

## **MedTech Europe AiSBL – Internal Rules**

*Approved by the MedTech Europe Board of Directors on 24 October 2024*

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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 specification<sup>1</sup>. 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 powers<sup>2</sup>.” 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.”<sup>3</sup>

The Internal Rules are binding upon the Members of the Association<sup>4</sup>.

### Board of Directors: Change of Role

The Association’s General Assembly, organised in four electoral groups, appoints and revokes the Directors<sup>5</sup>. 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 effect<sup>6</sup>. 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.

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

<sup>2</sup> Statutes Art. 22 and 44

<sup>3</sup> Statutes Art. 20(b)

<sup>4</sup> “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)

<sup>5</sup> Statutes Art. 13, 19.4 & 19.5.

<sup>6</sup> 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 criteria<sup>7</sup>.

## Choice of Domicile and Electronic Address

Unless otherwise notified, and in accordance with Article 52 of the Statutes on "Choice of Domicile and Electronic Address" and Article 2:54, Book 10 of the Belgian Code of Companies and Associations ("Code des Sociétés et des Associations" or "CSA"), to safeguard their privacy, newly elected members of the Board of Directors, as well as all current members of the Board of Directors, elect domicile at the registered office of MedTech Europe for all matters related to the exercise of their mandate. This option avoids prevents the need to disclose or publish their private residential addresses and ensures the Directors' availability and prompt communication in connection with their roles.

Any modifications to the postal private residential address or electronic address must be communicated in writing to the Secretariat to ensure continuous and effective communication.

## Members

### New Members: Wash-Out Period

Please refer to Section 2. "Transposition Obligations" of the "Scope" Chapter in the [MedTech Europe Code of Ethical Business Practice](#) for more information on the Wash-Out Period for compliance with the different aspects of the Code before and after becoming a full Member (both Corporate Members and Association Members). Please note this section also covers mergers and acquisitions.

### Membership Fees

As provided in Article 10.1, each year, the amount of Membership fees and the calculation method of the Membership fees for each category of Member shall be prepared by the Board of Directors for submission to the General Assembly. Without prejudice, if applicable, to the above and the principle of a common basis for Membership fees per Member category, the amount of membership fees may vary within a same Member category, based on the electoral bodies defined in Article 20.5, and, in order to avoid perception of inequitably, can be calculated based for example on turnover, number of employees, number of patents, etc.

<sup>7</sup> See Statutes Art. 19.2 for Director criteria

**Commented [AL1]:** This section is new but in fact there is no substantial change. This part was found in Application Forms of New Members as well as in Yearly Turnover Declarations that Members sign each year. To ensure transparency and consistency, this part was therefore moved from those different documents into the Internal Rules.

The membership fees will be determined based on the annual turnover in medical technologies (IVD and Medical Devices) and services. For avoidance of doubts this includes all medtech hardware as well as all medical Apps, medical wearables and medical software. Medical software is encompassing any software item or system used within a medical context, such as:

- standalone software used for diagnostic or therapeutic purposes;
- software embedded in a medical device (often referred to as "medical device software");
- software that drives a medical device or determines how it is used;
- software that acts as an accessory to a medical device;
- software used in the design, production, and testing of a medical device;
- software that provides quality control management of a medical device;
- software that provides access to medical information storage,

### Membership Costs – M&A Compensation fee

Each Member is responsible for paying annual membership fees<sup>8</sup>. 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")<sup>9</sup>. 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.

<sup>8</sup> See Statutes Art. 5, 6 & 9

<sup>9</sup> As decided by the AGM during its 30 Nov 2017 meeting

## Resignation

A Member may resign from the Association at any time<sup>10</sup>. 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 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.

## Additional [IHI] Financial Contribution

### **Purpose**

As per Article 10, par. 6 of the Statutes, in addition to membership fees, specific Members shall be subject to the payment of additional contributions linked to the European Research and Innovation Partnership (referred hereafter as "[Innovative Health Initiative](#)" or "IHI", which is a Joint Undertaking between the European Commission (EC) and industry associations representing the life science sector, i.e. [COCIR](#), [EFPIA](#) including [Vaccines Europe](#), [EuropaBio](#), and [MedTech Europe](#)) as per the below.

The goal of IHI is to help create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations. IHI aims at bringing together diverse stakeholders (i.e. universities, companies large and small, and other health stakeholders) in collaborative projects that address disease areas where there is a high burden on patients and/or society but also in collaborative projects that transform healthcare and healthcare delivery.

In view of the opportunity for both the medtech industry and the healthcare in general to develop impactful research and innovation, born out of collaboration, diverse perspectives, and shared dedication, MedTech Europe, as a founding member of IHI, signed a Letter of Engagement or Letter of Commitment on 9 December 2021 accepting the Single Basic Act that includes, among other points, the commitment to cover:

1. Its share of IHI office administrative costs: EUR 7,553M over 10 years
2. Corporate Members' commitment of in-kind contribution to projects: EUR 250M over 10 years.

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<sup>10</sup> Statutes Art. 8

### **Determination and Calculation of IHI Contributions**

For the duration of IHI, (2021-2031) an IHI Contribution 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, mentioned here above under point 1.

Corporate Member's formal commitment<sup>11</sup> to participate in and contribute to an IHI project, as "affiliated" to MedTech Europe, is determined by the Member at the time of the submission of the full proposal to the IHI office. This affiliation must reflect the nature of the contribution of the Member in the project (i.e. all the work that the Member will conduct in relation to medical technologies will fall under the MedTech Europe affiliation).

The payment of the IHI Contribution 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 Members and affiliated organisations (hereafter referred to as "Member"), as per Title III of the Statutes, in particular Articles 5, 6 and 7 as well as Article 10.6, may decide to submit a proposal to IHI. In the event that the project is deemed successful by IHI [Governing Board](#), the Member shall be responsible for the payment of the applicable IHI Contribution associated with the Project. The IHI Contribution shall be calculated on the basis of its full contribution over the duration of the project (In-Kind on Operational activities + In-Kind on Additional Activities + Financial 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 IHI Contribution, detailing the purpose, amount, due date, and any applicable payment instructions. Members are responsible for ensuring timely payment of the IHI Contribution. The invoice shall be sent to the official Member representative, typically the individual representing the Member in the Corporate Council, as well as, if applicable the R&I Committee member. For any additional Designated Contact the Member would like to add, written notification must be submitted to the MedTech Europe Secretariat.

At present, the IHI Contribution has been set to 3%. The Board of Directors may periodically review the need for this IHI Contribution and may adjust or discontinue it as circumstances dictate. Any adjustments or discontinuation of IHI Contributions shall be communicated to the Members.

### **Earmarking and Use of Funds**

All collected IHI Contributions shall be tracked separately within the Association's financial records to ensure they are earmarked exclusively for IHI-related costs.

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<sup>11</sup> Formal commitment of MedTech Europe Members is done at the time of the Call launch, which is taken as a basis to formally commit the matched IHI JU funding for public partners. The legally binding commitment is done at the time of the Consortium and Grant Agreement signature.

## 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.