Third Parties** operating on behalf of **Demetra**. The **Demetra Representatives** and **Third Parties** have the personal responsibility to operate in compliance with applicable laws and all provisions of the **Code of Conduct** and the specific policies and procedures applicable to them aimed at regulating, operationally, their activities.

## What to do when in doubt?

**Demetra** is committed to ensuring that any doubts can be addressed in an open, safe and transparent manner.

In the event that a **Demetra Representative** or a **Third Party** is faced with making decisions or carrying out activities that could give rise to doubts as to their correctness and compliance, the principles of this **Code of Conduct** must always be taken into account in assessing whether the choice/activity:

- Be in line with the contents of this Code, the procedures and policies applied;
- Be in line with **Demetra's** values and mission.

In any case, in case of doubt, you can contact your compliance officer or write to the Group Compliance Function at: [esmeralda.filippini@tecre.it](mailto:esmeralda.filippini@tecre.it)

## Reports

### How to make a report

In the event that a **Demetra Representative** becomes aware of, or has reasonable suspicion of, a breach of this **Code of Conduct**, he or she must report it promptly; the possibility of reporting is also open to **Third Parties** working with companies of the **Demetra Group**.

Reports can be sent:

- To the relevant compliance officer;
- To the Group Compliance Officer by email: [esmeralda.filippini@tecre.it](mailto:esmeralda.filippini@tecre.it)
- Through the Whistleblowing information platform, accessible 24/7, whose references can be found on the websites of the individual Group companies.

Anonymous reports can also be made through the platform.

### Confidentiality of the reporter

**Demetra**, through the reporting channels mentioned above, ensures and guarantees the confidentiality, also by means of anonymisation tools, of the reporter.

### Zero tolerance for retaliation and reports made in bad faith

**Demetra** will not tolerate any form of retaliation in connection with reports made in good faith.

By way of example, the following conduct will not be tolerated:

- Termination of contract, downgrading or non-employment;
- Reduction or change in pay, work duties, hours or shifts;
- Denial of benefits, privileges or promotions;
- Harassment, threats or other negative behaviour.

Retaliatory behaviour against bona fide whistleblowers will result in disciplinary action, which may include dismissal. Reporting a problem in good faith or providing information about a problem reported by others will have no negative consequences.

Please note that any unfounded reports made with malice or gross negligence will also be subject to sanctions in accordance with the applicable labour laws and internal procedures and, in the case of **Third Parties**, through the application of specific termination clauses as well as a claim for damages.

# Our vision, mission and values

## Mission

**Demetra Holding S.p.A.** is at the head of a multinational group operating in the medical device sector and invests in people as a key element in the conception, development, manufacture and marketing of innovative and avant-garde products aimed at improving people's lives.

## Vision

**Demetra's** ambition is to attract the best talents to build, and innovate, an offer that is a reference point in the bone cement sector, and not only, in order to improve, today and in the future, the quality of life for an ever-increasing number of people through the innovativeness, quality and effectiveness of our products.

## Demetra Values

**Demetra** embraces "Excellence, Trust and Reliability" as inspiring values for the actions and conduct of the **Demetra Representatives** and indispensable conditions for the realisation of the Group's Mission, Vision, and objectives.

- **Excellence:** the pursuit of excellence in every internal and external activity of the group is a fundamental element in our daily work to offer the best to our customers and patients
- **Trust:** every action and decision is based on the principles of respect and honesty – this guarantees the group ethically integral, professional and collaborative relationships.
- **Reliability:** anticipating and responding to the needs of patients, customers, collaborators drives us more and more to invest considerable resources to be always up to the mark.

## Sustainability

**Demetra's** commitment to sustainability is based on reconciling and balancing environmental, social and governance (ESG) activities in order to generate value in the name of sustainable development according to standardised and shared parameters.

**Demetra** therefore operates with the aim of creating a better and healthier world that has an increasingly positive impact on **Demetra Representatives**, the community and the environment.

**Demetra's** mission drives all its member companies and **Demetra Representatives** to constantly innovate while safeguarding the health of people, the community and the planet; to do this, **Demetra** guarantees the adoption of governance tools that ensure the achievement of sustainable goals.

## Environment

**Demetra** promotes environmental sustainability and the principles behind it as indispensable conditions for the preservation of ecosystems and the containment of negative environmental consequences of production activities.

It is necessary to comply with the Environmental Sustainability Policy aimed at promoting environmental sustainability. In particular, **Demetra** is committed to:

- Ensuring the necessary dissemination and training on environmental sustainability issues and related policies;
- Optimising the use of natural resources and reducing their consumption;
- Promoting waste recycling and re-use, as well as proper waste disposal;
- Reducing carbon emissions through careful and regular volume assessment;
- Complying with local environmental protection laws and regulations and the legislation governing activities in the field of environmental sustainability, depending on where **Demetra** companies operate.

## Human Rights

At **Demetra**, respect for others and their sensitivities is a fundamental requirement to guide the behaviour, actions and activities of the **Demetra Representatives**. **Demetra** adheres to the United Nations Universal Declaration of Human Rights and has identified behavioural guidelines aimed at improving the quality of life and reaffirming the importance of honesty and trust in every interaction between colleagues, superiors and **Third Parties**, as well as in the design and development of products intended for Health Professionals and Patients. The principles applied can be summarised as follows:

Diversity and Inclusion	<b>Demetra</b> hires personnel from all over the world in the belief that only the contamination of different cultures and skills is a source of success at work.
Prohibition of child labour	<b>Demetra</b> prohibits the employment of minors, subject to applicable labour law restrictions.
Working conditions	<b>Demetra</b> condemns any treatment detrimental to the dignity of the person, contrary to professional ethics and local and international labour law.
Discrimination	<b>Demetra</b> promotes a culture of equal opportunities and stigmatises all forms of discrimination on ethnic, religious, sexual orientation and other grounds.
Relationships with colleagues	<b>Demetra</b> condemns any behaviour designed to humiliate and/or intimidate, as well as any form of physical and/or verbal violence.
Compliance with contractual regulations	<b>Demetra</b> respects labour law and promotes training sessions for <b>Demetra Representatives</b> .
Trade Union Rights	<b>Demetra</b> respects and protects the right to join trade union organisations in accordance with local regulations and the employment contract.
Health and safety	<b>Demetra</b> is committed to protecting the health and safety of <b>Demetra Representatives</b> in all Group companies and non-compliance and/or violation of the relevant regulations is subject to reporting.
Alcohol and drugs	<b>Demetra</b> does not approve of the use and consumption of alcoholic beverages in the workplace, as well as the use or abuse of drugs and other substances that may cause harm to the <b>Demetra Representatives</b> and their performance, as well as to the reputation of the Group.

# Ethical business conduct

## Compliance with applicable laws

### *Why it is important*

**Demetra** requires compliance with the applicable laws, regulations and compliance standards of each country in which it operates. Compliance with the regulations applicable to us is a prerequisite for providing quality service and for guaranteeing the accessibility of our products.

### *What we expect from Demetra Representatives and our Third Parties*

We expect everyone to act in compliance with applicable laws, regulations and compliance standards, and to conform their conduct and actions to the applicable regulations in order to carry out their respective activities and interactions within and outside the companies of the Group without compromising the integrity and reputation of **Demetra**. In particular, non-compliance with the requirements set forth herein by **Demetra Representatives** and **Third Parties** entails the application of sanctions that may lead, depending on the relationship with **Demetra**, to dismissal or contractual termination.

## Public and private stakeholder interactions

### *Why it is important*

**Demetra** is aware of the *stakeholders'* expectations, needs and interest in the Group's business and activities, and believes it is appropriate to have and maintain high ethical, compliance and quality standards, as well as nurturing an ongoing dialogue to inform them, within the applicable legal limits, about new products, technologies introduced and related products. The ability to meet the needs of *stakeholders* must be up to the mark, whether they are public or private.

### *What we expect from Demetra Representatives and our Third Parties*

Each of us must be able to live up to the expectations of our *stakeholders* by orienting all interactions towards the values of respect, honesty and trust, in order to be a guarantee of reliability and integrity.

The **Demetra Representatives** must share data and information based on true and documented facts in order to contribute to innovation in the medical technology sector and to improve access to therapies by supporting, in compliance with the law, the need to adopt effective public policies. Only **Demetra Representatives** expressly and specifically designated and appointed by the competent functions may have relations with Public Administration Bodies.

The provision of unauthorised information to *stakeholders* is prohibited, as it could damage the integrity of **Demetra**. In addition, all **Demetra Representatives** and **Third Parties** shall make decisions not affected by conflicts of interest that may undermine the relationship of trust with *stakeholders*.

## Political contributions

**Demetra** encourages its corporate representatives to take part in community activities that may be political in nature. Company funds or assets may not be used as resources for political contributions, nor may reimbursements be made for contributions to political parties, candidates or activities.

## Anti-corruption policy

### *Why it is important*

**Demetra** will not tolerate any form of corruption, whether active or passive and/or in favour of a public or private subject. Corrupt acts damage the integrity and sense of trust placed in **Demetra** with repercussions on the accessibility of care by Patients.

### *What we expect from Demetra Representatives and our Third Parties*

As **Demetra**, we expect each **Demetra Representative** and **Third Party** to reject, not promise or offer goods in cash or in kind for the purpose of influencing or conditioning **Third Parties** in their responsibilities, decisions, activities and interactions, and to be guided solely by the values of excellence, trust and reliability for the maintenance of integrity and appropriate conduct, as well as in compliance with national and international laws and regulations.

Acts of courtesy are to be regarded as valid provided they comply with local regulations and do not entail a non-negligible advantage for those receiving them.

## Relations with Third Parties

### *Why it is important*

**Demetra's** success also depends on the reliability, integrity and competence of the **Third Parties** with whom it works; **Third Parties** who must share **Demetra's** values and mission to contribute to the implementation and innovation of quality healthcare.

### *What we expect from the Demetra Representatives*

The **Demetra Representatives** appointed and responsible for selecting and interacting with **Third Parties** must operate free from any personal ties or influences that might profile the risk of a conflict of interest, even if only potential.

**Third Parties** must be selected according to objective criteria aimed at ascertaining their competence, integrity and consistency with the standards and principles that govern and inspire our behaviour, relationships and professional activities. To this end, it is necessary to

- Respect the rules and procedures governing the selection process;
- Ensure the application of Third Party qualification processes based on risk assessment;
- Assess and verify possible conflicts of interest by taking appropriate mitigation measures;
- Operate in full compliance with the legal provisions of the country in which the Group companies and Third Parties operate;
- Formalise relations with Third Parties by adopting clauses requiring them to comply with the principles and values considered essential for **Demetra**;
- Ensure internal authorisation processes consistent with the types of supplies and the organisational structure applied, aimed at assessing both the technical and compliance aspects of Third Parties as well as the economic appropriateness of the fees paid to them;

Ensure processes to ensure the effectiveness of the services, in terms of goods and services, provided by **Third Parties** with which **Demetra** operates;

### *What we require from our Third Parties*

**Third Parties** that interact and cooperate with **Demetra** are required to guarantee integrity, fairness and professionalism. We expect our **Third Parties** to become familiar with the provisions and contents of this Code, and to act in accordance therewith; the same obligations apply in the event that, where permitted by **Demetra**, such **Third Parties** require the support of sub-contractors or consultants for the performance of activities in favour of **Demetra**.

## People and working environment

### *Why it is important*

**Demetra** cares about creating an inclusive, stimulating environment that respects people and their rights.

Integrity, loyalty, capability, professionalism and dedication of people are primary values for **Demetra**, which enable it to make a difference in achieving its goals and mission.

### *The Demetra Commitment*

**Demetra** makes respect for human rights and a policy of sustainability its concrete commitment to improving the quality of life of **Demetra Representatives** by helping them pursue professional fulfilment and personal satisfaction.

**Demetra** is committed to creating and maintaining conditions conducive to listening to and enhancing the skills and competences of **Demetra Representatives** by fostering meritocracy while respecting equal opportunities.

No form of bullying, harassment or discrimination or evaluation based on criteria related to race, sex, psycho-physical handicaps, religion, political orientation and any other aspect that is not based on meritocratic criteria is allowed.

**Demetra** does not tolerate any form of irregular work and, in compliance with the Conventions of the International Labour Organisation, the Company is committed to the respect of fundamental human rights, to the prevention of child exploitation and not to use any form of forced labour or work performed in conditions of slavery or servitude; therefore, all relations with personnel must be managed in compliance with labour, tax, social security and insurance regulations, as well as immigration and health and safety provisions on workers.

### *What we expect from Demetra Representatives and our Third Parties*

The **Demetra Representatives**, aware that the dignity of the person and inclusiveness are fundamental principles for **Demetra**, are required to maintain a respectful, professionally and ethically correct behaviour, ensuring compliance with the principles and values identified by the Code and the applicable legislation; the same commitment is required of the **Third Parties** working with **Demetra**.

The **Demetra Representatives** also have the duty to personally contribute to creating a working environment where there is respect for the sensitivities and dignity of others and must expressly and constantly take into account respect for the person, his or her dignity and values, avoiding any discrimination based on gender, racial and ethnic origin, nationality, age, political opinions, religious beliefs, state of health, sexual orientation, economic and social conditions.

## Health and Safety

### *Why it is important*

Ensuring the protection of the health and safety of staff and **Third Parties** is an essential condition to enable those who work at **Demetra** to perform their activities to the best of their ability and to pursue excellence in the objectives it has set itself.

### *Demetra's commitment*

**Demetra** undertakes to identify and implement procedures and processes to identify, prevent and mitigate health and safety risks and to enhance the monitoring and management of risks inherent in the activities to be performed. **Demetra** also operates in accordance with applicable health and safety provisions.

### *What we expect from Demetra Representatives and our Third Parties*

All **Demetra Representatives** are expected to maintain conduct in compliance with health and safety regulations and to contribute to the identification of risks, their prevention and mitigation in order to maintain a safe and environmentally friendly environment in which to operate. The **Demetra Representatives** are required to make proper and punctual use of the equipment and safety devices made available to them for the protection of themselves, their colleagues and **Third Parties**.

Similarly, **Third Parties** shall operate in compliance with applicable regulatory requirements by adopting behaviour aimed at risk mitigation and protecting the health and safety of their employees.

## Data privacy

### *Why it is important*

The collection, analysis and protection of data is a fundamental requirement for **Demetra**, also with a view to the realisation of products and services that best meet the needs of patients.

### *Demetra's commitment*

**Demetra** undertakes to respect and protect the personal data collected, whether they relate to **Demetra Representatives** and/or external parties.

Compliance with legal requirements regarding privacy, such as the General Data Protection Regulation (GDPR) issued by the European Union or other applicable national or international regulations, is a prerequisite for **Demetra**; to this end, **Demetra** implements control measures that comply with national and international legislative requirements.

### *What we expect from the Demetra Representatives and our Third Parties.*

As **Demetra** we expect the **Demetra Representatives** in matters of data privacy:

- Handle sensitive personal and health data in compliance with local and international laws, professional associations' codes of ethics, procedures and applicable contractual obligations;
- Protect personal data in accordance with identified security tools and safeguards;
- Ensure the management of consents in compliance with the regulations.

Similar obligations apply to **Third Parties** working with **Demetra**.

## Competition and antitrust policies

### *Why it is important*

Competition is an important stimulus for innovation and the creation of a product range that is ever broader, competitively priced and best suited to the needs of the markets and business areas where **Demetra** operates.

### *Demetra's commitment*

**Demetra** believes in the principles of the free market and stigmatises practices or agreements aimed at restricting or preventing fair and free competition and at conditioning the operators and users of the relevant market. **Demetra** believes in the quality of its products as the main and lawful lever through which to compete with other competitors.

### *What we expect from Demetra Representatives and our Third Parties*

All **Demetra Representatives** and any **Third Parties** involved in the conduct of business must operate in compliance with all applicable antitrust and competition laws.

They are also prohibited, by way of example:

- Agreements or understandings with competitors, customers or Third Parties aimed at restricting competition and free trade;
- Agreements or understandings with customers aimed at restricting competition as to the prices to be charged for **Demetra** products or the prices that customers will charge for resale;
- Exchanges of confidential information on prices or other data with competitors;
- The abuse of a dominant market position;
- Any other conduct that could lead to an infringement of competition law.

**Demetra Representatives** must be available, cooperative and proactive towards the antitrust authorities in case of inspection visits.

## Confidential information, corporate assets and intellectual property

### *Why it is important*

Stakeholders rely on the professionalism of **Demetra** and its ability to conduct its business in an ethical, safe, efficient and effective manner. **Demetra**, therefore, is committed to the protection of information considered confidential, the improper use and/or disclosure of which would risk harming or compromising the management of business activities, the achievement of objectives, the integrity of the Group, of the **Third Parties** with whom we collaborate and/or of our Clients and Patients.

### *Demetra's commitment*

**Demetra** ensures the application of processes aimed at the identification of information considered 'confidential' as well as the adoption of tools and technical safeguards aimed at their protection.

The communication of confidential information to Competitors, external parties or persons within the Company who do not have a legitimate business need to know it is strictly prohibited.

Company assets such as equipment, plant and electronic instruments that enable the production of **Demetra** branded goods must be adequately stored and secured against loss, theft, damage and destruction.

### *What we expect from Demetra Representatives and our Third Parties*

The **Demetra Representatives** are obliged to take all necessary actions to protect and guarantee the confidentiality of information and to preserve and maintain the tangible and intangible assets owned by **Demetra**.

The **Demetra Representatives** are obliged to protect information considered "confidential" in compliance with the indications provided in this Code, and in the policies and procedures adopted by **Demetra**; this obligation also extends to any **Third Parties** who, for business reasons, become aware of confidential information provided by **Demetra**.

As **Demetra**, we expect proprietary assets (e.g., equipment, machinery and technology equipment) to be used and

maintained with the diligence of a good family man and to be used for business purposes only, unless otherwise instructed by **Demetra**; these obligations also extend to **Third Parties** in the event that **Demetra**'s business assets are provided to them.

With respect to technological tools, which may contain confidential information, **Demetra Representatives** must take all necessary precautions against loss, theft, damage and destruction. Such precautions include:

- The use of access passwords for data protection;
- The obligation not to leave devices unattended or without an access lock;
- The obligation to comply with the applicable data security provisions and the applicable **Demetra** procedures.

## Intellectual Property

**Demetra** owns and uses trademarks, patents, copyrights and trade secrets vital to the business success.

To protect the company rights, the use by **Demetra Representatives** of such intellectual property must comply with all applicable laws. **Third Parties** are not permitted to use our trademarks or other intellectual property without prior authorisation.

Furthermore, **Demetra Representatives** shall not make unauthorised copies of printed materials (e.g. books, articles, magazines, drawings and logos), photographs, videotapes or advertising or promotional materials.

Intellectual property is a valuable resource that must be constantly protected.

All **Demetra Representatives** must use the company trademarks correctly, reporting any unauthorised use or confusingly similar trademarks to the legal department.

Similarly, **Demetra** undertakes not to infringe the trademark rights of others, and to avoid using trademarks that are similar to those of other companies and likely to cause confusion.

Any work produced in the course of their duties by **Demetra Representatives**, during working hours and using company resources or information, belongs to **Demetra**. In addition, any invention conceived or developed by a **Demetra Representative** shall be communicated to **Demetra** who shall determine whether the invention shall be treated as proprietary information or whether it shall be protected under patent law.

No invention, developed, licensed or purchased by **Demetra**, shall be used or marketed and no unpatented proprietary information shall be disclosed to **Third Parties** before obtaining the necessary authorisations.

## Product Safety and Quality

### *Why it is important*

**Demetra** aims to meet the health needs of patients by improving their quality of life through the manufacture of products that meet the highest standards of quality and safety. Safety and quality are prerogatives for the success of **Demetra**'s business in all phases of product development (research and development, production, marketing and post-marketing).

### *Demetra's commitment*

**Demetra** works to ensure that its products have all the necessary authorisations and enjoy the highest quality and safety standards, while complying with the requirements of the technical regulations on quality and surveillance of medical devices.

To do so, **Demetra** ensures the adoption of the necessary documentary, organisational and process controls to ensure full compliance with these requirements.

### *What we expect from Demetra Representatives and our Third Parties*

Each **Demetra Representative** must operate in accordance with the policies and procedures adopted by **Demetra** with respect to product quality and safety, including those concerning the collection and processing of safety reports.

Any interaction with bodies or authorities having a role in the authorisation, registration and monitoring processes of the safety and efficacy of **Demetra** products must be correct, clear, lawful and transparent.

Depending on the activities or role of **Third Parties**, processes must be in place to qualify them qualitatively, taking into account, among other things, the specific regulatory constraints applied to the medical device sector with regard to quality and safety; these **Third Parties** must also be aware of the specific obligations under the technical regulations with regard to the receipt and management of safety-relevant reports on medical devices.

## Interactions with Health Professionals, Health Organisations and Patient Associations

### *Why it is important*

Operating in a highly regulated market and through interaction with public and private *stakeholders* throughout the world entails the adoption of principles and rules aimed at ensuring the professionalism, integrity and fairness of **Demetra's** work; this is in order to achieve the set objectives by ensuring, over time, **Demetra's** role as a reliable and transparent technology partner.

### *Demetra's commitment*

**Demetra** shall ensure in all interactions with HCPs, HCOs, Patients, Caregivers and Patient Associations the application of standards of fairness, transparency and integrity, embracing both international regulations and locally applicable standards and principles. All **Demetra Representatives** and **Third Parties** working for **Demetra** shall adhere to the requirements set forth herein in all interactions with HCPs, HCOs and Patient Associations.

## Interactions with Health Professionals

Relationships with Healthcare Professionals must be conducted in accordance with applicable ethical and regulatory standards, and interactions must be based on properly documented legitimate business needs.

Any agreements with Healthcare Professionals that provide for a transfer of value to them must comply with the following principles:

- Such agreements can only be activated by virtue of a legitimate business need that cannot be fulfilled without the involvement of a Healthcare Professional;
- The selection of the HCP must be free of conflicts of interest and based on the HCP's actual ability to meet the identified business need;
- The definition of fees must be congruous, based on fair market values applied in the country where the HCP operates;
- Relations with the HCP must always be regulated by means of written contracts. Where necessary, any regulatory requirements related to, for example, possible authorisation requests by the HCP's Employers or transparency obligations of value transfers shall be managed;
- Evidence of the activities carried out by the HCP must be collected and archived.

## Product Promotion

Promotional activities must be labelled and carried out in accordance with applicable regional and local regulatory requirements. In case of doubts about interpretation, the stricter local guidelines will always apply.

The promotional information provided must be clear, truthful, objective, accurate, referenced, not misleading, balanced, and must be aimed at ensuring the safe and effective use of **Demetra** devices; promotional information must be addressed to the only persons authorised to receive it, in compliance with applicable international and local regulations.

No one is authorised to modify, change or revise approved promotional materials without the permission of **Demetra**; similarly, no one is authorised to distribute or use unauthorised, out-of-date or obsolete promotional materials.

## Events and conferences

**Demetra Representatives** involved in the process of organising or providing financial support to conference initiatives carried out by **Third Parties** (such as HCOs or Event Organisers) are required to operate in accordance with applicable international and local, legal and ethical requirements as well as the general principles listed below

- The choice of events to be supported must be based on their scientific value while ensuring, where required by rules and regulations, the necessary independence of the Event Organiser;
- Events organised or supported by **Demetra** must take place in modest, safe and logistically accessible venues for participants;
- No entertainment is allowed for the participants;
- Hospitality, if provided, may be provided to qualified Healthcare Professionals and must be moderate and reasonable according to local standards and incidental to the main purpose of the event;
- Individuals who do not have a legitimate business interest (e.g. guests) may not receive any support from **Demetra** in terms of financial support for travel, hospitality or registration costs. Any exceptions (e.g. presence of a caregiver) must be appropriately tracked and approved by the respective compliance officer.
- Initiatives should be inspired by principles of sobriety.

## Meals and hospitality

**Demetra Representatives** may occasionally offer modest meals as part of legitimate business discussions, where permitted by locally applicable regulations and practices.

Similarly, meals and hospitality may be offered on the occasion of the performance of assignments on behalf of **Demetra** (e.g. meals or hospitality required for the performance of an assignment) or on the occasion of conference initiatives supported by **Demetra**.

The same principles in terms of sobriety and prohibitions apply as under 'events and congresses'.

For further instructions, see the regional documents containing Frequently Asked Questions ('FAQ').

## Relations with Patient Associations, Expert Patients and Caregivers

**Demetra Representatives**, in the case of interactions with Patient, Expert Patients and Caregivers Associations, are expected to conduct themselves in a manner consistent with applicable laws, the codes of ethics of the professional associations in force in the country in which the Patient, Expert Patients and Caregivers Associations operate, company policies and this **Code of Conduct**.

Any form of interaction or collaboration must be of a non-promotional nature. Where applicable, **Demetra** fulfils its transparency obligations under laws or association codes.

## Gadgets, free gifts and items of medical utility

Gifts, gadgets, items of medical utility may only be given or accepted where permitted by the applicable association rules and regulations. **Demetra**, in any case, condemns any conduct aimed at offering money, goods in kind or other utilities to Professionals in the Health Sector, Health Organizations, current or potential business partners in order to illicitly influence their work and decisions in favor of **Demetra**; the same prohibition applies in the event that, based on the practices applied in the country, such transfers of value may be even only perceived as a way of illicitly influencing the stakeholders with which **Demetra** operates.

## Donations and gifts

Donations, whether in kind or in cash, must be made in accordance with the regulations and codes of ethics of the relevant professional associations, as well as with this **Code of Conduct**.

The **Demetra Representatives** must verify and assess the merits of both the funded initiatives and the beneficiary organisations, also assessing any potential conflicts of interest.

Such initiatives must be managed by functions that do not have a commercial role. Recipients of donations and gifts may not be individual HCPs or individuals.

## Research and development

**Demetra** is committed to maintaining the highest ethical and scientific standards in research and development. Research and development requires that **Demetra Representatives** involved in such activities act in accordance with applicable legal provisions and the principles set forth in the Declaration of Helsinki, applying the highest standards of research practices, patient safety and scientificity.

All interactions with bodies and committees involved in the study evaluation process must be characterised by fairness, integrity and transparency; these principles apply to **Third Parties** that support **Demetra** in its research activities.

It is also possible to support research activities promoted by **Third Parties** provided that the independence of the investigator, compliance with the applicable legal provisions and the absence of potential conflicts of interest are guaranteed.

# DEMETRA

LIFE DRIVEN TECHNOLOGIES

## DEMETRA HOLDING S.P.A.

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