CODE OF ETHICS

CONFINDUSTRIA
Dispositivi Medici

DECEMBER 2024

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FOREWORD

With this Code of Ethics, Confindustria Dispositivi Medici and its member companies wish to express their clear intention of directing their behaviour not only to the compliance with laws, regulations and the Articles of Association, but also to the observance of the moral principles that, in a democratic country such as Italy, should govern all aspects of our community life, as well as all relations and interactions between individuals, associations, private companies and public bodies and institutions.

In fact, while law is the rule of our "outward" behaviour, ethics is the law of our conscience, it is the rule of the intentions and motivations that lie at the basis of our behaviour and enrich it with psychological contents that go beyond the strict observance of regulations and qualify our conduct according to value-based standards.

As a result, the "positive" law passed by governments meets justice - it is, namely, a just law - only when it is consistent with ethics and finds its deep root in ethical principles, a sublimation that, in a sense, turns the positive law into a sort of "natural" law, as may be "read" and inferred from our very human nature.

The Code of Ethics is therefore the expression of a nobler and loftier concept of private enterprise, as it harmoniously unites the inevitable demand for productivity and profit with a moral dimension, with the idea that competitiveness and competition are free and yet governed by transparency and respect towards others, which is actually nothing but the other side of self-respect.

As a matter of fact, the market is really "free" only where and insofar as it eliminates any favouritism, pressures or conflicts of interest, and profit is proportionate exclusively to merit.

Moreover, Confindustria Dispositivi Medici and its member companies are aware of the special sensitivity and importance of their field of activity, the healthcare industry, and are gratified to significantly contribute, with their efforts, to the protection of a primary human need such as the health of the citizens and, hence, to the improvement of the healthcare system and the development of our community.

Compliance with laws and ethical values are at the basis of the relations of Confindustria Dispositivi Medici and its member companies with their in-house and free-lance collaborators, as well as with the public administration, healthcare professionals, customers and suppliers.

Within the framework of this entrepreneurial commitment ennobled by ethical values, public spending for healthcare is seen more as an investment than as a cost and consequently it is an ambition rather than a duty to provide, for the benefit of patients well-being and safety, high quality medical technologies and

related services that are constantly in step with the steady progress brought about by an accurate, balanced, fair, objective, disinterested and documented scientific information.

By Prof. Avv. Nicolò Amato

Chairman
of Confindustria Dispositivi Medici Control Commission

INTRODUCTION

All member companies (hereinafter referred to as the Members) working in the Healthcare industry are aware of the importance of this activity and of the responsibility that it implies, since it is an indispensable element for the satisfaction of a basic human need, such as the health of the citizens, and for the improvement of the Healthcare System and, hence, a key factor for the development of the Society: healthcare outlay is therefore an investment, not a cost.

The contribution of the Members to the health of citizens is fundamental and the improvements, innovations and achievements accomplished thanks to the medical technologies used in the diagnosis and care of patients bear witness to this and constitute a decisive contribution to the treatment of patients and an improvement in their quality of life and, more in general, to life expectancy.

Confindustria Dispositivi Medici Members acknowledge that compliance with any applicable laws and regulations and the observance of ethical principles are both an obligation and a critical step for the achievement of the aforementioned aims and may enhance the reputation and success of the medical devices industry.

This Code of Ethics intends to provide a guide on the minimum standards of business practice that all Members must abide by in Italy and, in general, elsewhere. It does not intend to replace or supersede national or European laws and regulations or any other professional or commercial codes (including corporate codes) that may concern any of the Members.

The Code of Ethics acts as a catalyst for the development of the moral condition of the Members and testifies to the effort to give shape to the ethical dimension so that it may be recognised by the community.

This Code of Ethics is an integral part of Confindustria Dispositivi Medici Articles of Association.

1. PRINCIPLES

1.1 ETHICS IN BUSINESS PRACTICE AND IN MANAGEMENT OF CORPORATE AND ASSOCIATION ACTIVITIES

Confindustria Dispositivi Medici Members undertake to produce and provide high quality medical technologies and related services in the interest of the safety and well-being of the patient.

The Members undertake to comply with all laws and regulations as well as the Articles of Association. Ethical behaviour is not only characterised by strict observance of such laws and regulations. It goes well beyond as it is based on the will to adopt the highest standards of behaviour in all different situations.

Compliance with applicable laws and observance of ethical standards are crucial for the requirement of close cooperation between the medical technologies industry and healthcare professionals.

This collaboration can occur in the following ways:

a. development of medical technologies;
b. supply of training, education, service and support so as to allow an efficient and safe use of medical technologies;
c. support of medical research, training and improvement of professional skills.

These activities are necessary for the progress of medical science and for the improvement of the treatment of patients, but they must be carried out with the utmost transparency, fairness and integrity.

Fairness and transparency must therefore characterise the activities and conduct of every Member that must undertake to avoid any misleading information and behaviours such as to obtain an undue advantage from other people's vulnerability or lack of knowledge.

In particular, when relations are established with the Public Administration, it is deemed appropriate to take more specific measures, as shown below.

To this end, transparent and objective internal procedures governing the behaviour of the Members constitute a safeguard also with reference to the provisions of Legislative Decree 231/2001 on the administrative liability of legal entities and on prevention and combating of corruption.

1.2 WORK ETHICS, PROTECTION AND DEVELOPMENT OF COLLABORATORS

The internal (in-house) and external (free-lance) collaborators of the Members are a fundamental resource for the development of the companies.

The wealth of knowledge, experience, intelligence and culture of collaborators must be enhanced and developed in order to contribute to their professional growth and well-being. Professional training and growth are respectively carried out and achieved by means of specific institutional training programmes.

All collaborators shall ensure that each business decision is taken in the interest of the structure they belong to and must avoid any possible conflict of interest that may arise between their personal or family business activities and their professional positions such as to affect their independent judgment and decision-making.

Professional development and management of collaborators are based on the principle of equal opportunities: acknowledgement of the results achieved and of individual professional potential and skills is an essential element for the appraisal of collaborators.

Free-lance collaborators (consultants, agents, distributors, representatives, retailers, etc.) are required to comply with the principles set out in this Code of Ethics, also through explicit commitment, included in the relevant contracts.

1.3 ETHICAL INFORMATION

The communication of the Members mainly regards scientific information, which must be accurate, balanced, fair, objective, unambiguous and straight, verifiable and supported by documentary evidence.

Information must be prepared and disclosed in compliance with the provisions of the law in this regard.

2. BEHAVIOURAL GUIDELINES: ETHICS IN BUSINESS PRACTICE AND IN THE MANAGEMENT OF CORPORATE AND ASSOCIATION ACTIVITIES

In order to ensure the implementation of ethical principles, specific guidelines on the appropriate behaviour to adopt shall be prepared and extended to all employees, agents, distributors or representatives in general.

The Members must implement efficient compliance programmes by drawing up and publishing policies and procedures and, where the Members are legal entities, by carrying out training programmes and implementing clear procedures, inspections and enforcement mechanisms.

Through its control bodies, Confindustria Dispositivi Medici reserves the right, in the last resort, to expel from the Association any Member that does not comply with the guidelines of this Code of Ethics.

The rules that the Members shall comply with are laid down below in detail.

2.1 COMPETITION

In a free market regime all actors have their own independence in determining and pursuing their business purposes.

The Members firmly believe in competition and free market, a wealth that must be defended against any possible and improper pressure both internal, coming from the same actors of the markets concerned, and external, from third parties, disregarding of the role played.

The Members must run their own business activity in compliance with law requirements on competition and supply contracts. The anti-trust law establishes specific rules in this regard and, in particular, severely punishes any subjects that enter into agreements limiting competition or that abuse of their dominant position in the market.

However, all this does not prevent Confindustria Dispositivi Medici from pursuing in full the institutional aims, established in the Articles of Association, in order to protect the requests expressed by its Members in full compliance with the principles governing competition.

The Members condemn any behaviour that goes against the principles of free competition and undertake to observe said principles by taking appropriate measures in order to prevent the Association meetings from becoming, also unintentionally, an occasion for anti-competitive behaviour.

In this perspective, the Members and their collaborators must not be involved, either personaly or through third parties, in any kind of initiative or contact between competitors (including but not limited to discussions on prices or quantities, market sharing, limitations on production or sales, agreements for sharing customers, exchange of information on prices, etc.), that could appear to be in breach of the regulations protecting competition and the market.

2.2 EXPORT CONTROLS AND SANCTIONS

The Members must guarantee compliance with applicable laws on export controls and other regulations that limit or restrict the trade with some countries.

2.3 PAYMENTS AND ILLICIT COMMERCIAL PRACTICES

The Members must not offer, perform or authorise, directly or indirectly, the payment of sums or of anything having a significant value, for the illicit purpose of:

a. influencing the judgement or behaviour of any subject, customer or company;
b. obtaining or maintaining commercial activities;
c. influencing any action or decision of any public officer;
d. gaining any advantage whatsoever.

This requirement extends to both direct and indirect incentives offered by a Member, under any form, through agents, distributors, consultants or other third parties. All Members must take into special account laws and regulations that prohibit or limit incentives aimed at influencing healthcare professionals or customers.

Moreover, the Members' directors, general managers, executives in charge of the drafting of corporate accounting documents, auditors and liquidators shall refrain from undertaking or omitting any action subsequent to the payment or promise of money or other form of benefit, for themselves or for others, in violation of the obligations inherent to their office or their engagement of fidelity.

2.4 DATA CONFIDENTIALITY

The Members must guarantee that data concerning patients and other types of confidential or personal information are kept and used in compliance with applicable law requirements.

2.5 CORPORATE IMAGE

The Members conduct within the market and towards competitors must be based on the utmost fairness; in particular, the Members shall not adopt any unfair behaviour that might be detrimental to the image of their competitors.

2.6 SUSTAINABLE DEVELOPMENT AND RESPONSIBILITIES TOWARDS THE COMMUNITY

The role played by the Members within the connective tissue of the community implies the obligation to take into account, within the planning of their development programmes, the needs of the community whose territory the company is based in, with the purpose of contributing to its economic, social and civil development.

The Members shall perform their business activity by using the best technologies available, promoting and fostering the development of activities aimed at the valorisation of natural resources and protection of the environment in accordance with all applicable laws and regulations.

2.7 RELATIONS WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND THIRD PARTIES. PRINCIPLE OF SOBRIETY AND TRANSPARENCY

Confindustria Dispositivi Medici Members acknowledge that the observance of ethical standards and compliance with applicable laws are essential for the development and support of collaboration between the medical technologies industry and Healthcare Professionals.

Who are the Healthcare Professionals?

Also referred to as HCP, Healthcare Professionals are any individuals performing their professional activities within the healthcare sector, whether public and/or private, (including, but not limited to, physicians, nurses, laboratory scientists, technicians, administrative employees within the healthcare veterinarians etc.), that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase, lease or prescription of medical technologies or related services.

The Members must adopt ethical business practices and maintain a socially responsible behaviour in relation to the interactions with the Healthcare Professionals.

The Members must also respect the obligation of Healthcare Professionals to take independent decisions as to the clinical-diagnostic practice.

This Code of Ethics establishes the appropriate standards for the different types of interactions with Healthcare Professionals, but it does not intend to replace or supersede any applicable national or European laws or regulations, professional codes or codes/regulations of any bodies the Healthcare Professional may belong to that impose special conditions for the Members or for the Healthcare Professionals when carrying out their activities, nor any codes of the Members, where more restrictive.

All Members must therefore independently guarantee that any of their interactions with Healthcare Professionals comply with the current national, European and local laws and rules, as well as the regulations and professional codes.

In general, from the moment the Members, even before the publication of a call for tenders (or any other document or similar deed), become aware of the existence of an administrative procedure aimed at its publication, it is advisable for them to refrain from offering any opportunity of collaboration or similar interaction, also free of charge (e.g. advisory services, speaking services, moderating activities, training, etc.) that offer any personal advantage to public employees that might have negotiation and/or authoritative powers, or any such powers as to be able in any way to influence the outcome of the procedure.

The Members will independently evaluate the opportunity to maintain any outstanding relationships at the time they become aware of the existence of any administrative procedure.

The provisions set out in the foregoing paragraph shall apply to all Healthcare Professionals operating also outside the Public Administration in all cases of transactions with private healthcare structures the Healthcare Professionals belong to for the provision of goods and services.

Any interactions among the Members, at international, national, regional and local level, including those relating to promotional and propaganda activities with public employees and public and private Healthcare Professionals, must be based on the principles of validity, transparency, ethical and professional fairness.

The Members and, on their behalf, any top managers and collaborators at any level, including external ones, must not promise or pay any amounts, promise or grant any goods in kind, gifts or other benefits to public employees and/or similar subjects, to public and private Healthcare Professionals, who may take part, in any capacity, either personally or not, in any procurement process with the aim of promoting or favouring the interests of the Members.

Within the interactions with the Public Administration it is forbidden, directly or indirectly, also through third parties, to carry out the following actions:

a. in accordance with article 53, sub-paragraph 16 ter of Legislative Decree 165/2001, within three years following the termination of public employment, to take on as employees any of the Members or entrust assignments to former public employees who, over the last three years of employment have exercised authoritative or negotiating powers upon any of the Members;

What do negotiating power and authoritative power mean?

"Negotiating power" means the power of negotiation that may affect the purchasing or spending power of any subject. Generally Healthcare or University administration managers or superintendents may have negotiating powers.
"Authoritative power" means the power generally held by the Public Administration that enables it to take administrative measures aimed at affecting unilaterally the personal legal situations of the recipients of such measures. The Public Administration may therefore provide for any rules affecting the interests of any subject within the sphere of their legal situation without any consent or collaboration of same.

b. to offer or provide in any way gifts that are not modest in value and which might be considered as a remunerative donation. It is advisable to centralise the purchase of gifts in a single central service and to guarantee in any way their traceability by means of appropriate documents (e.g.: transport document);

What does remunerative donation mean?

"Remunerative donation" means any form of payment relating, possibly or hypothetically, to a past service rendered or to a future service promised or even expected, hence, any form of payment that may be conceived within the "do ut des" notion of reciprocity.
The "remunerative donation" may be compared to the "potential remunerative power" of a form of payment, that is the possibility that it may be accepted by recipients or third parties as consideration or reward for what they have rendered or might render.

c. to solicit or obtain confidential information beyond what is required and allowed by the law;

d. to perform activities which unduly interfere with the formation of the will of the Public Administration with reference to the object of the bidding procedure.

There are several forms of interaction between the Members and Healthcare Professionals that contribute to the progress of medical science and the improvement of the diagnosis and the treatment of the patient, which lead to:

a. the progress of medical technology: the research and the development of innovative medical technologies as well as the improvement of existing products are often the result of collaboration processes between the Members and Healthcare Professionals. Innovation and creativeness are essential for the development and evolution of medical technologies, and they often arise from the collaboration with bodies, institutions and persons outside the structures of the member companies;
b. the efficient and safe use of the medical technology: this very often requires that the Members offer and provide proper instructions, training, services and technical support to Healthcare Professionals. The regulatory bodies may also require this specific type of training as a condition for the approval of products;
c. research and training: the Members' support to the medical research carried out in good faith, the training for the best and most appropriate use of the supplied technologies and, more in general, the improvement of professional skills are some of the elements that contribute to the safety of the patient and increase the access to the new technology and, consequently, to the most advanced and efficient therapies.

Subject to any authorisation requirements, the Member or the Healthcare Professional shall provide the top management of the hospital administration the Healthcare Professional concerned works for with the notification of any interaction between the Members and Healthcare Professionals, where such interaction implies a transfer of value or potential conflicts of interests.

The interaction between Members, Healthcare Organisations and/or Third Parties shall be addressed exclusively to subjects that meet the compliance requirements set out, by way of example, in Annex 1.

What is meant by Healthcare Organisations?

Healthcare Organisations means any legal entity or body (irrespective of its legal or organisational form), healthcare, medical or scientific association or organisation through which one or more Healthcare Professionals provide services or which may have a direct or indirect influence on any prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies and related services. Some examples: hospitals, group purchasing organisations, clinics, laboratories, pharmacies, research institutions, associations, foundations, universities, scientific or other teaching or professional institutions. This definition also includes Patient Associations, i.e. the Organisations that represent and support the patient and caregiver needs in the context of a specific pathology or health aspect.

What is meant by Third Parties?

Third Parties means subjects who propose, organise, manage all scientific, logistical and organisational aspects of any events in order to meet a scientific or other educational/training need as outlined in paragraphs 2.7.1 and 2.7.2 below.

The Members undertake, answering in this regard also for the actions of their parent companies and/or other companies of the group, not to organise, directly or indirectly, or not to participate under any form in conferences, meetings, workshops and similar events in which:

a. tourist and recreational aspects prevail over technical and scientific ones;
b. hospitality and travel expenses are extended to the persons accompanying the invited persons;
c. hospitality and travel expenses are extended to a period of time preceding the beginning and/or following the end of the event exceeding 24 hours;
d. the principle of sobriety, as described in paragraphs 2.7.1 and 2.7.2 below, is not respected.

The Members shall adopt internal independent procedures based on objective criteria in order to evaluate the requests for grants.

2.7.1 TRAINING, EDUCATIONAL AND PROMOTIONAL ACTIVITIES ON THE COMPANY'S PRODUCTS ORGANISED BY THE MEMBERS

The Members may organise, directly or through a third party, the following initiatives:

- scientific-clinical refresher courses linked to the product, clinical procedures and to its business;
- higher or advanced training or education on technical, regulatory, organisational and management (healthcare management) and/or political and social issues relating to the sector of reference;
- health protection and psychophysical well-being as well as the dissemination of the prevention culture.

With reference to the first point above, the scientific-clinical refresher courses linked to the product, clinical procedures and to Members' business may include, also, tours at companies' plants, also abroad (tours at contract manufacturing organizations, where manufacturing and packaging process of Members' products are put in place, are included).

The Members gathering in meetings with Healthcare Professionals to discuss the initiatives mentioned above, as a general rule, must hold such meetings near the place where the Healthcare Professionals work.

The selected place must not become the main attraction of the event.

The quality of the event must be assessed on the basis of strictly scientific criteria that must be devoid of any reference to comfort and splendour and rather be directed to the protection of the sector and to the compliance with the main purpose, that is the health of patients and the improvement of their treatment and care.

When selecting an appropriate place it is advisable to take into consideration any possible repercussion on public opinion in terms of image potentially produced by the event.

More precisely:

a. events must be held in premises used as clinics, laboratories, training centres, conference venues or other appropriate facilities, including premises owned by the Members or venues for meetings available for business activities, provided that they are fit for an efficient conveyance of knowledge and practical training. Events must be held in places and venues or facilities that can be easily reached by the participants and whose selection is based on logistical, scientific, organisational and economic considerations;
b. in case of events organised in Italy, it is strictly forbidden to organise, attend and support events from June 1 to September 30 at seaside resorts and from December 15 to March 31, as well as from June 15 to September 15 at mountain resorts. The prohibition does not apply to the Regional

and Provincial Capitals seat of prominent hospitals and universities. In case of events organized abroad, Member Companies cannot support or organize events in tourist destinations, in compliance with the ereference season period.

c. any events, held within venues classified as five-star, regardless of whatever tariff or special conditions may be offered, are absolutely prohibited, without prejudice to the provisions of the agreements signed by Confindustria Dispositivi Medici and the associations representing the hotels and congress venues, according to the plan approved as an integral part of this Code of Ethics by the AGM on 9th of June 2014.
The limitations related to the five-star category venues do not apply in the case of international events organized outside Italy by Third Parties, including affiliates of the Member Companies, on the understanding that the venues must be non-luxurious or well-known for entertainment, tourism or wellness. In any case, for events taking place abroad, Member Companies cannot pay or reimburse the accommodation costs of health professionals at top-class or luxury hotels.

The Members will bear the travel and accommodation costs solely for the Healthcare Professionals invited to the events, in accordance with all applicable regulations.

Flights will be exclusively in economy class except for intercontinental flights, for which business class tickets are allowed. First class tickets are forbidden.

The Members may offer meals at a reasonable price to the participants in the events and, for those requiring a night stay, additional hotel services may be necessary and must in any case be classified as not higher than a four-star category; they must be subject to the duration of and functional to the educational purpose of the event, and comply with all applicable regulations.

Costs regarding any accompanying persons will be borne in full by the Healthcare Professional.

The Members may not bear fully or partially any expense covering activities that are not strictly related to the scientific nature of the event (by way of example but not limited to: concerts, shows, social programmes, etc.).

The training, educational and promotional activities on company products organised by the Members through a third party organiser are considered company events and as such fall under the indications provided for in this paragraph.

2.7.2 SUPPORT TO TRAINING AND EDUCATIONAL ACTIVITIES ORGANISED BY HEALTHCARE ORGANISATIONS AND/OR THIRD PARTIES

In accordance with the provisions of paragraph 2.7 and with the sobriety standards set out in paragraph 2.7.1, the Members may give their support at independent, training, scientific conferences or at conferences that promote scientific knowledge, medical progress and an efficient healthcare service organised by Third Parties.

They can also give their support to higher or advanced training or education on technical, regulatory, organisational and management (healthcare management) and/or political and social issues relating to the sector of reference; support is also allowed for initiatives regarding the health protection and psychophysical well-being as well as the dissemination of the prevention culture.

The Members may also provide support either to procedure courses or training or to specific events whose programme is focused on the practical training on the safe and effective performance of one or more clinical procedures, where most of the training occurs in a clinical environment. In particular, the provisions set forth in paragraphs 2.7 and 2.7.1, relating to the possibility of providing direct support to Healthcare Professionals, shall apply to procedure training.

Without prejudice to the provisions of the above paragraph, it is expressly forbidden any direct financial support to individual Healthcare Professionals in order to cover costs of their attendance to training and educational events organised by Third Parties. Said support may be provided to the entity the Healthcare Professional works for or to the Third Party organising the event, either directly or by means of a third party that undertakes to comply with the provisions set forth in this Code.

Financial support provided by Members may cover matters such as travel, accommodation and hospitality (including meals). Member Companies should, however, be mindful of any specific notification or disclosure requirement, which must be fulfilled by the third party responsible for the management of the financial support, linked to support of hospitality.

The Members may provide this support also by buying sponsoring rights such as, by way of example but not limited to, the use of their logo on the event programme, on badges and on the conference website; the rental of booth spaces; the display of banners or the organisation of satellite symposiums by determining the relevant content and speakers.

Within the context of the sponsorship packages and, included in same, the Members may purchase a certain number of conference participation quotas for a certain number of healthcare professionals (registration fees and/or travel and

hospitality expenses), depending on the type of sponsorship activated, for the sole purpose of contributing to the upskilling of Healthcare Professionals promoting the enhancement and knowledge of technologies as well as the innovation of same.

It is agreed that in this case the individual Healthcare Professionals that can benefit from the participation in the event by means of said participation quotas will be chosen in full autonomy and independence by the promoting entity or by the entity the Healthcare Professional belongs to.

The Members shall be in no way involved in the process of identifying the Healthcare Professionals and shall refrain from any behaviour aimed at reaching agreements with the promoting entity, and/or with the entity the Healthcare Professional belongs to, on the prior identification of the Healthcare Professional(s) to be invited to a given event.

The Members, either directly or by means of third parties intermediaries that undertake to comply with the provisions set out in this Code, must enter into a specific sponsorship contract with the promoting entity, or with the entity the Healthcare Professional belongs to, in which every sponsorship right purchased and every single amount paid for each of the same are specifically and accurately indicated.

Within the subject matter of the sponsoring contract, the Members may determine the category of Healthcare Professionals that may benefit from their support and/or the geographic area and/or the healthcare institution the Healthcare Professionals belong to, without prejudice to the full and absolute guarantee that such support may in no way be attributed to any single identifiable Healthcare Professional.

All national and regional events organised by Third Parties and/or Healthcare Organisations set out in this paragraph shall be submitted for compliance, by the same Third Parties and/or Healthcare Organisations, to the prior assessment of the Conference Evaluation System (SVC), subject to the supervision of Confindustria Dispositivi Medici Control Commission.

The SVC shall assess all aspects aimed at ensuring the utmost sobriety of the event. Including but not limited to the event location, period, programme, type of hospitality and travel, etc.

The detailed programme should be available in sufficient time prior to the event, present a clear schedule with no gaps during the sessions in the case of in-person events, including hybrid events. The faculty must be identified.

The events shall be submitted for assessment with reasonable notice and details and manners thereof are set forth in an appropriate regulation.

The Members shall not provide any support to international, national and regional events that have not been submitted to the prior positive assessment of the Conference Evaluation System (SVC).

With reference to virtual events, which are not subjected to prior evaluation in SVC, they must comply with any part of the Code that is by its nature applicable to them. Therefore, Members may provide financial and/or in kind support to virtual events in accordance with the rules of this paragraph.

The Members that, due to the nature of their activity, are subject to the prior assessment of AIFA for their participation in the events set out in this paragraph, may apply the appropriate ethical rule to all relevant requirements, without prejudice to the full application of this Code of Ethics, where AIFA authorisation does not apply.

All financial supports to educational events shall be submitted to verification as per their final use, by means of a detailed report by the Third Parties or Healthcare Organisations involved.

The provisions set forth in paragraphs 2.7, 2.7.1 and 2.7.2 apply both in Italy and abroad, also for any activities of the parent companies and/or other companies of the group every time Healthcare Professionals carrying out their main professional activity within the Italian territory participate in an event and are subject to compliance with the transparency procedure as of article 4.

The provisions contained in paragraphs 2.7, 2.7.1 and 2.7.2 shall also apply in full to Healthcare Professionals who operate exclusively on a self-employed basis without being bound to public or private structures or part of the state run healthcare organisations, except for financial support to training and educational activities organised by Healthcare Organisations and/or Third Parties, which may be provided by direct financial support to Non-prescribing Professionals and always on condition that he/she is not bound by any kind of professional collaboration with public or private structures or part of the state run healthcare organisations. For the purposes of this provision, Non-prescribing Professionals are to be understood as all Healthcare Professionals who, within the National Health Service, do not have the power to authorize the assumption of a financial burden by the health administration.

2.8 DONATIONS

The purpose of donations is to support social, humanitarian, philanthropic or charitable projects. In particular, donations made in the following fields are considered acceptable:

- treatment of the poor;
- education of patients (including public awareness campaigns);
- improvement of patients condition;
- public education;
- humanitarian projects and donations in the event of natural disasters;
- support to events whose proceeds go to charity.

Donations must be made only upon specific request by the recipient entity, not be linked to any commercial interest, be solely to the benefit of organisations and entities that are qualified to receive them pursuant to the applicable laws and regulations and subject to verification of the absence of any conflicts of interest.

Therefore, any type of donation to individuals is forbidden.

All donations must be properly documented and evaluated, in compliance with an appropriate rotation principle.

Donations of money, goods, equipment etc. must be made in compliance with the regulations in force and based on the relevant beneficiary and must be authorised in advance by the top management.

The beneficiary must then provide evidence of the actual destination and use of the donation.

The Members must, in any case, observe the principle of transparency pursuant to article 4.

2.9 SCHOLARSHIPS

In compliance with the provisions in force on the matter, scholarships must be assigned under written agreements between the Member and the recipient Healthcare Organisation that has made the request; said agreements must specify that the selection of any candidate shall be made by the Healthcare Organisation according to its own evaluation procedures that must be transparent, objective and based on recognised scientific and training criteria.

The Member shall in no way be involved in any process of selection and evaluation of candidates.

Scholarships shall be provided exclusively to the recipient Healthcare Organisation that has made the request, in compliance with an appropriate rotation principle.

The Members must, in any case, observe the principle of transparency pursuant to article 4.

2.10 ASSIGNMENTS, CONSULTANCY AND STUDIES ENTRUSTED TO HEALTHCARE PROFESSIONALS

Healthcare Professionals may provide free-lance consultancy services to the Members as well as collaboration for the research, development and use of products in "case of legitimate business need (which means a current and actual business objective pursued by Members, such as the advancement of medical education, clinical research and/or the safe and effective use of the Members' products) and in accordance with applicable law provisions.

In accordance with article 53 of Legislative Decree 165/2001 (sub-paragraphs 6 and 7 bis) and article 4 of Presidential Decree 62/2013, special attention must be paid in cases where the award of compensation, barring the exceptions set forth in same Legislative Decree, is made to certain categories of public subjects and following major activities.

It is also necessary, bearing in mind the provisions of the Legislative Decree in question and in the cases indicated therein, to communicate the amount paid to the related public administration within fifteen days following the payment of the consideration.

A consultancy agreement between the Members and public or private Healthcare Professionals can be considered to be in good faith if:

a. it is stipulated solely where, preliminarily and with the underlying rationale, the scientific interest is identified by the Member with respect to its activities, coherently with the skills of the Professional;

b. it is stipulated in writing, duly signed by the parties and containing the activities and services that are to be provided, as well as the consideration and any incidental expenses;
c. it is compliant with the laws and regulations of the country in which the Healthcare Professional exercises his/her profession, having received the necessary prior authorizations issued by the relevant top management;
d. the compensation to the Healthcare Professionals that carry out their activities to the benefit of the Members must be determined in advance according to objective fair market value criteria that are proportionate to the services actually rendered and based on the Professional's qualifications and experience and on the nature of the assignment;
e. the payment shall be made only against submission of:
    - consistent documentation attesting the performance of the service;
    - invoice/bill issued by the Professional payable using a traced instrument to the benefit of the latter.

The Members may pay the reasonable expenses borne by the consultants when carrying out what is provided for in the consultancy agreement.

Consultants must be selected based on their qualifications and experience and by means of an internal process of selection and evaluation in order to implement the identified purpose.

The place and circumstances for the meetings between the Members and consultants must be appropriate to the subject-matter of the consultancy. Travel and hospitality expenses, if any, shall be subject to the duration and the main purpose of the meeting, in accordance with the standards provided for in paragraph 2.7 above.

Members may engage also Healthcare Organisations to provide consultancy services as well as collaboration for research, in accordance with the above provisions applicable to them.

The Members must, in any case, observe the principle of transparency pursuant to article 4.

2.11 RESEARCH PROJECTS

The decision to undertake or support a research project in collaboration with public or private entities in the case of scientific research or trials promoted respectively by the Members or by entities to which the Members provide external support, must always be inspired by a genuine scientific interest, aimed at the development of clinical procedures or to the clinical evaluation of products.

Within the company's organisation, the Members should therefore separate the evaluation and decision-making process relating to research projects (e.g. evaluation of interest and opportunity of carrying out or supporting a clinical research project, selection of research sites, principle of rotation, where applicable, etc.) from the promotional and sales processes and dynamics and, in general, from the commercial organisation, also in the event the entity takes a different approach.

The decision to carry out, or support, a research project conducted by an entity must be fully documented, clearly set forth the scientific objectives it aims at and the benefit for the company and for the patient.

Every collaboration with entities that has research purposes must be set up taking into account the existence of a Research Protocol, the approval of or reporting to the relevant Ethics Committee, the entering into a research contract or convention with the entity involved and the performance of the research itself in accordance with all the applicable laws and regulations.

Any compensation awarded to the entity that carries out the research on behalf of the Member must be determined on the basis of the fair market value principle.

In the case where the promoter of the research is a Healthcare Professional, in addition to the compliance with the above-stated rules, the Member shall ensure that the collaboration is based on the principle of transparency and has obtained all the necessary authorizations and permission by the entity/employer of the Professional.

Any medical devices required for the performance of the research can be handed over to the researcher only through the entity he/she belongs to and must be indicated in the contract along with their return at the end of the research project.

The Members must, in any case, observe the principle of transparency pursuant to article 4.

2.12 GIFTS TO HEALTHCARE PROFESSIONALS

The Members may occasionally provide gifts modest in value to Healthcare Professionals.

The gifts must serve a promotional function and relate to the Healthcare Professional's practice or be of benefit to the patients.

Gifts must not be provided as cash or equivalent (e.g. book or fuel vouchers, prepaid cards, etc.).

This section does not apply to the lawful practice of providing appropriate product samples and opportunities for their valuation.

2.13 QUALITY GUARANTEE

The reputation of the Members is based on the high quality of their medical devices, services and therapies, so that Healthcare Professionals may be able to provide the patient with the best possible result.

The commitment of all Members is not limited to the compliance with the quality and safety standards prescribed by the laws; where feasible, it goes beyond that to ensure increasingly efficient products, services and therapies.

2.14 ROYALTIES

Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or medical technologies.

They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A royalty arrangement between a Member Company and a Healthcare Professional should be entered into only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations.

The foregoing is without prejudice to Members' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations.

Arrangements involving the payment of royalties by or on behalf of Members to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royalties paid in exchange for intellectual property should not be conditional on:

- a requirement that the Healthcare Professional purchase, order or recommend any product, services or medical technology of the Member or any product or technology produced as a result of the development project; or
- a requirement to market the product or medical technology upon commercialisation.

Subject to national regulations and requirements, Members should exclude from the calculation of royalties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.

3. COMMITMENT OF THE MEMBERS AND APPLICABILITY OF THE CODE OF ETHICS

This Code of Ethics is an integral part of Confindustria Dispositivi Medici Articles of Association.

By joining Confindustria Dispositivi Medici, all Members undertake to observe and promote the principles and rules established in the Code itself.

All Members undertake to observe and ensure that their parent companies and/or other companies of the group and/or agents and distributors comply with this Code of Ethics.

The members of the Executive Bodies of the Association undertake to spread and promote the association decisions exclusively by means of the official documents drawn up by Confindustria Dispositivi Medici.

The members of the Executive Bodies also undertake to maintain the utmost confidentiality on the matters being treated and dealt with.

The Members undertake to include clauses of compliance with the principles set forth in the Code of Ethics in the contracts signed with their agents and distributors and to provide for related penalties in the case of non-compliance.

4. TRASPARENCY OF TRANSFERS OF VALUE BETWEEN THE ASSOCIATES, HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND OTHER THIRD PARTIES

4.1 TRANSPARENCY OBLIGATION

The Members must yearly document and publish all direct and indirect transfers of value to Healthcare Professionals, Healthcare Organisations and Third Parties by means of a specific Transparency Template which constitutes an integral part of this Code (Annex 2).

The costs of data publication shall be borne by the Member (or by its parent companies and/or other companies of the group), that shall arrange the payment/transfer of value.

The data shall be published on individual basis or in aggregate form as described below.

The data shall be published on the company's website in compliance with the requirements on personal data protection.

The Members shall retain, also by automated means and for a period of at least 3 years, specific documentation showing that the Healthcare Professional has given consent to the publication of the data regarding him/her.

Transfers of value related to promotional material, meals, beverages and product samples are excluded from the publication obligation.

4.2 METHODS OF APPLICATION

Data related to transfers of value shall be published annually starting from 1 January 2021, with reference to data regarding the 2020 calendar year.

The Members shall publish the transfers of value made each year within the first six months of the following year.

With reference to the Members associate throughout the year:

- if the Members associate by June 30, the fulfilment of the obligation is postponed to December 31st;
- if the Members associate between July 1st and December 31st, the fulfilment of the obligation is postponed to the following year.

The information shall remain in the public domain for a period of at least 3 years from the time of publication.

Moreover, the Members shall retain, also by automated means, the documentation supporting the data published for a period of at least 5 years and make it available, also in a detailed form upon request of Healthcare Professionals/Healthcare Organisations/Third Party.

The data regarding transfers of value shall be published in the country where the beneficiary has established his/her domicile and the publication obligation in the case of groups of companies is also deemed extended to the parent companies of the member companies, and/or to other companies belonging to the group, in accordance with the relevant national codes and regulations.

4.3 PUBLICATION OF DATA REGARDING THE INTERACTION BETWEEN MEMBERS AND INDIVIDUAL HEALTHCARE PROFESSIONALS

The Members, on an individual basis and for each recipient, shall disclose the amount of transfers of values made over the course of the previous year with reference to:

a. costs for the participation in training, educational and promotional events on company's products organised by the Members (excluding meals and beverages);
b. fees for consultancy activities and professional services, including speaking services, set forth in a specific contract between the Member and the Professional indicating the type of service rendered, including the related travel and accommodation costs (excluding meals and beverages).

Where the Healthcare Professional does not give consent to the processing of personal data, the Members shall in any case arrange for the publication of data on an aggregate basis.

4.4 PUBLICATION OF DATA REGARDING THE INTERACTION BETWEEN THE MEMBERS AND THE HEALTHCARE ORGANISATION AND OTHER THIRD PARTIES

The Members must make public, on an individual basis, the amount of the transfers of value made to each Healthcare Organisation or other Third Parties by way of:

a. financial support to events (e.g. sponsorship of conventions, congresses and scientific meetings, etc.) aimed at meeting a scientific or other educational/training need as described in paragraphs 2.7.1 and 2.7.2 (excluded meals and beverages);

b. fees for consultancy activities and professional services, including speaking services, as of a specific contract between the Member and the Healthcare Organisation, indicating the type of service rendered, including the related travel and accommodation costs (excluding meals and beverages);
c. donations in cash or cash equivalents provided to the Healthcare Organisation.

4.5 PUBLICATION OF OTHER AGGREGATED DATA

The following transfers of value shall also be published in aggregate form:

a. all donations in cash and cash equivalents to Third Parties, other than the Healthcare Organisation;
b. costs for research and development activities;
c. scholarships.

4.6 METHODOLOGY

In all cases where it is necessary to publish data on an aggregate basis for each of the categories identified in the paragraphs above, the following information must be identifiable:

- the number of recipients as a whole and as a percentage of the total number of recipients;
- the aggregated data attributable to Healthcare Professionals who have not given their consent to the processing of data;
- the percentage of the transfers of value in aggregate form over the total number of transfers.

The Members shall publish a summary report of the method used to prepare the data with reference to information regarding VAT, currency or any other tax-related aspects linked to the transfer of value in an individual or aggregate form, including the cash or accrual accounting principles applied for the preparation of their own financial statements.

5. CODE OF ETHICS SUPERVISORY BODIES

The Control Commission and the Jury are the bodies in charge of the control and of the implementation procedures of the Code of Ethics.

They are established within Confindustria Dispositivi Medici.

5.1 CONTROL COMMISSION

5.1.1 COMPOSITION

The Control Commission is a collective body and consists of:

- as many members as one for each industry association constituting Confindustria Dispositivi Medici;
- a Chairman and a member chosen among legal experts and subjects highly experienced in the legal field, outside the Association.

The Chairman of the Control Commission appoints a Secretary.

The members of the Commission are elected every even four-year period and they are eligible for re-election only for another four years.

5.1.2 POWERS

The Control Commission:

a. builds cases relating to the alleged violation of the Code of Ethics;
b. submits to the Jury the cases which it has grounds to believe are proven violations of the Code of Ethics;
c. acts as a supervisory body in relation to the technical assessments to be carried out, also by means of an external auditor appointed from time to time. Where the intervention of an external auditor is necessary following disputes among the Members, any costs the latter may incur for auditing or consultancy services shall be borne by the losing party to the extent of two thirds and by the reporting party to the extent of one third;
d. may adopt its own internal regulations as well as all measures available to it to protect the confidentiality of its work;

When exercising its functions, the Commission may:

- request information and explanations from the Members concerned through confidential communication;
- if necessary, arrange the hearing of the Member concerned, without prejudice to the right to defence and the principle of cross-examination;

- use consultants selected according to the needs of the case;
- send, upon request of the Management Committee, a report on the activity carried out.

In no case shall the reporting companies names be disclosed to the reported companies making the request.

5.1.3 REPORTING

Any reports shall be sent in writing in non-anonymous form in a sealed envelope to the secretary of the Control Commission, well in advance of the scheduled date of discussion.

Alternatively, reports may be sent in writing, accompanied by all useful information to *commissione.controllo@confindustriadm.it*

5.1.4 CONVOCATION

The Chairman convenes the Commission when he/she deems it advisable or, at any moment, on the joint request of at least two members.

The Control Commission is convened by its Chairman by means of a written communication, also by electronic means, to be sent to the members at least five days before the date of the meeting.

In urgent cases, it is possible not to observe this term.

The Control Commission is validly constituted with the presence of the majority of its members.

The decisions of the Control Commission are taken by the majority of the members present: in the event of a tied vote, the Chairman shall have the casting vote.

In the case of serious grounds of expediency, the member concerned shall abstain from voting.

The meetings of the Control Commission are not open to the public.

5.2 JURY

5.2.1 COMPOSITION

Cases of violation of the Code of Ethics are submitted to the Jury.

The Jury consists of a President and two members.

They are appointed by the Shareholders Meeting and chosen, one from among the representatives of the Members or from among persons of special merit and competence outside Confindustria Dispositivi Medici, and two from among legal experts.

Members of the Jury are elected every odd four-year period and they are eligible for re-election only for another four years.

The external members of the Jury, when accepting the office, must expressly declare that they do not have any existing professional relations nor any relations of interest with the Members and that they undertake not to set up such relations for the entire term of office.

5.2.2 CONVOCATION

The Jury is convened by its President when it is deemed advisable, by means of a written communication, also by electronic means, to be sent to the members at least five days before the date of the meeting.

In urgent cases, it is possible not to observe this term.

The meetings of the Jury are not open to the public.

The Jury is validly convened with the presence of all its members and its decisions are taken by the majority of the members present.

One of the members of the Jury appointed by its President acts as a Secretary.

5.2.3 PROCEEDINGS BEFORE THE JURY

Upon receiving the preliminary investigation from the Control Commission, the President appoints a speaker, notifies the start of the proceedings to the Member concerned, assigning a term of not less than fifteen days to file inferences and briefs, copy documents and produce new ones.

The Member concerned is summoned before the Jury within the shortest time possible for the hearing that is carried out orally.

A specifically delegated representative of the Control Commission takes part in the hearing.

After the hearing is fully treated, the Jury:

a. formulates its own decision if the case is sufficiently prepared;
b. acquires additional elements of pre-trial investigation, setting the date of the new hearing, if it deems it necessary.

At any moment of the proceedings, the Jury may request the opinion of the Control Commission.

Before the Jury, the Member concerned may ask for the presence of its own lawyers.

5.2.4 DECISION OF THE JURY

The Jury, no later than ten days from the date of the hearing, issues its decision, whose operative part is immediately notified to the Chairman of Confindustria Dispositivi Medici and to the parties.

Within the following ten days, the Jury files the announcement with the Secretary's office that sends a copy to the parties.

The decisions of the Jury are final.

5.2.5 CONTENTS OF THE DECISION

In the case of proven violation of the Code of Ethics, the Jury may impose the following sanctions on the Members:

a. written official reprimand;
b. suspension of the right of the Members to take part in the Meeting of Confindustria Dispositivi Medici or in the meeting of the Associations to which they belong;
c. revocation of the representatives of the Members who hold executive offices in Confindustria Dispositivi Medici or in the Associations to which they belong;
d. suspension of the right to vote and/or right to stand as a candidate in Confindustria Dispositivi Medici or in the Associations to which they belong;
e. expulsion from Confindustria Dispositivi Medici.

The Jury may inflict, together with the aforementioned disciplinary sanctions, also monetary penalties graded according to the seriousness of the violation.

The Jury may disclose the decisions, with the means that shall be considered most appropriate, if it discovers that the violation of the ethical principles compromises the honour and reputation of Confindustria Dispositivi Medici.

5.2.6 ENFORCEMENT OF THE DECISION

After filing of the decision, the Chairman of Confindustria Dispositivi Medici is responsible for its enforcement.

Subsequent to the infliction of the sanctions, the Members shall bear all legal expenses incurred in advance by Confindustria Dispositivi Medici.

6. ENTRANCE INTO FORCE

This Code of Ethics enters into force on the date of approval of all its parts.

With reference to transparency requirements (paragraph 4 above), they automatically expire when the public online register (called “Sanità Trasparente”), provided for by Law no. 62, May 31 2022, will come into operation.

ANNEX 1

CONFINDUSTRIA
Dispositivi Medici

THIRD PARTIES SELF-CERTIFICATION

1 DETAILS OF THE ENTITY

Name/Business name	
Registered office/Administrative office	
VAT Reg. No./Taxpayer's Code	
Director/CEO/Legal Representative/Owner	
Website of the entity:	

2DIRECTORS/LEGAL REPRESENTATIVES OF THE COMPANY (PLEASE ADD NEW ROWS TO THE TABLE IF NECESSARY), MEMBERS OF THE BOARD OF DIRECTORS (IN NON-PROFIT ENTITIES)

Name	Address	Position/powers(*)

3 MEMBERS OF THE COMPANY (PLEASE ADD MORE ROWS TO THE TABLE IF NECESSARY)

Name	Address	Position (*)

3.1 Is any director, representative or member of the company/member of the board of directors for non-profit entities linked or related within fourth degrees of each other to any public officers? (**)

[ ] No [ ] Yes (If yes, please provide the relevant details in the table below or on a separate sheet of paper):

Relationship with the Company	Relationship with Public Officers, Agencies or Entities

1

3.2 Please provide the following documents:

a) updated chamber of commerce certificate, for for-profit entities;

b) current articles of association for non-profit entities;

c) affidavit as of Presidential Decree 445/2000 certifying:

- absence or presence of convictions (including final ones) for subjects as of points 2 and 3
- Age.na.s accreditation if any.

4 POLICIES E COMPLIANCE

4.1 Does the Company carry out suitable Due Diligence activities on individuals and legal entities, including non-profit ones, with which it collaborates to ensure that no benefits are offered to employees or public officers, customers or other subjects for unlawful purposes?

[ ] No [ ] Yes if the answer is no, please give the reason why

4.2 Does the Company ensure that the conduct of individuals and business entities, including non-profit ones, with which it collaborates, is compliant with the current anti-corruption laws?

[ ] No [ ] Yes if no, please give the reason why

4.3 Please indicate if the company/entity holds ISO 9001 certification and/or other valid certifications

[ ] No [ ] Yes

4.4 Please indicate if the company/entity has an Organisational Model, in accordance with Legislative Decree 231/01, and a supervisory board

[ ] No [ ] Yes

4.5 Please indicate if the company/entity has its Code of Ethics and mention any training activities carried out

[ ] No [ ] Yes

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4.6 Please indicate if the company/entity or any of its representatives is under investigation or is subject to or has been subject to precautionary measures or convictions (including non-final ones) for the crimes relevant as of Legislative Decree 231/01, under articles 356 and 356 bis of the Italian penal code (bid-rigging)

[ ] No [ ] Yes

If yes, for which crimes

4.7 The company/entity undertakes to scrupulously comply with the Assobiomedica Code of Ethics.

4.8 The company/entity undertakes to immediately give notice of any changes to the statements provided herein.

Date _____

Stamp and signature

_____

*Please indicate if A) Legal Representative; B) Director with power of attorney, [if yes, specify]; C) Director without power of attorney; D) Executive Officer.

**Public Officer means a public employee who has authoritative or negotiation powers.

ANNEX 2
TRANSPARENCY TEMPLATE

	Full Name	HCPs: City of Principal Practice HCOs: City where registered	Country of Principal Practice	Principal Practice Address	Donations	Scholarship	Contribution to costs of Events			Contribution to costs of Training			Costs for the participation in training, educational and promotional events on company's products organised by the Members	Fee for service and consultancy		Transfers of Value Research & Development	Total
							Sponsorship agreements with HCOs/Third Parties appointed by HCOs to manage an event	Registration Fees	Travel & Accomodation	Sponsorship agreements with HCOs/Third Parties appointed by HCOs to manage an event	Registration Fees	Travel & Accomodation		Fees	Related expenses agreed in the fee for service or consultancy contract, including travel e accommodation relevant to the contract		
HCPs (Healthcare Professionals)	**INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)**																
					NA	NA	NA*	NA*	NA*							NA	
					NA	NA	NA*	NA*	NA*							NA	
					NA	NA	NA*	NA*	NA*							NA	
					NA	NA	NA*	NA*	NA*							NA	
	AGGREGATE DISCLOSURE - per HCPs																
	Aggregate amount attributable to transfers of value to such Recipients				NA	NA	NA*	NA*	NA*							NA	
	Number of Recipients in aggregate disclosure				NA	NA	NA*	NA*	NA*							NA	
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed				NA	NA	NA*	NA*	NA*							NA	
Healthcare Organizations and Third Parties	**INDIVIDUAL NAMED DISCLOSURE - one line per HCOs (i.e. all transfers of value during a year for an individual HCOs will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)**																
					Only HCO	NA				NA	NA	NA	NA			NA	
					Only HCO	NA				NA	NA	NA	NA			NA	
					Only HCO	NA				NA	NA	NA	NA			NA	
					Only HCO	NA				NA	NA	NA	NA			NA	
ealthcare Organizations and Third Parties	**AGGREGATE DISCLOSURE**																
	Aggregate amount attributable to transfers of value to such Recipients				Only Third Parties		NA	NA	NA	NA	NA	NA	NA	NA	NA		
	Number of Recipients in aggregate disclosure				Only Third Parties		NA	NA	NA	NA	NA	NA	NA	NA	NA		
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed				Only Third Parties		NA	NA	NA	NA	NA	NA	NA	NA	NA		

* In the case of direct support for the formation of HCPs that they exercise in a private context, it will be necessary to publish the data in individual or aggregate form, depending on whether the HCP has given consent

ANNEX 3

CONFINDUSTRIA
Dispositivi Medici

PROTOCOL OF UNDERSTANDING'S FACSIMILE SIGNED WITH CONFINDUSTRIA ALBERGHI, FEDERALBERGHI, ASSOHOTEL

CONFINDUSTRIA DISPOSITIVI MEDICI with registered offices at Viale Pasteur 10, Rome, Tax Code 97123730158, in the person of its Chairman and legal representative and

……

given that

- Confindustria Dispositivi Medici is the national association for firms operating in the sector of biomedical devices and technologies;
- …… is a union organization representative of firms operating in the tourism-hotels sector;
- by joining Confindustria Dispositivi Medici firms agree to comply strictly with the association's Code of Ethics, which are an integral part of the Statute and govern the minimum standards of business practice to be followed in Italy and abroad (attachment);
- in view of the need for interaction and close collaboration between the medical equipment/medical technologies sector and professionals in the healthcare sector, art. 2.7 of the Code of Ethics specifically governs the relations between professionals in the healthcare sector and the public administration, with a view to guaranteeing the absolute sobriety of the organization of and/or participation at events organized by the firms and by third parties;
- by mere and incomplete way of example, the instructions governing frugality contained in the Code of Ethics are summarized below:
  - prevalence of the technical-scientific aspects of events over the recreational-tourism aspects;
  - no coverage of the hospitality and travel expenses of companions;
  - hospitality and travel expenses limited to the 24-hour periods before and after an event;
  - no sponsorship and/or organization of events in the period from 1 June to 30 September at seaside locations and from 15 December to 31 March, as well as from 15 June - 15 September, at mountain locations;
  - organization of events at five-star facilities, regardless of the rates or promotional offers made;
  - air travel solely in economy class, except for intercontinental flights;
  - easily reachable event locations;
  - moderate cost of meals;
  - it is of paramount importance for Confindustria Dispositivi Medici to safeguard the image of the sector and the primary goals represented by the good of patients and progress in their treatment and care;

– in order to secure the use of suitable facilities for sector events, having regard for their capacity and other factors, by signing this Protocol of Understanding Confindustria Dispositivi Medici and …… intend to define certain required parameters for facilities signing the Protocol, so that they may be recognized as compliant with the principle of sobriety required by the Code of Ethics of Confindustria Dispositivi Medici.

Given all of the above inclusive of chance and other factors, it is agreed and set down as follows:

1) The recitals are an integral and essential part of this Protocol, which is valid and effective for all member firms of Confindustria Dispositivi Medici and binding on all facilities that are members or signatories of ……

2) Signature of this Protocol of Understanding, with the agreed parameters of sobriety, is intended to overcome the restrictions on the classification of hotel/conference facilities, solely for those that are signatories, without prejudice to the period-of-use restrictions (at seaside and/or mountain locations), which always apply.

3) Facilities signing this agreement will be deemed compliant with the Code of Ethics of Confindustria Dispositivi Medici. For this purpose, …… agrees to send Confindustria Dispositivi Medici a list, and subsequent updates, of firms that have signed this Protocol.

4) By signing this Protocol, the Parties agree to comply with the following parameters:

– exclusion of services not strictly associated with the conference event (well-being centers, saunas, swimming pools, golf, spas, beaches, sports equipment, etc.). These services may be used by event participants at their own expense.

– definition of packages with suitable maximum tariffs, with particular emphasis on shuttle, bar and restaurant services (use of ID badges to obtain discounts), as well as wi-fi, without exceeding current market prices.

5) By signing this Protocol, the Parties agree on the following indicative tariffs, given by way of example, which represent reference parameters for the definition of offers:

– coffee break: 14 euro;

– light lunch: 25-35 euro;

– working lunch: 35-50 euro;

– dinner: 50-80 euro (drinks included);

– lodging (including breakfast) for Rome, Milan, Bologna, Florence, Naples, Venice: up to 230 euro in double room for single use

– lodging for the other cities (including breakfast): up to 190 euro in double room for single use;

– Hotel parking: 20 euro per day;

– wi-fi: free access.

The above amount are VAT excluded.

The Parties will meet once each year to review the above tariffs, which may be negotiated on a reasonable basis directly by the signatory firms.

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6) The Parties agree to determine together how this Protocol will be communicated and the texts of any press releases. For this purpose, the following contact persons are appointed:

- for Confindustria Dispositivi Medici: Guido Beccagutti
- for ……:…… ……

Failure to comply with this provision will result in immediate termination of this Protocol.

7) Should Confindustria Dispositivi Medici or …… receive formal notification from their members of behaviour inconsistent with that agreed in the Protocol, the General Managers of the respective associations shall meet within 15 days of receipt to consider the adoption of appropriate measures. If the Parties fail to agree on the measures to be taken, or if the inconsistent behaviour is repeated, the Parties shall be free to withdraw from this Protocol by sending a formal withdrawal notice by registered letter with proof of receipt.

8) This Protocol is valid and effective from the date of signature. During January each year, the General Managers of the Parties shall meet to consider the renewal of this Protocol and any amendments to the conditions set down herein.

Read, confirmed and signed

Rome, December 2024

Confindustria Dispositivi Medici	Association
Chairman	.....
	Chairman .....