LTMed OÜ
Peterburi tee 81, Lasnamäe linnaosa
11415 Tallinn, Harju maakond, Estonia

STANDARD OPERATING PROCEDURE

Code of Marketing Practices

Ethical interactions with healthcare professionals, healthcare organisations, manufacturers and intermediaries

Document title	Code of Marketing Practices
Issued by	LTMed OÜ
Edition	In force from 1 February 2025
Review	At least once a year, and whenever the law or a partner's requirements change
Languages	English, Russian, Estonian
Contact	info@ltmed.eu

1. Purpose

This SOP sets out how LTMed OÜ ("LTMed") promotes, demonstrates and sells medical devices, and how it works with healthcare professionals, healthcare organisations, manufacturers and intermediaries, so that every interaction is lawful, ethical and transparent.

2. Scope

This SOP applies to all LTMed employees and to all sub-distributors, agents and other third parties acting for LTMed in Estonia, Latvia, Lithuania, Poland, Kazakhstan, Moldova and Belarus. In Kazakhstan, Moldova and Belarus, LTMed operates through local partners, and the applicable national requirements apply.

It covers every activity that promotes, demonstrates or sells the devices LTMed distributes, including meetings with HCPs and HCOs, events, sponsorship, demonstration products and samples, consulting arrangements and tenders.

3. Definitions

Term	Meaning
HCP (healthcare professional)	A person, such as a physician, nurse, technician or procurement officer, who in the course of professional activity may purchase, recommend, use or procure medical devices.

LTMed OÜ
Peterburi tee 81, Lasnamäe linnaosa
11415 Tallinn, Harju maakond, Estonia

Term	Meaning
HCO (healthcare organisation)	An organisation through which HCPs provide care or which influences purchasing, such as a hospital, clinic or professional association.
Intermediary	A sub-distributor, agent or other third party that sells, promotes or markets devices on behalf of LTMed.
Demonstration product	A device or mock-up supplied free of charge for training and not used on patients.
Sample	A limited number of devices supplied free of charge for clinical familiarisation.
Fair market value	Remuneration that reflects what is normally paid for comparable services, determined under a documented method.
Vigilance	The reporting and handling of complaints and suspected incidents involving devices.

4. Responsibilities

Role	Responsibilities
Management	Approves this SOP, provides the resources needed to apply it and makes sure it is followed.
Compliance contact	Owns this SOP; carries out or arranges the independent reviews in section 7.6; receives reports of concerns; organises training; keeps the records in section 8.
Vigilance contact	Receives complaints and incident reports, forwards them to the manufacturer and, where required, to the competent authority, and keeps the complaint register.
Employees	Follow this SOP, complete the training, ask before acting when unsure and report concerns.
Intermediaries	Comply with this SOP as required by their contract, complete the training and provide compliance confirmations.

5. Legal basis and references

- Regulation (EU) 2017/745 on medical devices (MDR), including the general obligations of distributors in Article 14.
- The Estonian Medical Devices Act and the national laws of each country where LTMed operates.

- Anti-bribery and corruption laws and public procurement rules.
- Regulation (EU) 2016/679 (GDPR) and national data protection law.
- The MedTech Europe Code of Ethical Business Practice, whose principles LTMed applies as a reference standard.

This SOP does not replace the law. Where the law, a customer's rules or a manufacturer's code is stricter, the stricter rule applies.

6. Core principles

Every interaction with an HCP or HCO must meet five principles.

- **Image and perception.** Before acting, we consider how the interaction would look to the public, patients and the press.
- **Separation.** Interactions must never be used to influence purchasing, prescribing or recommendation decisions, and nothing is offered in return for them.
- **Transparency.** We follow national laws and professional codes on disclosure. Where the employer of an HCP must be informed or consent is required, we do this in writing before the activity.
- **Equivalence.** Payment for services is limited to fair market value for work that is actually needed and performed.
- **Documentation.** We keep written agreements, activity reports and invoices for the period required by law.

7. Procedure

7.1 Interactions with healthcare professionals and organisations

Our employees may present products, train users on safe use and answer technical questions. They may not offer anything of value to obtain or reward a purchase.

Information and promotion. Product information must be accurate, balanced, consistent with the manufacturer's approved labelling and instructions for use, and must not make claims that the manufacturer has not substantiated.

Consulting arrangements. We engage an HCP as a consultant only to meet a legitimate business need that is identified before the consultant is chosen. Selection is based on qualifications, never on the volume of business the HCP can bring. Each arrangement needs a written agreement signed

before the work starts, payment at fair market value under a documented method, and records of the services delivered. Where required, the HCP's employer is informed or consents beforehand.

Gifts and promotional items. We do not give gifts to HCPs or HCOs. The only exception is an inexpensive, modest item that relates to the HCP's practice or benefits patients; it is never cash or a cash equivalent, never linked to a personal event, and never given on request.

Meals and hospitality. Hospitality is limited to modest meals connected to a legitimate work purpose and must comply with local rules. We do not fund entertainment, personal travel or accompanying persons.

7.2 Events and sponsorship

Our own events. Product training and demonstration events are held at venues suitable for the purpose, with a clear professional programme. Entertainment is kept separate from the programme, and we do not pay for social events, personal travel or guests of HCPs.

Third-party educational events. We may support a congress or training organised by a third party only through a written agreement with the organiser, never by paying an individual HCP directly. The organiser, not LTMed, chooses the participants, and we do not ask for their names.

Grants and donations. A grant or charitable donation goes to an organisation, not to a person, for a stated educational or charitable purpose set out in a written agreement. It is never linked to purchases, tenders or recommendations, and it is approved before payment through the independent review in section 7.6.

Where a manufacturer or an industry body has an approval procedure for events, we follow it before committing support.

7.3 Demonstration products and samples

We may provide demonstration products and samples free of charge so that HCPs can learn how to use a device safely. They must never be used to induce a purchase.

- Demonstration products are for training and are not used on patients. Samples are limited to a reasonable number for clinical familiarisation.
- The free-of-charge terms are put in writing no later than when the product is supplied.
- We record every delivery and return, and the owner of a reusable item keeps title to it.
- We collect reusable items promptly once the evaluation or training period ends.
- Devices are handled and used in line with the manufacturer's instructions and the MDR.

7.4 Third-party intermediaries

LTMed works with sub-distributors and agents, and treats their conduct on its behalf as its own responsibility. Before engaging an intermediary, we:

1. Check country risk, local legal requirements, unusual arrangements and publicly available information about the intermediary, with the depth of the check matching the risk.
2. Sign a written contract that requires compliance with this SOP and applicable law, gives LTMed audit rights, including access to relevant books and records where possible, and allows early termination for breach.
3. Train the intermediary on this SOP, in a language it understands, and repeat the training regularly.

During the relationship we repeat due diligence at renewal, monitor activity according to risk, ask for regular written confirmations of compliance, and take corrective action when problems are found.

7.5 Product complaints and vigilance

Patient safety comes before any commercial interest. Any LTMed employee or intermediary who receives a complaint, or a report of a suspected incident involving a device, must pass it without delay to the LTMed vigilance contact, who forwards it to the manufacturer and, where required, to the competent authority (in Estonia, the State Agency of Medicines, Ravimiamet).

We keep a register of complaints, non-conforming devices, recalls and withdrawals, support field safety corrective actions, and do not make available a device that we have reason to believe does not comply with the MDR.

Complaints can be sent to **info@ltmed.eu**.

7.6 Independent review, reporting concerns, training and monitoring

Independent review. Before LTMed commits to a consulting arrangement, a grant or donation, event support, or a loan of demonstration products, the proposal is reviewed and approved in writing by a person who is independent of sales. The review is documented.

Reporting concerns. Anyone, inside or outside LTMed, can report a suspected breach of this SOP to **info@ltmed.eu**. Reports are handled confidentially, and no one suffers retaliation for a good-faith report. We follow the applicable whistleblower protection law.

Training. All employees receive training on this SOP when they join and at regular intervals. Intermediaries are trained as described in section 7.4.

Monitoring and review. LTMed checks compliance according to risk, corrects any breach found, and reviews this SOP at least once a year and whenever the law or a partner's requirements change.

Questions. If you are unsure whether an action is allowed, ask before you act.

LTMed OÜ
Peterburi tee 81, Lasnamäe linnaosa
11415 Tallinn, Harju maakond, Estonia

8. Records

- Written agreements for consulting, grants, donations and event support, with the related independent review decisions.
- Activity reports and invoices.
- Delivery and return records for demonstration products and samples.
- Due diligence files, contracts and compliance confirmations for intermediaries.
- The register of complaints, non-conforming devices, recalls and withdrawals.
- Training records.

Records are kept for the period required by law.

Reg. Nr. 14269125
VAT Nr. EE101975869
info@ltmed.eu
www.ltmed.eu