CZECHMED CODE OF ETHICS

Whereas:

- CZECHMED, an interest grouping of legal persons (hereinafter referred to as "CzechMed"), is a member of the European association MedTech Europe;
- Article 6(a) of the Statutes provides that the Association contributes to market transparency;
- Article 6(e) of the Statutes provides that the Association promotes a high standard of ethics;
- Article 7(f) of the Statutes provides that the Association contributes, through its Code of Ethics, to the cultivation of the healthcare landscape;
- Article 7(g) of the Statutes provides that the Association advocates for the consolidation of ethical standards of cooperation between suppliers of medical devices and the professional medical community;

CzechMed hereby publishes this Code of Ethics (hereinafter referred to as the "Code") on cooperation with healthcare professionals:

I. Introduction

In accordance with Article 25 of the CzechMed Association's Statutes, each member of CzechMed is obliged to comply with this CzechMed Code.

The Code:

- does not replace or have primacy over the legislation of the Czech Republic;
- constitutes a set of simple rules that, in content, respect the provisions of the MedTech Europe Code of Ethical Business Practice, although these are not copied entirely in the Code's structure;
- sets CzechMed members minimum standards applicable to various types of relations with healthcare professionals.

All members must ensure that their cooperation with healthcare professionals is in accordance with applicable legislation and this Code. Members are mindful of the fact that, in order for the medical technology/devices industry to be able to continue to cooperate with healthcare professionals, applicable laws and ethical standards must be observed.

The purpose of this Code is to provide a minimum ethical standard for the cooperation of CzechMed members with institutions or individuals who purchase, lease, recommend, use, modify for purchase or lease, or prescribe medical devices of CzechMed members (hereinafter referred to as "healthcare professionals").

There are numerous forms of cooperation between CzechMed members (hereinafter referred to as "members") and healthcare professionals that increase the level of medical science and improve patient care. These include:

Advancement of treatment technologies. The development of new medical devices and the improvement of existing products is often the result of cooperation between members and healthcare professionals. Innovation and creativity are essential for the development of medical devices and often take place outside the premises of companies manufacturing medical devices.

Safe and effective use of medical technologies. The safe and effective use of medical technologies often requires members to provide appropriate guidance, education, practical training, services and technical support to healthcare professionals. Regulatory authorities may even make such training a condition of product approval.

The Code emphasises fundamental principles, which are further incorporated into specific chapters. These principles are:

1. Maintaining the Association's reputation and image;
2. In interactions with healthcare professionals and healthcare facilities, preventing abuse that may influence them unduly;
3. Remunerating healthcare professionals and healthcare facilities in a non-discriminatory way for their

cooperation;
4. Proportionality, which should be described in more detail in the internal regulations of individual members so that the amount and frequency of a particular fee, financial contribution, gift, sample, etc., are always defensible;
5. Ensuring transparency;
6. Documenting interactions with healthcare professionals and healthcare facilities.

II. Product training and education supported by members

Where appropriate or where it follows from Czech legislation, members will provide healthcare professionals with product training and practical training to enable them to use a particular medical device safely and effectively.
These programmes should always take place in suitable locations and venues that are equipped to facilitate the effective transfer of knowledge. They should also be designed so that their content is professional and does not include excessive social, entertainment and/or leisure activities.

Members:

- will organise such training, depending on the professional purpose thereof, at accessible locations to ensure that time is spent efficiently;
- product training and education may be conceived as company symposia held at the same location and at the same time as a third-party educational congress;
- may provide participants with reasonable refreshments during training;
- may reimburse programme participants' reasonable travel and accommodation costs in accordance with applicable legislation; economy class tickets (for flights up to 5 hours) or business class tickets (for flights over 5 hours) and hotels with a maximum of four stars are considered reasonable;
- participants cannot be reimbursed for personal activities unrelated to the professional programme;
- must not reimburse travel or other expenses to partners or guests of healthcare professionals.

Speakers' expenses. Members may support healthcare professionals who are active participants in an event by providing them with a reasonable fee.

III. Support for third-party educational congresses

Congress support. Members may provide employers of healthcare professionals with financial grants or indirectly reimburse their costs through an account set up by the employer of a healthcare professional and/or another public-sector employee, or through an institution providing education to a student, in particular to:

- cover congress fees;
- cover reasonable travel costs; economy class tickets (for flights up to 5 hours) or business class tickets (for flights over 5 hours) are considered reasonable;
- cover the reasonable cost of meals;
- cover reasonable cost of accommodation; hotels with a maximum of four stars are considered reasonable.

Speakers' expenses. Members may also indirectly contribute to the cost of speakers in the form of a financial contribution to the congress organiser. At a third-party congress, members may pay for speakers' fees only if a block of lectures/meeting/panel is financially supported by the members and this fact is explicitly stated in the official programme of the third-party event.

A particular emphasis must be placed on justifying support for the participation of healthcare professionals if such a congress is held at an attractive foreign destination. If such a scientific congress takes place in a luxury five-star hotel, only the cost of the registration fee and transport can be covered, but not accommodation in the congress hotel. The coverage of travel expenses must match the dates of the congress, with a tolerance of ±1 day. This support must comply with Czech law and must be clearly specified before the congress.

Members are obliged to ask the beneficiary (the employer or educational institution) for written proof of the actual use of the funds used to cover expenses and to archive it along with other documents evidencing the coverage of costs.

Advertising and demonstration events. Members may purchase advertising time or rent space for a company exhibition stand at congresses. It is forbidden to serve alcohol at stands.

IV. Sales and promotional meetings

If members meet healthcare professionals to discuss the properties of medical devices and sales matters, such meetings must generally be held at or near the healthcare professional's workplace. At such meetings, members may cover the cost of reasonable hospitality for healthcare professionals. Members may not reimburse participants for their travel or accommodation. Situations where a non-portable medical device or equipment is being demonstrated are an exception to this rule. It is not permissible to cover the cost of food, travel or other expenses for guests and/or family members of a healthcare professional.

V. Contracts with consultants

Healthcare professionals may become members' consultants in the areas of research, professional advice, presentations at meetings financially supported by the members, and cooperation in the development of medical devices. Reasonable fees may be paid to healthcare professionals for these services. Such fees must not be related to the past, present or future sale or lease of a medical device whose volume/implementation the consultants may influence in their own practice. Payment must be made for services actually provided and in accordance with applicable tax and other legislation.

Members may be reimbursed for reasonable expenses associated with the provision of consultancy services, such as accommodation, meals and travel expenses. However, all billable items should be predetermined in a consulting agreement.

Consulting contracts with healthcare professionals must be in writing, signed by both parties (before the date of the service), must indicate specifically and precisely which services are to be provided, and must comply with applicable legislation.

The number of consultants must not exceed the number of consultants objectively necessary to achieve the provision of a given service.

An independent selection process must be applied when selecting a consultant(s). A consultant's actual or potential influence on a member's sales volume MUST NOT, under any circumstances, be a criterion for the selection of consultants.

The consultant selection criteria must be a consultant's qualifications and experience, which must be such that the consultant is able to fulfil the stated purpose of the contract.

Members also undertake to inform the consultant's employer in writing in all cases by means of a notification describing the purpose and scope of services, or they must contractually transfer this responsibility to the consultant.

The venue and circumstances of meetings between members and consultants must reflect the subject matter of the consultation. Hospitality financially supported by a member in connection with a consultation meeting must be of proportionate value, incidental in terms of the time thereof, and must be consistent with the primary purpose of the meeting.

Financial compensation for consultancy services rendered must be reasonable and reflect the fair market value. Members also undertake to maintain records of contractual performance in the form of photographic documentation, presentation materials, etc.

VI. Gifts

Members may occasionally provide healthcare professionals with small gifts or promotional items, which must be of modest value and must comply with applicable Czech legislation. As a general rule, gifts should relate to the healthcare professional's type of work and be beneficial for patient care or for the improvement of the healthcare professional's working conditions, or be purely educational.

It is expressly forbidden to provide gifts in any cash form.

Members may occasionally provide a healthcare facility with gifts of greater value in the form of training aids, provided that such aids are to be used by the facility's professionals and improve patient care. These should only be devices that are consistent with the area of treatment in which the member does business.

No gifts may be tied to a member's sales, not even as an acknowledgement, compensation or incentive.

Members are obliged to keep records of all gifts.

VII. Charitable donations

Members may provide charitable donations (including grants), e.g. in support of non-commercial research for the advancement of medical science or education, care for the needy, and financial support for events where the proceeds are intended for charitable purposes. All donations must be properly documented.

Advancement of medical education. Members may create grants for the advancement of the purely medical education of medical students and assistant professors participating in specialist programmes that are charitable or associated with academic activity, or other healthcare professionals, provided that this is done in accordance with the introductory provision of section VII. (For further details on educational grants, see section III. Support for third-party educational congresses.)

Advancement of scientific research. Members may create grants for the advancement of non-commercial research. The purpose of such grants must be clearly documented (for guidance on the restrictions that apply to contracting between a member and a healthcare professional on research on behalf of a member, see section V. Contracts with consultants). For more details, see section IX.

Public education. Members may create grants to advance the education of patients or the public on important health issues.

VIII. Samples and demonstration products

Member companies may provide their products in the form of demonstration products and/or samples, free of charge, to enable healthcare professionals to familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related services.

Demonstration products: Member companies may provide healthcare professionals with examples of their products in the form of mock-ups (e.g. non-sterile single-use products) that healthcare professionals can use for patient information, education, and training. Demonstration products are not intended for clinical use or for resale and distribution.

Samples: Member companies may provide healthcare professionals with a reasonable number of samples free of charge to enable them to familiarise themselves with the products and gain experience in their use in clinical practice. The quantity of samples of single-use products must not exceed a reasonable quantity necessary for the healthcare professional to gain adequate experience in the use thereof.
In terms of reusable product samples, the specific time required for the healthcare professional to become familiar with the product will depend on the frequency of intended use, the duration of the training required, the number of healthcare professionals who will need to gain experience, and other factors. In each case, member companies must ensure that they retain ownership of samples of reusable products and have a process in place to rapidly withdraw such a sample from the clinical site at the end of the familiarisation period.

The provision of demonstration products and/or samples must not unreasonably reward and/or motivate healthcare professionals to purchase, recommend, prescribe or use the products or services of member companies. Any offer and/or supply of such products or samples must always comply with applicable national laws, regulations and professional codes of conduct.

In all cases, member companies must keep appropriate records of the provision of demonstration products and/or samples to healthcare professionals, e.g. confirmation of receipt when any demonstration products or samples are provided. Records of samples must be transparent and drawn up in writing, and the samples must be provided free of charge.

IX. Research

If there is a legitimate reason to do so, members may initiate or fund professionally valid research to generate the necessary data, not only in connection with the marketing of products. Reasons that are considered legitimate are patient safety, the support of further scientific advancement, the measurement of product performance and quality indicators, regulatory reasons, or evaluation of economic impacts usually in connection with the setting of reimbursement.

All research activities must be documented in writing and follow an appropriate clinical protocol. Members are obliged to obtain all necessary approvals from local authorities before commencing the research and to conduct the research in accordance with applicable law and ethical requirements. Members must ensure the transparency of the data generation and evaluation process.

Members may also initiate user evaluations of products/services by third parties, provided that a written contract is concluded for such evaluations. Members are obliged to keep records of such evaluations and, at the same time, to record the samples that are to be used for evaluations in accordance with section VIII.

X. Intellectual property and licence fees

If a healthcare professional, a group of healthcare professionals or a healthcare facility makes a scientific discovery, breakthrough or major innovation, or if this can be expected (for example, the development of a new product, method, process or technology), a member may enter into an appropriate licensing agreement. The agreement does not release the member from fulfilling any other obligations under applicable legislation.

The agreement must always be drawn up in writing. The fee must not unreasonably reward and/or motivate healthcare professionals to purchase, recommend, prescribe or use the products or services of member companies.

XI. Transparency

Members must ensure transparency and properly document all activities and expenses linked to their cooperation with healthcare professionals in accordance with Czech law, the relevant decrees and guidelines, and the CzechMed Code of Ethics.

Information on grants provided in support of third-party educational congresses will be published by members via a European platform ("MedTech Transparency") in aggregate form (grantor's name, facility's name and total amount for the past calendar year) no later than the end of February of the following year.

XII. Force and certification

Force. This Code enters into force on 1 January 2018. Members are obliged to have implemented it fully in the course of 2018 but no later than 31 December 2018. The guideline is binding on all members as of 1 January 2019.

Certification. Members who declare in writing (with their signature) that they accept the Code will be certified by CzechMed as an Ethical Member of CzechMed. The Certificate will remain valid indefinitely.

Certified members will be listed on the CzechMed website and may feature in other CzechMed lists and materials. They may also use the Certificate for their own communication purposes.

Members will also inform their distributors and relevant business partners about the Code and its implications.

XIII. Consultations and dispute resolution

Consultations. At CzechMed, members may use PSPE, especially in the form of active or passive participation in group working meetings. If necessary, a separate group meeting may be initiated or an individual consultation can be arranged. MedTech members may also draw on the assistance of another competent MedTech authority – The MedTech Europe Code Committee.

Dispute resolution. Any complaint about or initiative to review a member's conduct that is not in accordance with the Code of Ethics should be addressed to the CzechMed president. If no satisfactory settlement is reached, the author may refer the issue to the level of the CzechMed board.

If there is any ambiguity in the interpretation of the Code, the president and/or the board will consider the full text of the MedTech Europe Code of Ethical Business Practice.

Involvement of MedTech Europe. If it is not possible to resolve a case at the CzechMed level, or if there are relevant grounds to do so (for example, the transnational dimension of the case), the case should be referred to MedTech (The MedTech Europe Compliance Panel) for resolution.

Breach of guideline. If the CzechMed board and/or a MedTech authority finds that there has been a breach of the Code or a guideline, it draws up a written report containing a draft resolution and the reasons for the conclusions and draft resolution.

Annexes:

1. Approval of the adoption of the Code
2. Sample text to inform the employer about cooperation
3. Sample text to apply for the actual use of funds provided

Annex 1

APPROVAL OF THE ADOPTION OF THE CZECHMED CODE

I approve the adoption of the CzechMed Code of Ethics. I also confirm that I am acquainted with the content and implications thereof.

Member company's name	Representative's name	Signature
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Annex 2

INFORMATION TO THE EMPLOYER ON AN EMPLOYEE'S CONSULTING ACTIVITIES

addressee

address1

address2

This is to inform you that

_____

(employee's name)

is performing work for reasonable remuneration, in addition to normal work duties arising from their employment at your facility, for

_____

(name of company / contracting entity)

entailing acts connected with the writing of expert articles, on agreed topics, and/or the preparation of training and communications for use at professional conferences, seminars, etc.

Place: …….., dated: …….

Name and signature: ……

Telephone: ……

Email: ……

Annex 3

“The parties hereby agree that the amount donated will be used by the Beneficiary exclusively to cover employees’ costs incurred in connection with the educational event ……. held on (dates) ……. to the following extent: (i) … travel expenses …, (ii) … registration fee …, (iii) …….

The Beneficiary hereby undertakes to provide, no later than 60 days from the date of the end of the above-mentioned event, copies of documents evidencing the use of the donation in accordance with the purpose defined above.”