

MedTech Europe AiSBL – Internal Rules

As amended by the MedTech Europe Board of Directors on 6 October 2023

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Introduction

Purpose and Drawing up of the Internal Rules

The Internal Rules aim to clarify the [Statutes of MedTech Europe](#) (“the Statutes”), the registered office of which is located at Rue Joseph II 40, 1000 Brussels (Belgium) and whose purpose is set forth in Article 3 of the Statutes of MedTech Europe (“the Association”).

The purpose of the Internal Rules is to supplement and/or explain certain provisions of the Statutes. These internal rules set out specific Association rules and policies pertaining to a variety of scenarios which require additional detail and specification¹. As provided for in the Statutes, “[w]ithin the limits allowed by the law, to detail and complete the provisions of these Statutes, the Board of Directors may adopt, amend and/or revoke internal rules, internal procedures, and/or any other kind of rules that fall within the scope of its powers².” Furthermore, it is the Association’s Board of Directors (“The Board”) who is responsible for “*the adoption, the amendment, and the revocation of the internal rules.*”³

The Internal Rules are binding upon the Members of the Association⁴.

Board of Directors: Change of Role

The Association’s General Assembly, organised in four electoral groups, appoints and revokes the Directors⁵. During a Director’s tenure he/she may change roles, which requires an assessment of the new role to determine if it also meets the Director requirements as per Article 19.2 of the Statutes.

Changing Corporate Member Companies

Where a Director of Corporate Member “X” takes a new position at Corporate Member “Y,” that Director’s mandate shall terminate as of right and with immediate effect⁶. While in his/her new role, the Director may meet the Statutes’ Director eligibility criteria, the corresponding Electoral Group elected the individual due to his/her role at Corporate Member “X,” and would not have necessarily done so at Corporate Member “Y.” Moreover, a Member cannot have more than one Director on the Board and it may be that Corporate Member “Y” is already represented in the Board. As a result, the individual’s directorship does not and cannot automatically transfer.

¹ These MedTech Europe Internal Rules are not exhaustive and will be reviewed and revised as necessary.

² Statutes Art. 44

³ Statutes Art. 20(b)

⁴ “By accepting the membership of the Association, each Member also commits itself to acting in compliance with these Statutes **and the internal rules**, if any....” (Statutes Art. 10, emphasis added)

⁵ Statutes Art. 13, 19.4 & 19.5.

⁶ See Statutes Art. 19.6

Changing Roles within same Corporate Member

Where a Director of a Corporate Member moves into a new role or position within the same Corporate Member, his/her directorship may continue, if, and only if, the individual's new role meets the Director eligibility criteria⁷.

Members

New Members: Wash-Out Period

Any medical technology, device, or in vitro diagnostic company, as well as any medical device or in vitro diagnostic National Association meeting the Statutes requirements may become a Member of the Association⁸. All Members are responsible for compliance with the Statutes and its requirements, including but not limited to, compliance with the MedTech Europe Code of Ethical Business Practice (hereafter referred to as "[the Code](#)"). At the time a new applicant becomes a Member, it must begin to take all the necessary steps required to meet these obligations.

However, the Association recognizes the complexities involved and the time needed to make changes associated with these new obligations. For example, an applicant may have previously committed to participate in or support a Congress or Third-Party Educational Event that has not been approved by the [Conference Vetting System](#) ("CVS"), but that takes place two months after they have become Members. It would be unreasonable, and could deter interest in membership, to require the new Member to back out of those obligations. As a result, Corporate Members have one (1) year from the date of Membership ratification by the Board of Directors to fully comply with the Code. Please note, this one-year time frame does **not** include an exemption from the Code's ban on direct sponsorship. From the moment an applicant becomes a Member, direct sponsorship of HCPs is prohibited.

Association Members will have one (1) year from the date of membership ratification by the General Assembly to transpose the Code, as per Article 2.2. of the Procedural Framework of the Code.

For avoidance of doubt, where an Association membership modifies the MedTech Europe Geographic Scope, as provided by the Code, either by changing its own geographic scope or when a new Association becomes a member of MedTech Europe, MedTech Europe Corporate members will have one year to comply with the Code in these new territories.

After the passage of one (1) year from the date of the relevant General Assembly ratification, all Members must fully comply with all obligations under the Statutes, Code, etc. Any infringement or violation will trigger the necessary Enforcement Mechanism and/or processes⁹.

⁷ See Statutes Art. 19.2 for Director criteria

⁸ See Statutes Art. 4-6 for membership types and criteria

⁹ See Statutes Art. 8 and the Code *Part 3: Procedural Framework*

Membership Costs – M&A Compensation fee

Each Member is responsible for paying annual membership fees¹⁰. However, in the event that a Member is acquired by another Member, through a merger, combines with another Member, or who transfers substantially all its assets to another Member, (hereinafter referred to as a “consolidation”), it must pay to the Association a fee (hereinafter referred to as a “merger fee”). This merger fee shall be calculated using a percentage of the Active member’s dues payment during the year of the consolidation (the “dues payment”)¹¹. The total merger fee may be paid either in full within 30 days of the effective date of the consolidation, or over a period of five years. The merger fee shall be calculated one of two ways and the consolidated entity shall have the choice between the two options:

- (1) The consolidated entity may choose a one-time pay out equal to three hundred percent (300%) of the phaseout amount (i.e. the phase-out amount is the amount of the membership fee that the acquired company used to pay); or
- (2) The consolidated entity may choose to pay the merger fee over a five-year period, declining payments shall be made according to the following schedule:

Year Following Consolidation:	Merger fee based on the last fee paid by the target entity (i.e. merged/acquired) the year of the consolidation:
Year 1	80% of dues payment
Year 2	70% of dues payment
Year 3	60% of dues payment
Year 4	50% of dues payment
Year 5	40% of dues payment

In subsequent years, the consolidated entity’s dues shall be calculated according to MedTech Europe’s dues schedule.

Resignation

A Member may resign from the Association at any time¹². Upon the Chief Executive’s receipt of a Member’s resignation, that company will no longer be a Member of the Association. As a result, from that moment the Member will lose all associated membership rights (but shall remain liable for its obligations towards the Association, as provided by Article 8 of the Statutes) including but not limited to, the right to vote in the General Assembly and the right to submit nominations for election to the Board of Directors. However, the Chief Executive may at his/her discretion, and for a limited time which cannot be longer than the period covered by the Membership Fee, allow the Member to continue to receive certain benefits such as participation in the

¹⁰ See Statutes Art. 5, 6 & 9

¹¹ As decided by the AGM during its 30 Nov 2017 meeting

¹² Statutes Art. 8

Association's Working Groups (unless that Working Group has specifically requested otherwise), receipt of discounted prices for events, receipt of the Members Newsletter, etc.

For avoidance of doubt, the payment of the phase-out amount does not prevent the consolidated entity to pay as of year Y+1 a fee that depends on the consolidated turnover.

Special [IHI] financial contribution/levy

Background

As per Article 10, par. 5 of the [Statutes](#), in addition to membership fees, interested Members can voluntarily agree to be subject to the payment of additional contributions to finance specific projects, services, or initiatives. These levies are distinct from membership fees and may be imposed on an *ad-hoc* basis.

With the objective of advancing "MedTech Strategic Development Opportunities" and in particular the European Research and Innovation Partnership (referred hereafter as "[Innovative Health Initiative](#)" or "IHI") as per the Association's priorities agreed on 11 December 2020, the MedTech Europe Board of Directors agreed on 2 December 2021 that a specific levy fund shall be introduced to ensure the sustainability and growth of this initiative.

The levy

For the duration of IHI, (2021-2031) a levy shall be collected by the Association and be earmarked and used exclusively for the specified purpose of covering the costs related to the MedTech Europe contribution to the IHI Office administrative costs.

The payment of the levy is contingent upon the accepted/approved status of the project undertaken pursuant to IHI rules (hereinafter referred to as the "IHI Project"). Any MedTech Europe Full and Associate Corporate Members (hereafter referred to as "Member"), as per Articles 5 & 6 of the Statutes, may decide to submit a proposal in response to an IHI call ([here](#)). In the event that the project is deemed successful by IHI [Governing Board](#), the Member shall be responsible for the payment of the applicable levy associated with the Project. The levy shall be calculated on the basis of its full in-kind contribution as declared to the IHI Office at the time of signature of the Grant Agreement.

The Association shall provide written notice to each and all Members affected by the levy, detailing the purpose, amount, due date, and any applicable payment instructions.

The Board of Directors may periodically review the need for this IHI levy and may adjust or discontinue it as circumstances dictate. Any adjustments or discontinuation of levies shall be communicated to the Members.

Dispute Resolution

In the event a Member wishes to dispute any of the elements of the obligation to pay a special levy, the Member shall make a reasoned request for review of the dispute elements of the levy to the Board of Directors, addressing it to the Chief Executive of MedTech Europe.

The Member requesting the review may request that any member of the Board of Directors who represents a direct competitor of the Member abstains from voting on the matter, as well as from participating in any discussions.

The Board of Directors shall issue a decision on the review of the elements of the levy in first and last instance.

Miscellaneous

Privacy Notice

As part of its legal obligations under the General Data Protection Regulation EU 2016/679 (“GDPR”) as an international non-profit association constituted under Belgian law, these internal rules include and refer to the Association’s Member Privacy Notice (“Privacy Notice”). This Privacy Notice aims to give Members’ employees information on how their personal data (i.e. information that directly or indirectly identifies a Member employee) is processed by the Association. Members are responsible for informing their employees of the existence of this Privacy Notice, as updated from time to time (available on Sharepoint – link to the Notice [here](#)).

Amendment of the Internal Rules

The Internal Rules are adopted by the Board of Directors and may be amended and/or revoked by the same Board. Any new or amended Internal Rules shall be shared with Members (i.e. internal newsletter) and uploaded on the Association’s website.