

## ETHICAL BUSINESS PRACTICE POLICY

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### OVERVIEW

Healthcare 21 (hereinafter referred to as the “Company”) places the utmost importance in performing business in an ethical manner. One of the Company’s core values is transparency - “We are honest, open and transparent in everything we do. We always do what’s right for our community, colleagues and our partners”.

The Company is a member of Medtech Europe and the Irish Medical & Surgical Trade Association (IMSTA) whose commitment to high ethical standards governs all interactions between the Company and healthcare professionals. The Company has adopted these standards and guidelines across the Group.

### PURPOSE

The Company is committed to ethical business practices giving the Company a positive professional reputation among vendors, clients and potential business partners. Maintaining good ethical business practices sustains strong business relationships for the benefit of the Company.

### SCOPE

This policy applies to all employees and any third-party representatives or sub-contractors.

### POLICY

The Company acknowledges that the medical technology is subject to national and supranational law which govern many aspects of our business operations.

The following laws may be relevant to the Company’s business practice.

- Safety, Quality and Performance Laws;
- Advertising and Promotion Laws;
- Data Protection Laws;
- Anti-corruption laws;
- Environmental Health and Safety Laws;
- Competition Laws.

Medtech and IMSTA provide detailed guidelines which clarify and distinguish between appropriate and inappropriate activity such as:

- appropriate support of scientific and educational conferences;
- legitimate consulting agreements with Healthcare Professionals;
- provision of educational grants and charitable donations;
- provision of modest hospitality and gifts.

### GENERAL CRITERIA & GUIDELINES FOR EVENTS

The Company may invite healthcare professionals to Company events and third party educational events, however there are a number of specifics that need to be adhered to and the following will be considered in great detail:

- event programme;
- event location and venue;
- guests;
- reasonable hospitality;
- travel;

- transparency.

**Event Programme:**

The Company organises a number of educational conferences throughout the year and on occasion enlists the expertise of healthcare professionals. It is important to consider that the event programme should directly relate to the healthcare professionals who are attending the event or be sufficiently relevant to justify the attendance of the healthcare professional. For third party organised educational events, the agenda should be under the sole control and responsibility of the third party organiser.

The Company will not organise educational events that include sporting, social and / or leisure activities, nor support such elements of third party events.

**Event Location and Venue:**

The Company recognises that the venue of the meeting must not be the main attraction and the public perceptions of the location and venue must be considered. i.e. no luxury 5-star resorts. The venue must be centrally located to facilitate ease of access for participants.

**Guests:**

The Company does not permit to facilitate meals, travel or accommodation for guests of healthcare professionals or any attendees who don't have a legitimate professional interest in the event.

**Reasonable Hospitality:**

The Company may provide reasonable hospitality to healthcare professionals in the context of company events and third party organised educational events, but any hospitality offered must be subordinate in time and focus to the event purpose. "Reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct. The Company will not pay for or reimburse healthcare professionals' accommodation at a 5-star luxury resort. The Company does not permit accommodation offered beyond the official duration of the event.

**Travel:**

The Company will only pay or reimburse for reasonable and / or actual travel. If travelling by air, the Company will only reimburse economy or standard flights. In the instance where the flights are over five hours in duration, business class flights may be considered.

**Transparency:**

The Company will ensure full compliance with national laws with regard to the disclosure or approval requirements associated with such financial support and shall at all times maintain appropriate transparency. The Company may provide financial and / or in-kind support to third party organised educational events in accordance with the rules of the code.

**GRANTS & CHARITABLE DONATIONS****General Principles:**

Grants and charitable donations are not to prompt or influence past, present or potential future purchases for the Company. It is imperative that the Company's charitable and philanthropic work is not viewed as a reward to favoured customers.

The Company will not provide grants or charitable donations to individual healthcare professionals. Grants and charitable donations will only be issued when the request has been made in writing, by an employee or officer of the qualifying organisation.

The payment in the form of a grant or charitable donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. It must, in all cases, be lawful under applicable national laws and regulations for the grant or charitable donation beneficiary to receive and benefit from the particular type of donation.

The Company has implemented an independent decision making / review process team (Education Committee) to identify, prevent and counteract against potential bribery and corruption risks arising in connection with the provision of a grant or a charitable donation to a specific prospective recipient. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

Grants and charitable donations will only be granted in response to a written request containing sufficient information to permit an objective evaluation of the request to be carried out by the Company. No grant or charitable donation shall be provided until a written agreement is signed by both parties.

### **EDUCATIONAL GRANTS**

Any educational grants or funds must be provided directly to the qualifying organisation or entity. The Company may provide restricted educational grants for the advancement of genuine medical education. The Company shall document and publicly disclose all educational grants in accordance with the Code's Disclosure Guidelines.

#### **Support for third party organised educational events**

As a general rule, any third party organised educational event supported by way of an educational grant from the Company must comply with the general criteria for events, as stated above and where applicable have approval via the Conference Vetting system.

#### **Support for Healthcare Professionals Participation at Third Party Organised Educational Events**

Where the educational grant is provided for the purpose of supporting healthcare professionals' attendance at third party organised educational events, the healthcare organisation receiving the grant shall be solely responsible for selection of participants and this should be reflected in the written grant agreement.

Where the prospective beneficiary of the educational grant is the organiser of the third party organised educational event, in this instance the recipient shall be solely responsible for the programme content, the selection of faculty and the payment of the faculty honoraria.

#### **Scholarships and Fellowships:**

The Company may provide educational grants on a restricted basis in the form of grants for scholarship and fellowships to support advancement of genuine medical education of healthcare professionals. Only healthcare organisations where healthcare professionals are in training shall be eligible to request or receive such educational grants.

#### **Grants for Public Awareness Campaigns**

The Company may provide educational grants on a restricted basis to healthcare organisations for the legitimate purpose of providing information, promoting awareness or educating patients in areas of particular interest to the company.

#### **Research Grants**

Where permitted by national law, regulations, national guidelines and professional codes of conduct the Company may provide restricted research grants. This will be to support clearly defined third

party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the member company is interested or involved.

These may include in kind or financial support for legitimate, study-related, documented expenses or services, and or reasonable quantities of single-use and / or multiple-use free of charge product(s) for the limited duration of the research.

All requests for research grants from prospective grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestone and the budget, the duration of the research and the requirements for the education committee, regulatory and / or other authorisations or approvals. The Company may consider a request for a research grant prior to the education committee.

#### **ARRANGEMENTS WITH CONSULTANTS**

The Company may engage with healthcare professionals as Consultants and Advisors to provide consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company events and product development.

The Company may pay healthcare professionals reasonable remuneration for performing these services. In all instances, consulting arrangements will be permitted under the laws and regulations under the country where the healthcare professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

Consulting arrangements shall not be contingent in any way on the prospective Consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the member company products or services.

When selecting a Consultant, the Company shall implement an independent decision-making / review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants.

Consulting arrangements must also cover the following:

- a) be entered into only where a legitimate business need for the services is identified in advance;
- b) the number of Consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- c) selection of Consultants must be based on criteria directly related to the identified business need and the relevance of the Consultant's qualification, expertise and experience to address the identified need;
- d) be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must stipulate the nature of the services to be provided and the basis of services for those services;
- e) the hiring of the Consultant must be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Company's products or services;
- f) the remuneration of services rendered must be reasonable and reflect the fair market value of the services provided;
- g) the Company will maintain records of the services and associated work products provided by the Consultant healthcare professionals and of the use made of those services by the member company.

**Remuneration**

The remuneration paid to healthcare professionals engaged as Consultants by the Company shall reflect fair market value for the services provided. All payments made for services will comply with all applicable tax and other legal requirements. The Company may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation or expenses incurred by Consultants if attending meetings with, or on behalf of member companies.

**DISCLOSURE AND TRANSPARENCY**

The Company will ensure they fully comply with all applicable national laws, regulations and professional codeCs of conduct requiring any publication, disclosure or approval in connection with the use by the Company of healthcare professionals as consultants.

All necessary consents and approvals must be obtained by the healthcare professional, to include from the hospital or the healthcare professional's superior as applicable. Where no such requirement applies, the Company will maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy agreement.

**EDUCATIONAL ITEMS AND GRANTS:**

The Company may provide inexpensive educational items and / or gifts, in accordance with national law, regulations, industry and professional codes of conduct of the country where the healthcare professional is licensed to practice in exceptional circumstances.

- Educational items and / or gifts may be provided but these must relate to the healthcare professional's practice, or benefit patients, or serve a genuine educational function.
- No educational items and / or gifts should be provided in response to requests made by healthcare professionals.
- Educational items and / or gifts must not be given in the form of cash or cash equivalents.
- Educational items and / or gifts must be modest in value and can be branded or non-branded items.
- The Company may occasionally provide educational items of greater value to a healthcare organisation, provided that the item serves a genuine educational function for the healthcare organisation and is of benefit to patients. Such items shall not be provided to healthcare professionals for their personal use. The item may also be related to the therapeutic areas in which the Company is interested and / or involved. For higher value educational items, the Company must maintain appropriate records of their provisions of such educational items to healthcare organisations. Such items should not be part of the healthcare organisation's normal overheads or routine cost of operations.
- The provision of educational items and / or gifts must not improperly reward, incentivise and / or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Company's products or services.

**DEMONSTRATION PRODUCTS AND SAMPLES:**

The Company may provide products as demo products and / or samples at no charge in order to enable healthcare professionals and / or healthcare organisations to evaluate and / or familiarise themselves with the safe, effective and appropriate use and functionality of the product and / or related service

and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and / or service in the future.

Demo products may be single-use or multi-use. The Company may provide products from another company in conjunction with its own demonstration products and / or samples on an exceptional basis if those other company's products are required to properly and effectively demonstrate, evaluate or use the Company's products. e.g. computer software

Provision of demo products and or samples must not improperly reward, induce and or encourage healthcare professionals to purchase, lease, recommend, prescribe, use, supply, or procure the Company's products or services. Any offer and / or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

The Company shall maintain appropriate records in relation to the provision of demo products and samples to Healthcare Professional and or healthcare organisations e.g. recording proof of delivery of samples and / or proof of return for multi-use demonstration products.

This provision of demos and samples and related services at no charge, is not intended as a prerequisite to products or demos under other arrangements. e.g. provision within the framework for trials and / or other research or commercial supplies by way or rebates or pricing incentives in a public procurement context.

**Demonstration products:**

The Company may provide examples of their products to Healthcare Professionals and / or healthcare organisations in the form of mock-ups or unsterilized single use products that are used for healthcare professionals and patient awareness, education and training.

**Samples**

The Company shall provide a reasonable number of samples at no charge to allow Healthcare Professionals and / or healthcare organisations to familiarise themselves with the products or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or not they would like to proceed with orders and purchases in the future.

For single use samples, the numbers must not exceed a reasonable number necessary for the Healthcare Professional to acquire adequate experience.

For multi-use samples, the length of time required by the healthcare professional to familiarise themselves with the product will depend on the frequency of use, the duration of required training and the number of Healthcare Professionals using the products. The Company will remove the samples at the end of the familiarisation period.

**DISCLOSURE OBLIGATIONS:**

The Company shall document and disclose all payments related to educational grants that it makes to a healthcare organisation. The Company shall disclose for each clearly identifiable and separate recipient, the amounts paid as educational grants to such recipient in each reporting period. Itemised disclosure shall be made available upon request by the relevant recipient and / or authorities. Each disclosure must fall under the following categories:

- educational grants to support third party organised events or healthcare professionals attendance at educational events;

- other educational grants to healthcare organisations including scholarships, fellowships and or grants for public awareness campaigns.

The Company's disclosures will be reviewed by our independent education committee. The committee will create a methodology note which clearly highlights why and how much will be granted. This methodology note should be made available upon request.

Disclosures shall be made on an annual basis and each report shall cover a full calendar year. These disclosures will be made public by IMSTA on the 31<sup>st</sup> August of that particular year.

CONFIDENTIAL