

Statutes of MedTech Europe AiSBL

[The official text will be in French – English convenience translation for information purposes only]

Adopted by the Extraordinary General Assembly (EGM) on 18 June 2026

TITLE I. NAME. LEGAL FORM. TERM. REGISTERED OFFICE, ELECTRONIC ADDRESS.

Article 1. Name. Legal form. Term

The international non-profit association named “MedTech Europe” (hereafter referred to as the “**Association**”), is constituted for an indefinite period under the provisions of Book 10 of the Code of Companies and Associations “Code des Sociétés et des Associations”, abbreviated as “CSA”.

Article 2. Registered office. Electronic address and website

The registered office of the Association is in the region of Brussels (“*Bruxelles Capitale*”).

It may be transferred to any other location in this region by a decision of the Board of Directors, subject to compliance with the legal provisions governing the use of official languages in Belgium.

The Association may establish offices in any country or place.

The Association may adopt an electronic address and a website according to article 2:31 of the CSA, for the communication with the members relating to the execution of the present statutes, as well as communication with the administrators and if necessary with the commissioner, the certified expert accountant and the Chief Executive Officer (CEO).

This electronic address and website may be modified by the Board of Directors, who will inform without delay all interested parties, via a publication in the *Moniteur Belge*.

TITLE II. NON-PROFIT PURPOSE. ACTIVITIES

Article 3. Non-profit purpose. Activities

3.1. Non-profit purpose

The non-profit purpose of the Association shall be, within the European Union and worldwide, to:

(a) Represent, promote and defend in the broadest sense of the word the common interests of its Members in particular, and those of the medical and life science technology industry in general; and

(b) Provide common means and services to its Members to improve the activities of its Members in particular, and to improve synergies, joint actions and projects between the Members in general.

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3.2. Activities

To that effect, the Association may develop, alone or in collaboration with third parties, directly or indirectly, all activities related, directly or indirectly, to its purpose. The Association may, in particular develop the following non-exhaustively listed activities for the general or specific account of its Members and/or third parties:

(a) Identify, explore, compare, examine, and provide advice in policy issues in the field of the medical and life science technology industry;

(b) Contribute to the elaboration, approval, and implementation of local, national, European Union and/or international policies, legislation, and regulations in the field of the medical and life science technology industry;

(c) Represent and promote the common interests of its Members vis-à-vis the European Union institutions, the national governments, public authorities, international organisations, and the general public;

(d) Disseminate information and issue publications;

(e) Adopt, develop, and/or amend standards, and/or encouraging and accelerating the coordinated adoption of standards;

(f) Organise and arrange congresses, seminars, workshops, and other programs and convenings at international and national levels;

(g) Develop and execute integrated communication programs that demonstrate the value of the medical and life science technology;

(h) Perform qualitative and quantitative research, tests, and studies and conduct technical analyses;

(i) Collect and analyse statistical data;

(j) Assist Members with problems raised by their relations with European Union institutions and/or with national authorities;

(k) Undertake alone or with others, joint activities as partner or in any other capacity with the institutions of the European Union, national, federal or local governments, or other public and semi-public authorities and private corporations and organisations;

(l) Establish, accredit, maintain, operate, cooperate, and maintain close contacts with initiatives and/or organisations having a purpose similar to the purpose of the Association, as well as other regional and/or international initiatives and/or organisations; and

(m) Conclude any service agreement, partnership agreement or contract of any kind with Members and/or third parties, as may be needed or useful to achieve the Association's purpose.

For the avoidance of doubt, the activities of the Association may also be profit-generating, such as for example the collection and analysis of statistical data or the organisation of congresses, seminars or workshops provided that all profits generated through said activities shall be at all times and entirely dedicated to the realization of the non-profit purpose of the Association.

In addition, the Association may support and have interests in any other activities or legal entities which are similar or related to those defined above. The Association shall perform and develop its activities either in Belgium or abroad and may be member of or set up other non-profit entities with purposes related to those of the Association.

TITLE III. MEMBERSHIP & OTHER TYPES OF AFFILIATION

Article 4. Membership

The Association shall have two (2) membership categories: Full Members and Associate (non-voting) Members.

All references in these Statutes to "Member" or "Members" without any other specification are references to Full Members and Associate Members collectively.

Article 5. Full Members

The category of Full Member is open and accessible to the following entities:

- (a) Any firm or corporation that through itself or through any of its subsidiaries, branches, divisions or otherwise legally controlled entities is engaged in the medical technology, medical device and/or in vitro diagnostic sectors, and has at least one wholly-owned manufacturing plant; and/or a multi-country presence in Europe or the Extended Geographic Area, as defined under Article 51, and/or have significant sales of CE-marked medical technologies, as well as Research Use Only (RUO) products, in Europe or the Extended Geographic Area, commercialized under their own name.

Notwithstanding the above, State-Owned-Entities (SOE) are not eligible for the Full Member category within MedTech Europe. SOEs are defined as entities that are owned by, or under the control of, a national, provincial, or local government.

- (b) Any medical device and/or in vitro diagnostic National Associations situated and having their registered office in Europe, as defined under Article 51, and which represent the interests of the national medical technology industry (hereinafter 'National Associations').

National Association Members shall, in principle, be limited to two per country, one representing the Medical Device industry and the other the In Vitro Diagnostics industry, except if approved otherwise by the General Assembly, acting upon a proposal from the Board of Directors. If more than two such Associations per country seek Membership, the one that represents manufacturing industry rather than distributors shall take precedence.

Any National Association which meets these criteria, but is not approved by the General Assembly to be the National Association Members which have Full Membership in the relevant country in question, is also eligible for Associate Membership as provided under Article 6.

- (c) Notwithstanding Article 5 a) and b) hereto, the Board of Directors may also propose individual companies as Full Members subject to General Assembly approval, where the Board of Directors is satisfied that, even where not fulfilling all the requirements attached to Full Membership, the Membership of the concerned company will nevertheless positively enhance the representativeness and operation of the Association, and the achievement of its objectives as set out in Article 3 hereto.

Without prejudice to the differences relating to electoral bodies as provided in Article 20.5, the Full Members shall have the following, but not limited to, rights and obligations:

- (a) Right to vote in the General Assembly;
- (b) Right to submit nominations for election of the Board of Directors;
- (c) Right to participate and to vote in all committees and working groups;
- (d) Right to consult any of the social documents, related to the legal set up and governance of MedTech Europe, as provided by the CSA;
- (e) Right to benefit from the discounts granted to the Full Members on the occasion of events organised by MedTech Europe;
- (f) Obligation to pay a yearly Membership fee;
- (g) Obligation to act in compliance these Statutes, in particular with Article 11 below;
- (h) Any other right and/or obligation that could be decided by the Board of Directors and/or the General Assembly.

Article 6. Associate Members

The category of Associate Membership is open and accessible to any medical technology, including but not limited to [Small and Medium Enterprises \(SMEs\)](#) as well as any trade, production, distribution of goods or healthcare related service association or organisation (hereinafter "Associate Members")¹ excluding consulting firms and other companies providing services which partially or exclusively assist the Full Member companies, and which:

- (a) Has the legal personality in accordance with the laws and practices of its country of origin;

¹ Examples of companies falling in the scope of this article, but are not limited to, are technology and/or material suppliers active in packaging; raw material; specific pieces suppliers; technology for the creation of medtech supplies.

- (b) Does not meet the criteria to be eligible as a Full Member; and
- (c) Supports the work or works which form the purpose of the Association, by its advice, influence, and/or activity.

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Associate Members shall have the rights specifically granted to them in or pursuant to these Statutes. These rights shall not include voting rights. As such, Associate Members shall have the following rights and obligations:

- (a) Right to receive notice of General Assembly meetings and to attend;
- (b) Right to participate in all groups/taskforces and designated a representative, as approved by the Board of Directors;
- (c) Right to benefit from the discounts granted to the Associate Members on the occasion of events organised MedTech Europe;
- (d) Right to have access to MedTech Europe publications, the Members' only pages on the MedTech Europe website that are relevant to their work within the Association and related conferences/ events;
- (e) Obligation to pay a yearly affiliation fee;
- (f) Obligation to act in compliance with these Statutes, in particular Article 11 below;
- (g) Any other right and/or obligation that could be decided by the Board of Directors and/or the General Assembly.

Article 7. Supporter Organisation

The category of Supporter Organisation is open and accessible to all consulting firms and companies providing services which partially or exclusively assist the Full Member companies, and which are interested in supporting the Association. These Supporter Organisations shall:

- (a) Be established as a legal entity according to the laws and practices of their country of origin;
- (b) Not fulfill the criteria for eligibility as a Full or Associate Members;
- (c) Supports the work or works which form the purpose of the Association, by its advice, influence, and/or activity.

Supporter Organisations shall have the rights specifically granted to them in or pursuant to these Statutes. As such, Supporter Organisations have the following rights and obligations:

- (a) Right to receive notice of General Assembly meetings and to attend;
- (b) Right to benefit from the discounts granted to the Full Members on the occasion of events organised MedTech Europe;
- (c) Obligation to pay a yearly Supporter Organisation fee;
- (d) Obligation to act in compliance with these Statutes, in particular Article 11 below;
- (e) Any other right and/or obligation that could be decided by the Board of Directors and/or the General Assembly.

For avoidance of doubt, Supporter Organisations are not considered as Members, nor have they been granted with any voting rights, or any right to participate or send a delegate to the committees or working groups active within the Association. They can however be invited as observers.

Article 8. Admission to membership or as a supporter organisation

Any applicant to membership or supporter organisation of the Association shall submit a completed Application Form, along with any required supporting information via regular mail or any other means of written communication (including e-mail) to the attention of the CEO.

The Application Form, which may be amended by the Secretariat from time to time, shall include the complete identity of the legal entity, as well as the homepage of the organisation, the electronic address to be used in order to exercise the rights and obligations of members, as laid out in article 51.

For applications for membership, the CEO shall submit such application to the Board of Directors. Where necessary, the Board may request a due diligence review to confirm the applicant's alignment with membership criteria. The approval of such application by the Board of Directors confers membership and shall be followed by a notification to the next General Assembly. Approvals do not need to be motivated.

For the applications to become a Supporter Organisation the CEO shall submit the application to the Board of Directors. Such approval automatically confers the status of Supporter Organisation without any further formalities.

For avoidance of doubt, where the applicant organisation has vested interests, which could potentially impede MedTech Europe's ability to engage with national, European or international policy-makers, the Board of Directors may reject such application.

Article 9. Resignation. Suspension. Exclusion

Members and other affiliated organisations as per Title III are free to resign from the Association at all times by giving written notice via registered mail, with acknowledgment of receipt, or signed email, at least six (6) months before 31 December of each year at the attention of the CEO. The CEO shall submit the resignation to the Board of Directors, which shall in turn take note of it. The resignation shall be effective on December 31 of the year during which the written notice has been received by the CEO, subject to the limitations provided in the paragraphs below.

A Member or other affiliated organisations as per Title III which (i) ceases to satisfy the definition of the Membership/affiliation category it belongs to as set out in Articles 5 and 6 of these Statutes, or (ii) is not duly or timely or fully complying these Statutes, the internal rules, if any, and/or any decision validly taken by the bodies of the Association, or (iii) does not pay all its Membership/affiliation fees within the stated period, or (iv) infringes the interests of the Association, or (v) is in a situation of judicial administration, bankruptcy, judicial reorganisation, dissolution or liquidation, or is subject to insolvency proceedings of a similar nature under the laws of any jurisdiction, or (vi) has substantially modified its activities, or (vii) for any other reasonable cause, may be suspended and/or excluded from Membership, upon a motivated proposal by the Board of Directors, subject to absolute majority ratification at the next General Assembly.

The Board of Directors reserves the right to suspend membership in the event of significant changes impacting the Member's eligibility, such as mergers, acquisitions, or other corporate restructurings. Suspension may also occur if questions arise regarding compliance with Membership obligations as well as when the Member has vested interests, which could potentially impede MedTech Europe's ability to engage with national, European or international policy-makers. During the suspension period, the Member's rights and privileges are temporarily paused until a thorough review, including any necessary due diligence, is completed to determine continued eligibility. The CEO, on behalf of the Board of Directors, shall notify the Member of the suspension and the anticipated duration of the review process. If the review concludes that the Member no longer meets the membership criteria, the below provisions on exclusion shall apply.

Before submitting a proposal to exclude a Member, the Board of Directors shall provide the concerned Member with the relevant details in writing via registered mail or signed email thirty (30) calendar days in advance of the submission of the proposal for exclusion. The concerned Member shall have a right to be heard by the Board of Directors before the vote regarding the proposal for exclusion takes place, and shall be given reasonable time to remedy the consequences of the breach or breaches having led to the proposal of exclusion. All Membership rights of the Member concerned by the above-mentioned proposal for exclusion procedure may be suspended until the decision of the General Assembly.

A Member and other affiliated organisations as per Title III which, in whatever way and for whatever reason, ceases to be a Member of the Association or affiliated shall (i) remain liable for its obligations towards the Association, including for the payment of the Membership fees, up to the end of the financial year in which the termination of its Membership became effective, (ii) have no claims for compensation on the Association or for its assets, (iii) forthwith cease to hold itself out as affiliated or a Member of the Association in any manner, and (iv) upon decision of the CEO, promptly deliver to the Association all material, equipment, software, and documents, in written, electronic or other form, in its possession that have been provided by the Association.

A Member and other affiliated organisations as per Title III which, in whatever way and for whatever reason, ceases to be a Member of the Association after 30 June shall remain liable for the payment of the Membership/affiliation fees due for the financial year following the financial year in which the termination of its Membership became effective.

A Member and other affiliated organisations as per Title III which has resigned or has been excluded from the Association and wishes to re-join the Association as a Member/affiliation cannot re-apply before the end of a six (6) months.

Article 10. Membership fees and additional contributions

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10.1 As set out in Articles 5 and 6 of these Statutes, each Member shall pay membership fees per year, as decided upon by the General Assembly, on proposal by the Board of Directors. Membership fees should not be superior to one (1) million Euros. 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.

10.2 All Members and affiliated organisations as per Title III are obligated to submit in a timely manner, accurate and complete data and documents required to determine the amount of their annual membership fees as well as any additional contributions. This includes, but is not limited to, financial statements, turnover declarations, and any other relevant documentation. The Secretariat reserves the right to verify the accuracy of the submitted data and documents, and Members must comply with any requests for additional information or clarification within a reasonable timeframe. Failure to provide the required data and documents may result in sanctions, as deemed appropriate by the Board of Directors. All submitted data and documents shall be treated as confidential and used solely for the purpose of determining membership fees and additional contributions.

10.3 If a Member and other affiliated organisations as per Title III fail to pay its Membership fees within thirty (30) calendar days after a reminder has been sent to it by the CEO, its voting rights may be automatically and membership may be immediately suspended until the payment of the Membership fees due.

10.4 Members and other affiliated organisations as per Title III joining the Association part way through a financial year shall pay the amount of affiliation/membership fees as calculated for their membership category on a pro rata basis.

10.5 In addition to membership fees, the Board of Directors may decide on additional contributions to finance specific projects, additional services or benefits to Members, to be paid by relevant and/or participating Members and/or affiliated organisations. The amount of the additional contributions shall be approved by the CEO. Members shall be notified of any additional contribution in advance.

10.6 A specific additional contribution shall be paid by relevant participating Members and/or affiliated organisations, between 2021-2031, which is the duration of the European Research and Innovation Partnership (referred hereafter as "Innovative Health Initiative" or "IHI"). IHI is a Joint Undertaking between the European Commission (EC) and industry associations representing the life science sector, including MedTech Europe. The 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 Association's contribution to the IHI Office costs and as otherwise specified in the Internal Rules.

Article 11. Compliance with the Statutes and the internal rules

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By accepting the membership of the Association, each Member and other affiliated organisation as per Title III also commits itself to acting in compliance with these Statutes and the internal rules, if any, and in particular the MedTech Europe Competition Law Guidelines as well as the MedTech Europe Code of Ethical Practice, as revised from time to time.

TITLE IV. ORGANISATIONAL STRUCTURE

Article 12. Bodies

The bodies of the Association are:

- (a) The General Assembly;
- (b) The Board of Directors;
- (c) The Chairman;
- (d) The Vice-Chairmen;
- (e) The Treasurer;
- (f) The Operations Management Committee (OMC);
- (g) The Working Group(s) & Committees; and
- (h) The Chief Executive Officer (CEO).

TITLE V. GENERAL ASSEMBLY

Article 13. Composition. Voting rights

13.1. The General Assembly shall be composed of all Members of the Association. Each Member shall be represented at the General Assembly by its representative(s).

13.2. Each Full Member shall have one vote, but is allowed to send as many representatives as deemed necessary to the General Assembly. The Member shall appoint the representative who shall cast the vote of his/her Member at the General Assembly and inform the CEO in writing (per post or per email) about this appointment. Each representative must have full capacity powers to represent his/her Member. If a representative ceases to be employed by or is no longer otherwise linked to the Member in respect of which he/she was nominated/appointed, (i) he/she shall, as of right, lose his/her capacity as representative (including any capacity to cast the vote of his/her Member, if any) and (ii) the said Member shall immediately replace this representative.

13.3. Associate Members shall have the right to attend the meetings of the General Assembly without voting rights and with the right to be heard.

13.4. Unless otherwise provided in writing (per post or per email) to the CEO prior to the General Assembly, each Director of the Association shall be deemed to be the representative of the Full Member in respect of which he/she was nominated/appointed.

13.5. The General Assembly shall be chaired by the Chairman of the Board of Directors. If the Chairman is unable or unwilling to chair the General Assembly, the General Assembly shall be chaired by one of the Vice-Chairmen.

13.6. The General Assembly may decide to invite one or more third parties to attend without voting rights the General Assembly.

Article 14. Powers

The General Assembly shall have the powers specifically granted to it by law or these Statutes. In particular, the General Assembly shall have the following powers:

- (a) The appointment and revocation of the Directors;
- (b) If applicable, the appointment and revocation of a statutory auditor and the determination of his/her/its remuneration;
- (c) The discharge to be given to the Directors and, if any, to the statutory auditor;
- (d) The approval of the annual accounts and the budget of the Association;
- (e) The amendment of these Statutes;
- (f) The transfer of the registered office;
- (g) The change of language of the Statutes;
- (h) The approval of any merger, or other significant reorganisation of the Association's legal structure; and
- (i) The dissolution of the Association, the allocation of the Association's net assets in case of dissolution, and the appointment of one or more liquidator(s).

Article 15. Meetings

The General Assembly shall meet at least once a year upon convening by the CEO, and at such time and place as determined in the convening notice. A meeting of the General Assembly entrusted with the approval of the annual accounts and the budget shall be held each year (hereafter referred to as the "**Ordinary General Assembly**").

An extraordinary General Assembly shall be convened at any time by the CEO whenever required by the interests of the Association. An extraordinary General Assembly shall be convened by the CEO at the written request of (i) either two thirds (2/3) of the directors, or (ii) at least fifty percent (50%) of the Full Members. If necessary, the statutory auditor may convene the General Assembly. He must convene the General Assembly when one fifth of the Members of the Association request it.

Article 16. Proxies

Each Member shall have the right, via regular mail or via any other means of written communication (including e-mail), always with copy to the CEO, to give a proxy to either the CEO or the Chairman or another Member to be represented at a General Assembly meeting. No Member may hold more than two (2) proxies. The CEO and the Chairman may hold an unlimited number of proxies.

Article 17. Convenings. Agenda

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Without prejudice to Articles 15, 49, and 50 of these Statutes, convening notices for the General Assembly shall be prepared and notified to the Members by the CEO via regular mail or via any other means of written communication (including collective e-mail) at least thirty (30) calendar days before the meeting. The convening notice shall mention the date, time and place of the meeting of the General Assembly. The agenda and the material documents necessary for the discussion shall be attached to the convening notices or made available on a website.

Any proposal of additional item(s) on the agenda of the General Assembly signed by at least (i) half of the Directors or (ii) twenty-five percent (25%) of the Full Members and notified to the Chairman and/or the CEO at least fourteen (14) calendar days before the meeting must be included in the agenda. In such a case, the CEO shall inform the Members of the additional item(s) on the agenda of the General Assembly via regular mail or via any other means of written communication (including e-mail) at least seven (7) calendar days before the meeting of the General Assembly. If an agenda item is proposed during the meeting, the General Assembly may vote on this item only if an absolute majority on the question of the inclusion in the agenda is reached.

Each Member shall have the right, before, during or after a meeting of the General Assembly, to waive the convening formalities and periods required by the present Article. Unless he/she disagrees, any Member present or validly represented and any Director present at a meeting of the General Assembly shall be considered to have been regularly convened to this meeting.

In accordance with the CSA, the Association may organise participation to a General Assembly via videoconference, teleconference or any other means of distance communication.

The General Assembly may be convened and held by written procedure, including where a signed mail was sent to all recipients and without notice. The individual and unanimous agreement of the members shall be required. Where the General Assembly is convened via convocation, this shall be considered as a valid Assembly where there is the unanimous agreement of the members who take part to the written procedure.

The Association may also organise a remote vote before the General Assembly, in electronic form, as stated in article 10: 7/1, § 2 of the CSA.

Article 18. Quorum. Votes

Unless otherwise stipulated in these Statutes, the General Assembly shall be validly constituted when at least half of the Full Members are present or validly represented.

If half of the Full Members are not present or validly represented at the first meeting, a second meeting of the General Assembly may be convened pursuant to Article 17 of these Statutes, at least thirty (30) calendar days after the first meeting of the General Assembly. The second meeting of the General

Assembly shall validly deliberate, irrespective of the number of Full Members present or validly represented, in accordance with the majorities stipulated in the third paragraph of this Article.

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Unless otherwise stipulated in these Statutes, decisions of the General Assembly shall be validly adopted if they obtain a majority of more than fifty percent (50%) of the votes cast by the Full Members present or validly represented.

Blank votes, invalid votes and abstentions shall not be counted. In the event of a tie, the Chairman shall have the decisive vote.

Even if a vote concerns a private person, the votes are issued by a call out, or by a show of hands, unless a secret ballot is requested by at least one third (1/3) of the Full Members present or validly represented.

The votes are issued by a call out, or by a show of hands, unless a secret ballot is requested by at least one third (1/3) of the Full Members present or represented.

Article 19. Register of minutes

Minutes shall be drawn up at each General Assembly meeting. They shall be approved and signed by the Chairman and kept in a register of minutes. Copies of resolutions shall be sent via regular mail or via any other means of written communication (including e-mail) by the CEO to the Members who have requested to receive copies of resolutions. The register of minutes shall be kept at the registered office of the Association where all Members may consult it, without, however, displacing it.

TITLE VI. BOARD OF DIRECTORS

Article 20. Composition

20.1. The Association shall be administered by a Board of Directors composed of maximum twenty-one (21) Directors.

20.2. In order to be eligible as a Director, the candidate must meet the following criteria:

- (a) Shall have an employment relationship with a Full Member (i.e. no consultants);
- (b) Shall be a senior European or EMEA executive (i.e. coming from senior/top-level management) or alternatively be a senior operating officer with responsibilities beyond only national ones of his/her Full Member. For avoidance of doubt, a candidate with mainly company internally oriented tasks, such as the position of CFO or HR director/vice-president might be considered inappropriate. The candidate should preferably have "external" business/P&L responsibilities (e.g. preferably a CEO or a EMEA/European business leader).
- (c) Shall be able to engage the Full Member in respect of which he/she was nominated/appointee; and

(d) Shall be able to commit time to invest in meetings & representation; and

(e) Has a valid contact e-mail address as outlined in article 52 of these statutes and indicated in the Full Member's application.

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Without prejudice to the above, for Directors representing National Associations Full Members, as provided in Article 20.3, the Director may be either senior regional, European or EMEA executive as described above, provided that he/she is also a member of the Board of Directors of the National Association or, if not possible, the Chief Executive of the National Association. For avoidance of doubt, a CEO or Chief Executive of the National Association, who is also employed by another entity, must have double membership with MedTech Europe, i.e. also the other legal entity must be a member of MedTech Europe.

For the avoidance of doubt; each Director is appointed in respect of and linked to a specific Full Member who nominated such Director in accordance with Article 20.5 below. Without prejudice to the personal nature of the mandate of Director, the nomination and continued exercise of such mandate are intrinsically linked to the Director's fulfilment of the eligibility criteria in relation to that Full Member.

20.3. The Board of Directors shall be composed as follows:

- (a) Five (5) directors from Corporate Members registered in the In Vitro Diagnostics fee category.
- (b) Five (5) directors from Corporate Members registered in the Medical Devices fee category.
- (c) Three (3) directors proposed by the National Association Members Council Medical Devices
- (d) Three (3) directors proposed by the National Association Members Council In Vitro Diagnostics
- (e) Maximum five (5) co-opted directors from any of the four groups mentioned below (see 20.5).

20.4. The General Assembly shall ratify the proposed Directors. The Directors are appointed for a three (3) years term, renewable. The mandate ends at the annual ordinary General Assembly of the year where the mandate expires. Their mandate shall be non-remunerated.

20.5. For the purposes of the Board of Directors election, four (4) electoral groups shall be set up:

- a) National Association Members Council Medical Devices
- b) National Association Members Council In Vitro Diagnostics
- c) Corporate Members registered in the In Vitro Diagnostics fee category.
- d) Corporate Members registered in the Medical Devices fee category.

Not later than four weeks prior to the date set for election of Directors at a General Assembly, the CEO shall request all Full Members to submit in writing nominations for Director vacancies to their respective

electoral groups, such nominations to be received by the CEO not later than fourteen days prior to the General Assembly.

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Each Full Member shall be entitled to nominate a candidate for election. If a Member is registered in more than one fee category (i.e. In Vitro Diagnostics and Medical Devices), he/she must choose the electoral group to which to submit the candidate. In absence of choice, he or she shall be presumed having been nominated in the electoral body where the Member paid a higher Membership fee. For the avoidance of doubt, if there are two National Associations respectively Members of the two National Associations Medical Devices and In Vitro Diagnostics Councils, both may present a candidate and if both are elected, that country would be represented twice.

As provided by Article 45 of these Statutes, Internal Rules shall determine the procedure for the selection of a transparent and fair selection of the sixteen Board of Directors candidates to be presented at the General Assembly.

Once the National Association Councils and the two Corporate Member electoral groups have elected their sixteen (16) Director candidates, that new group shall:

- Elect the Chairman of the Board of Directors, who shall have the decisive vote, in the event of a tie; and
- Co-opt the five (5) additional Directors.

These latter five (5) additional Directors shall be co-opted based on the principle of non-discrimination and fair geographical and industry-wide representation. Preferably, at least one candidate Director should represent a small-sized company. The process and outcome of the co-optation of the five (5) additional Directors shall be documented in writing, and available upon request, including the names of the co-opted Directors and a brief statement confirming (i) that they fulfil the eligibility criteria set out in Article 20.2 and (ii) how the principles set out above (non-discrimination and fair geographical and industry-wide representation, and preferably SME representation) were taken into account.

Each Full Member which has nominated a Director shall retain the right to designate a replacement in case of premature termination of that Director's mandate, in accordance with Article 20.9.

In the event of the termination of the Chairman's mandate, for whatever reason, prior to end of the Board of Directors term, any of the Directors, including the co-opted Directors, may present themselves as candidate for the position of the Chairman and all Directors, including the co-opted Directors will elect the new Chairman.

No Full Member can propose more than one candidate to the Board of Directors. Proposed Corporate Member candidates will take precedent over proposed National Association Council candidates in event of two nominees coming from the same full Corporate Member. In the event that the candidates proposed by the four electoral groups would result in improper multiple representation under this rule, the electoral groups shall discuss an amicable solution and (failing agreement) the current Board of Directors shall determine which candidate(s) shall withdraw. In such event, the relevant electoral group may propose an alternative candidate.

20.6. The mandate of a Director terminates by expiry of his/her directorship. The mandate of a Director terminates as of right and with immediate effect:

- i. by death or incapacity, or
- ii. if a Director ceases to fulfil any of the criteria of article 20.2., or
- iii. if the Full Member in respect of which the Director was nominated, is in a situation of judicial administration, or bankruptcy, judicial reorganisation, dissolution or liquidation, or is subject to insolvency proceedings of a similar nature under the laws of any jurisdiction.

For the avoidance of doubt, a Director shall be deemed to cease to fulfil the criteria of Article 20.2 where, while remaining employed by the same Full Member, the Director no longer holds responsibilities that are materially relevant to the sectoral, geographic or functional scope for which he or she was nominated.

20.7. The mandate of a Director also terminates upon revocation by the General Assembly. The General Assembly may revoke a Director at any time and does not need to motivate its decision, and provided that the Director concerned is convened at the meeting and has received the possibility to present his/her position during the meeting of the General Assembly and prior to the voting on the revocation.

20.8. The Directors are also free to resign from their office at any time by submitting, via registered mail with acknowledgment of receipt or signed e-mail, their resignation to the Chairman. In case of termination of the mandate of a Director for whatever reason, except the cases of automatic termination of the mandate of a Director, or revocation, the Director shall continue performing the duties of his/her office until he/she has been replaced within sixty (60) calendar days.

20.9. If the mandate of a Director ceases before its term for whatever reason, the Full Member that nominated the departing Director shall have the right to designate a substitute candidate, provided that such candidate fulfils the eligibility criteria set out in Article 20.2. Such substitute candidate shall be designated in respect of the same electoral group and the same category of seat as that occupied by the departing Director

The designation of such substitute candidate shall be notified in writing to the CEO within a period of 60 calendar days and shall be submitted for co-optation by the Board of Directors.

The Board of Directors shall confirm such co-optation, its review being limited to the verification of compliance with the eligibility criteria set out in Article 20.2.

The next General Assembly shall ratify the appointment of the substitute Director in accordance with these Statutes.

Only in the absence of a designation by the relevant Full Member within the above period shall the replacement be organised by the relevant electoral group.

20.10. In case of termination of the mandate of a Director for whatever reason, the Director shall have no claims for compensation on the Association or for its assets, without prejudice to the mandatory labour law provisions, if applicable.

20.11. The Board of Directors shall be chaired by the Chairman. If the Chairman is unable or unwilling to chair the Board of Directors, the Board of Directors shall be chaired by the oldest Vice-Chairman

(in age). If the Chairman and the oldest Vice-Chairman (in age) are either unable or unwilling to chair the Board of Directors, the Board of Directors shall be chaired by the youngest Vice-Chairman (in age) present. If the Chairman and the Vice-Chairmen are all unable or unwilling to chair the Board of Directors, the Board of Directors shall be chaired by the oldest Director (in age) present.

20.12 The Board of Directors may invite one or more third party(ies) to attend without voting rights one or more meeting(s) or part(s) of their meeting(s).

Article 21. Powers

The Board of Directors shall have all powers necessary to accomplish the purpose of the Association, except for the powers that are specifically granted to other bodies of the Association by law or these Statutes. The Board of Directors shall act as a collegial body (in French: “*organe collégial*” / in Dutch: “*collegiaal orgaan*”).

The Board of Directors shall in particular have the following powers:

- (a) The transfer of the Association’s registered office;
- (b) The adoption, the amendment, and the revocation of the internal rules, if any;
- (c) The determination of the Association’s strategy and policy to be implemented by the Operations Management Committee and/or the CEO, as the case may be;
- (d) The monitoring of the budget expenditures and the allocation of the budget;
- (e) The execution of the decisions of the General Assembly;
- (f) The admission of new Members, prior to ratification of the General Assembly;
- (g) The exclusion of Members;
- (h) The appointment and revocation of the Chairman, the Vice-Chairmen, and the Treasurer; in the specific case of the Chairman, the provisions described in article 20.5 will apply;
- (i) The appointment and revocation of the members of the Operations Management Committee;
- (j) The determination of the calculation method and the amount of the annual membership fees;
- (k) Upon receipt of the draft annual accounts and the draft budget from the Operations Management Committee, the finalization and approval of the draft annual accounts and the draft budget that must be submitted to the General Assembly for approval;
- (l) The adoption of propositions to be submitted to the General Assembly; and
- (m) The decisions to establish and delegate tasks to one or more Sector Committees and/or Working Group(s) and the overseeing of this/these.

Each year, before the approval of the annual accounts, the Board of Directors shall report to the Ordinary General Assembly on the annual activity of the Association which includes at least information regarding (i) the use of the budget, (ii) the setting of the calculation method and the amount of the annual Membership fees, and (iii) the activities of the Association.

At any time, the Board of Directors may delegate specific powers to one or more Director(s) or other persons or bodies, with or without sub-delegation powers. This delegation of power can neither concern the general management of the Association, nor the general powers of the Board of Directors.

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Article 22. Meetings

The Board of Directors shall meet every time the interests of the Association so require and at least twice a year and at such time and place as determined in the convening notice. If the Chairman is unable or unwilling to convene the Board of Directors, the Board of Directors shall be convened by the oldest Vice-Chairman (in age). If the Chairman and the oldest Vice-Chairman (in age) are either unable or unwilling to convene the Board of Directors, the Board of Directors shall be convened by the youngest Vice-Chairman (in age). If the Chairman and the Vice-Chairmen are all unable or unwilling to convene the Board of Directors, the Board of Directors shall be convened by the oldest Director (in age).

A absent Director may be represented neither by another person within his/her organisation, nor by another Director, notwithstanding article 23 below.

Article 23. Proxies

Each Director shall have the right, via regular mail or via any other means of written communication (including signed e-mail), to give a proxy to another Director, to be represented at a Board of Directors meeting. No Director may hold more than two (2) proxies, except for the Chairman who may hold up to ten (10) proxies.

Article 24. Convenings. Agenda

Convening notices for the Board of Directors shall be notified to the Directors via regular mail or via any other means of written communication (including signed e-mail). The convening notices shall mention the date, time and place of the meeting. The agenda and the material documents necessary for the discussion shall be prepared by the CEO, in collaboration with the Operations Management Committee, and attached to the convening notices or made available on a website.

Each Director shall have the right to propose additional items to be included on the agenda of the Board of Directors, which shall be notified via regular mail or via any other means of written communication (including signed e-mail) by the CEO to the Board of Directors.

Each Director shall have the right, before, during or after a meeting of the Board of Directors, to waive the convening formalities and periods required by the present Article. Unless he/she disagrees, any Director present or represented at a meeting of the Board of Directors shall be considered to have been regularly convened to this meeting.

Article 25. Quorum. Votes

Unless otherwise stipulated in these Statutes, the Board of Directors shall be validly constituted when at least half of the Directors are present or validly represented.

If half of the Directors are not present or represented at the first meeting, a second meeting of the Board of Directors may be convened pursuant to Article 23 of these Statutes, at least seven (7) calendar days after the first meeting of the Board of Directors. The second meeting of the Board of Directors shall validly deliberate irrespective of the number of Directors present or represented, in accordance with the majorities stipulated in the third paragraph of this Article.

Unless otherwise stipulated in these Statutes, decisions of the Board of Directors shall be validly adopted if they obtain an absolute majority, i.e. more than fifty percent (50%), of the votes cast by the Directors present or validly represented. Each director shall have one (1) vote.

Blank votes, invalid votes and abstentions shall not be counted. In the event of a tie, the Chairman shall have the decisive vote and in his/her absence (whether represented or not), the oldest Vice-Chairman (in age).

A duly convened meeting of the Board of Directors shall be validly held even if all or some of the Directors are not physically present or validly represented, but participate in the deliberations via any means of telecommunication that allow Directors to directly hear each other and directly speak to each other, such as a telephone or video conference. In such a case, the Directors shall be deemed present.

Article 26. Register of minutes

Minutes shall be drawn up at each Board of Directors meeting. They shall be approved and signed by the Chairman and kept in a register of minutes. Copies of resolutions shall be sent via regular mail or via any other means of written communication (including signed e-mail) by the CEO to the Directors. The register of minutes shall be kept at the registered office of the Association where all Directors may consult it, without, however, displacing it.

Article 27. Written procedure

Subject to the requirements imposed by applicable laws, the Board of Directors may take decisions via written procedure.

For this purpose, the CEO, upon request of the Chairman, shall send a letter, via regular mail or via any other means of written communication (including signed e-mail) to all Directors, mentioning the agenda and the propositions of the decisions to be taken, with request to the Directors to approve the propositions via regular mail or via any other means of written communication (including signed e-mail) to the registered office of the Association or any other place mentioned in the letter, duly signed and within the mentioned deadline .

If the approval of at least half of all Directors regarding the items on the agenda and regarding the procedure in writing is not received within this period, the decisions are deemed not to be taken. In the absence of unanimity of participants in the procedure, the decisions are also deemed not to be taken and the topic shall be re-discussed at the next meeting.

Article 28. Conflict of interest

Any Director, or in absence of the Director, any person cognisant of an actual or possible conflict of interest, shall disclose such conflict at the beginning of the meeting and indicate which agenda item(s)

cause the conflict of interest. The conflicted Director may present in the Board of Directors meeting but shall leave the meeting during the discussion of and the vote on the agenda items involving the conflict.

TITLE VII. CHAIRMAN, VICE-CHAIRMEN, AND TREASURER

Article 29. Appointment and function of the Chairman, Vice-Chairmen, and Treasurer

A Chairman shall be appointed as provided in Article 20.5.

Where appropriate, the Board of Directors shall appoint up to three (3) Vice-Chairmen and a Treasurer among the Directors.

The mandate of the Chairman, the Vice-Chairmen, and one Treasurer shall be non-remunerated. Their term of office is a three (3) year term, renewable.

Each new appointed Chairman, Vice-Chairman, or Treasurer to replace a Chairman, Vice-Chairman, or Treasurer, whose mandate has terminated, shall only be appointed for the remaining of the term of the Chairman, Vice-Chairman, or Treasurer being replaced.

The mandate of the Chairman, the Vice-Chairmen, and the Treasurer terminates by expiry of the term of their mandate or, as of right and with immediate effect, by expiry of their directorship.

The Board of Directors may further revoke the Chairman as Chairman, the Vice-Chairmen as Vice-Chairmen, and the Treasurer as Treasurer at any time and does not need to motivate its decision, without any compensation or cost becoming due by the Association, and provided that the Chairman, Vice-Chairman, or Treasurer concerned is convened at the meeting and has received the possibility to defend his/her position during the meeting of the Board of Directors and prior to the voting on the revocation. The concerned Chairman, Vice-Chairman, or Treasurer shall not participate in the deliberation of the Board of Directors regarding such decision or action, and also not to the relevant voting.

The Chairman, Vice-Chairmen, and Treasurer are also free to resign from their office at any time by submitting, via registered mail or via any other means of written communication (including e-mail) with acknowledgment of receipt, their resignation to the Board of Directors. In case of termination of the mandate of the Chairman, the Vice-Chairman, or the Treasurer for whatever reason, except the cases of automatic termination of the directorship, or revocation, the Chairman, Vice-Chairman, or Treasurer as the case may be shall continue performing the duties of his/her office until the Board of Directors has provided in his/her replacement within ninety (90) calendar days.

In case of termination of the mandate of the Chairman, the Vice-Chairmen, or the Treasurer for whatever reason, the Chairman, Vice-Chairmen, or Treasurer as the case may be shall have no claims for compensation on the Association or for its assets, without prejudice to the mandatory labour law provisions, if applicable.

Article 30. Powers of the Chairman, Vice-Chairmen, and Treasurer

The Chairman shall have the powers specifically granted to him/her by these Statutes. In particular, the Chairman shall have the following powers:

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- (a) Presiding the meetings of the General Assembly, the Board of Directors, and the Operations Management Committee;
 - (b) Acting as a conciliator when differences of opinion occur, both within the Association and vis-à-vis third parties;
 - (c) In the event of a tie vote in the election of the five (5) co-opted Directors, having the casting vote; and
 - (d) In the event of a tie vote, having the casting vote within the Board of Directors and/or the Operations Management Committee.

The Vice-Chairmen shall have the powers specifically granted to them by these Statutes. As a general rule, one of the Vice-Chairmen shall replace the Chairman in his/her absence.

The Treasurer shall have the powers specifically granted to him/her by these Statutes and by the Board of Directors. As a general rule, the Treasurer shall oversee the financial affairs of the Association and report in this respect to the Board of Directors and the Operations Management Committee.

TITLE VIII. OPERATIONS MANAGEMENT COMMITTEE (OMC)

Article 31. Composition

At any time, the Board of Directors may establish an Operations Management Committee which shall be composed of at least five (5) and maximum seven (7) Directors.

The Operations Management Committee shall be composed according to the following criteria:

- (a) Each member of the Operations Management Committee shall be a Director;
- (b) The Chairman, the Vice-Chairmen, and the Treasurer shall automatically be members of the Operations Management Committee;
- (c) At least two (2) members of the Operations Management Committee must be from the In Vitro Diagnostics sector; and
- (d) Without prejudice to the above, only Directors with senior European or EMEA executives' responsibilities are eligible to be members of the Operations Management Committee.

The Board of Directors shall appoint the members of the Operations Management Committee. The members of the Operations Management Committee are appointed for a three (3) year term, renewable. Their mandate shall correspond and be linked to the Directors mandate. Their mandate shall be non-remunerated.

The mandate of the members of the Operations Management Committee terminates by expiry of the term of their mandate or, as of right and with immediate effect, by expiry of their directorship or by expiry of their mandates as Chairman, Vice-Chairman, or Treasurer.

The mandate of a member of the Operations Management Committee also terminates upon revocation by the Board of Directors. The Board of Directors may revoke a member of the Operations Management Committee at any time and does not need to motivate its decision, without any compensation or cost becoming due by the Association, and provided that the member of the Operations Management Committee concerned is convened at the meeting and has received the possibility to defend his/her position during the meeting of the Board of Directors and prior to the voting on the revocation.

The members of the Operations Management Committee are also free to resign from their office at any time by submitting, via registered mail or via any other means of written communication (including e-mail) with acknowledgment of receipt, their resignation to the Chairman. In case of termination of the mandate of a member of the Operations Management Committee for whatever reason, the effect is immediate except otherwise decided by the Board of Directors.

If the mandate of a member of the Operations Management Committee ceases before its term, for whatever reason, the Board of Directors may freely appoint a new member of the Operations Management Committee for the remainder of the term, provided that the member of the Operations Management Committee appointed fulfils the criteria for the composition of the Operations Management Committee applicable to the replaced member.

In case of termination of the mandate of a member of the Operations Management Committee for whatever reason, the member of the Operations Management Committee shall have no claims for compensation on the Association or for its assets.

The Operations Management Committee shall be chaired by the Chairman. If the Chairman is unable or unwilling to chair the Operations Management Committee, the Operations Management Committee shall be chaired by one of the Vice-Chairmen.

The Operations Management Committee may invite one or more third party(ies) to attend without voting rights one or more meeting(s) or part(s) of meeting(s) of the Operations Management Committee.

The CEO shall have the right to attend the meetings of the Operations Management Committee without voting right and with the right to be heard.

Article 32. Powers

If set up, the Operations Management Committee shall have the powers specifically granted to it by these Statutes. In particular, the Operations Management Committee shall have the following powers:

- (a) The monitoring of the general (“day-to-day”) management and administration of the Association, which may be partially or entirely delegated to the CEO;
- (b) The support to the CEO regarding his/her/its work on ensuring efficient decision making in the Board of Directors and the implementation of the Association’s strategy decided by the Board of Directors;
- (c) The supervision of the human resources strategy of the Association;
- (d) The financial and legal compliance of the Association;
- (e) The appointment and revocation of the CEO;
- (f) The discharge to be given to the CEO;
- (g) The preparation of the meetings of the Board of Directors; and

(h) After consultation with the Treasurer, the preparation of the draft annual accounts and the draft budget that must be submitted to the Board of Directors for finalisation and approval.

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The Operations Management Committee shall always act under the responsibility of the Board of Directors and shall report periodically to the Board of Directors on its actions and activities.

As long as the Board of Directors has not decided to establish an Operations Management Committee, all the powers specifically granted to the Operations Management Committee by these Statutes shall be exclusively granted to and exercised by the Board of Directors. As soon as the Board of Directors has decided to establish an Operations Management Committee, all the powers specifically granted to the Operations Management Committee by these Statutes shall be exclusively granted to and exercised by the Operations Management Committee.

Article 33. Meetings

The rules regarding the meetings of the Board Directors provided for in Article 22 of these Statutes shall apply mutatis mutandis to the meetings for the Operations Management Committee.

Article 34. Proxies

The rules regarding the right for each Director to give a proxy to another Director provided for in Article 23 of these Statutes shall apply mutatis mutandis to the right of each member of the Operations Management Committee to give a proxy to another member of the Operations Management Committee.

Article 35. Convenings. Agenda

The rules regarding the convenings for the Board Directors and the establishment of the agenda of the Board of Directors provided for in Article 24 of these Statutes shall apply mutatis mutandis to the convenings for the Operations Management Committee and the establishment of the agenda of the Operations Management Committee.

The rules regarding the right to propose an additional item to be included on the agenda of the Board Directors and the information of the Directors of the additional item(s) on the agenda of the Board of Directors provided for in Article 24 of these Statutes shall apply mutatis mutandis.

Each member of the Operations Management Committee shall have the right, before, during or after a meeting of the Operations Management Committee, to waive the convening formalities and periods required by the present Article. Unless he/she disagrees, any member of the Operations Management Committee present or represented at a meeting of the Operations Management Committee shall be considered to have been regularly convened to this meeting.

Article 36. Quorum. Votes

Unless otherwise stipulated in these Statutes, the Operations Management Committee shall be validly constituted when at least half of the members of the Operations Management Committee are present or represented.

Unless otherwise stipulated in these Statutes, decisions of the Operations Management Committee shall be validly adopted if they obtain a majority of more than fifty percent (50%) of the votes cast by the members of the Operations Management Committee present or represented. Each member of the Operations Management Committee shall have one (1) vote.

Blank votes, invalid votes and abstentions shall not be counted. In the event of a tie, the Chairman shall have the decisive vote.

A duly convened meeting of the Operations Management Committee shall be validly held even if all or some of the members of the Operations Management Committee are not physically present or represented but participate in the deliberations via any means of telecommunication that allow the members of the Operations Management Committee to directly hear each other and directly speak to each other, such as a telephone or video conference. In such a case, the members of the Operations Management Committee shall be deemed present.

Article 37. Register of minutes

The rules regarding the minutes of the Board Directors provided for in Article 26 of these Statutes shall apply mutatis mutandis to the minutes of the Operations Management Committee.

Article 38. Written procedure

The rules regarding the written procedure of the Board of Directors provided for in Article 27 of these Statutes shall apply mutatis mutandis to the written procedure of the Operations Management Committee.

TITLE IX. SECTOR COMMITTEES & WORKING GROUP(S)

Article 39. Sector Committee(s)

On the request of a relevant number, but at the minimum three (3), of companies commercially active in the same sector of the medical technology industry, the Board of Directors may set up Sector Committee.

Sector Committees shall support MedTech Europe in fulfilling its purpose through devoting their efforts to sector-related matters by promoting the interests of the specific type of industry, internally and externally, including vis-à-vis relevant authorities and other stakeholders. Sector Committee may not act in a way that contradicts the interests and the objectives of MedTech Europe.

In order to be eligible as Sector Committee, the following criteria must be met:

- (a) Member companies shall represent in total annual sales in the Europe or Extended Geographic Area region exceeding one billion Euros;
- (b) Member companies shall be operating in the same disease/clinical area or manufacture similar technologies.

- (c) It should be a “homogeneous” group of companies, i.e. share common interests and be operating in the same disease/clinical area or manufacture similar technologies;
- (d) Members of the Sector Group shall be EMEA senior business executives.

At least every three years, the Board of Directors shall review, as a standing agenda item, the compliance to the above criteria as well as the adequacy and activities of the Sector Committee.

Sector Committees may decide to allocate additional funds to special sector related projects, which would be contributions in addition to the annual dues, in which case, Article 10, paragraph 5 shall apply.

A Sector Committee may be composed of one or more Working Groups created for well-defined sector-related activities.

Article 40. Working Group(s)

On the request of a relevant number of Members, but at least three (3) Working Groups, committees and other groups may be established in areas and aspects of interest and relevance to MedTech Europe and its Members. The Working Group(s) shall have a supporting role to the bodies of the Association on specific issues. Based on internal rules or guidelines as decided upon by the Board of Directors, the CEO may confirm among others the mission, composition, powers, and meeting modalities of the Working Group(s).

The Working Group(s) shall act under the responsibility of the Board of Directors and report periodically to the CEO on its/their activities, and/or at the request of the CEO, who in turn shall report to the Board of Directors.

The Working Group(s) may invite one or more third party(ies) to attend without voting rights one or more meeting(s) or part(s) of meeting(s) of the Working Group(s).

Decisions within Working Groups and Committees shall preferably be sought by consensus; failing consensus, decisions shall be adopted by simple majority of the votes cast.

TITLE X. CHIEF EXECUTIVE OFFICER

Article 41. Appointment and function of the Chief Executive Officer (CEO)

The Operations Management Committee shall appoint a CEO. The CEO may be a natural person or legal entity being appointed as CEO.

The Association makes available to the CEO an e-mail address with the domain name of the Association, which constitutes the e-mail address in accordance with article 2:32 of the CSA. As detailed in article 52 of these statutes he/she may not renounce this e-mail address.

The office of the CEO may be remunerated. The Association shall cover all reasonable expenses exposed by the CEO, based on Internal Rules as provided in Article 45 or other internal guidelines, if

applicable. The CEO's mandate may be of a definite or indefinite duration. The terms and conditions of his/her/its office shall be determined by the Operations Management Committee.

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The mandate of the CEO terminates as of right and with immediate effect, (i) by death or incapacity, or (ii) if the CEO is in a situation of judicial administration, or bankruptcy, judicial reorganisation, dissolution or liquidation, or is subject to insolvency proceedings of a similar nature under the laws of any jurisdiction, or (iii) by expiry of his/her/its mandate as CEO.

The Operations Management Committee may revoke the CEO at any time and possibly with immediate effect, without (i) having to motivate its decision, (ii) any compensation or cost becoming due by the Association, and (iii) prejudice to the mandatory labour law provisions, if applicable. Such decision shall require the unanimity of the Operations Management Committee, except in the following event, where Article 36, paragraph 2 shall apply:

- the CEO has committed an act involving dishonesty, disloyalty, corruption or fraud with respect to MedTech Europe or its activities;
- the CEO commits gross negligence or wilful misconduct with respect to the performance of its duties;
- the CEO systematically refuses to perform tasks as reasonably directed by Operations Management Committee;
- the CEO becomes physically or mentally disabled, partially or entirely, and is consequently substantially unable to perform his/her functions under these Statutes for an aggregate period of two (2) months or more in any consecutive 12-month period.

The CEO is free to resign from his/her/its office at any time by submitting, via registered mail or via any other means of written communication (including e-mail) with acknowledgment of receipt, his/her/its resignation to the Operations Management Committee, without prejudice to the mandatory labour law provisions, if applicable. Unless decided otherwise by the Operations Management Committee, in case of termination of the mandate of the CEO for whatever reason, except the cases of automatic termination of the mandate of the CEO, or revocation, the CEO shall continue performing the duties of his/her/its office until the Operations Management Committee, has provided in his/her/its replacement within ninety (90) calendar days.

In case of termination of the mandate of the CEO for whatever reason, the CEO shall have no claims for compensation on the Association or for its assets, without prejudice to the mandatory labour law provisions, if applicable.

The CEO shall report periodically to the Operations Management Committee on his/her/its actions and activities, and at the request of the Operations Management Committee.

The CEO shall be a permanent observer at the Board of Directors and the Operations Management Committee, and shall have the right to attend all meetings of the aforementioned bodies, without voting rights and with the right to be heard. All convening notices to all meetings of the aforementioned bodies must simultaneously be notified to the CEO.

Article 42. Powers of the Chief Executive Officer

The CEO shall have the powers specifically granted to him/her/it by these Statutes. In particular, the CEO shall have the following powers:

- (a) The daily management of the Association;
- (b) Participate and contribute to the administration of the Association;
- (c) With the support of the Operations Management Committee working on ensuring efficient decision making in the Board of Directors and the implementation of the Association's strategy decided by the Board of Directors;
- (d) Determining the working and governance rules of one or more Working Group(s) and reporting of its/their activities to the Board of Directors;
- (e) Submitting the applications for admission to membership to the Board of Directors;
- (f) Executing the decisions of the Board of Directors;
- (g) Hiring and dismissing the staff of the secretariat of the Association;
- (h) Managing and supervising the secretariat of the Association;
- (i) Sending the convening notices of the General Assembly, the Board of Directors, and the Operations Management Committee;
- (j) Preparing the minutes of the meetings of the General Assembly, the Board of Directors, and the Operations Management Committee; and
- (k) Ensuring the public relations of the Association, particularly regarding communication with third parties.
- (l) Opening and closing of bank accounts

The CEO shall always act under the responsibility of the Operations Management Committee and shall report periodically to the Operations Management Committee on its actions and activities, and/or at the request of the Operations Management Committee.

TITLE XI. RESPONSIBILITY**Article 43. Responsibility**

The Directors, the Chairman, the Vice-Chairmen, the Treasurer, the members of the Operations Management Committee, and the CEO are not personally bound by the obligations of the Association. Their liability shall be limited to the execution of their assigned tasks and the faults committed in the (-non) performance of their duties and tasks, unless applicable legislation stipulates otherwise.

TITLE XII. EXTERNAL REPRESENTATION OF THE ASSOCIATION**Article 44. External representation of the Association**

The Association shall be validly represented vis-à-vis third parties and with regard to all judicial and extra-judicial deeds (i.e. including the signature authority) by the Chairman acting alone, or by two (2) Directors, acting jointly.

Within the framework of daily management, the Association may also be validly represented vis-à-vis third parties and with regard to all judicial and extra-judicial deeds (i.e. including the signature authority) by the CEO, acting alone. He/she has the power of representation of the Association to open and close bank accounts.

None of the aforementioned persons must justify his/her/its powers vis-à-vis third parties.

In addition, the Association shall also be validly represented vis-à-vis third parties (i.e. including the signature authority), within the framework of their mandates, by one or more proxy holder(s) duly mandated by the Board of Directors, the Chairman acting alone, or two (2) Directors, acting jointly, or, within the framework of daily management, by the CEO, acting alone.

TITLE XIII. INTERNAL RULES AND PROCEDURES**Article 45. Internal rules and procedures**

Within 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.

The internal rules and procedures and any modification of these are communicated to members via their e-mail addresses. A compiled version is made available through the website, if there is one.

The current version of the internal rules is available on the website of the Association ([here](#)).

The Board of Directors may adapt this reference and publish it.

TITLE XIV. FINANCIAL YEAR. ACCOUNTS. BUDGET. AUDITING OF THE ACCOUNTS**Article 46. Financial year**

The financial year of the Association shall run from 1 January to 31 December.

Article 47. Annual Accounts. Budget

The Board of Directors shall establish each year the draft annual accounts of the past financial year, as well as the draft budget for the next financial year. The currency of the Association shall be the Euro for the annual accounts and all other official accounting, tax and legal documents.

Each year the Board of Directors shall submit the draft annual accounts and the draft budget to the Ordinary General Assembly for approval.

The draft annual accounts and the draft budget shall be circulated amongst all Members at least thirty (30) calendar days before the Ordinary General Assembly.

Article 48. Auditing of the accounts

If the law requires so, the General Assembly shall appoint a statutory auditor, chosen between the members of the Belgian "*Institut des Réviseurs d'Entreprise / Instituut der Bedrijfsrevisoren*", for a three (3) years term.

If the Association is not required by law to appoint a statutory auditor, the General Assembly may still appoint a statutory auditor or a certified accountant to audit the annual accounts.

The statutory auditor or the external accountant, as the case may be, shall draw up an annual report on the annual accounts of the Association. This report shall be submitted to the Ordinary General Assembly before the approval of the annual accounts.

TITLE XV. AMENDMENTS TO THESE STATUTES

Article 49. Amendments to these Statutes

The General Assembly can validly decide on amendments to these Statutes only if (i) at least half of the Full Members are present or represented and (ii) they obtain a two-thirds (2/3) majority of the votes cast by the Full Members present or validly represented. Blank votes, invalid votes and abstentions shall not be counted.

If half of the Full Members are not present or validly represented at the first meeting, a second meeting of the General Assembly may be convened pursuant to Article 16 of these Statutes, at least thirty (30) calendar days after the first meeting of the General Assembly. The second meeting of the General Assembly shall validly deliberate, irrespective of the number of Full Members present or validly represented, in accordance with the majorities stipulated in the first paragraph of the present Article, and decide the amendments.

The main terms of any proposal to amend these Statutes shall be explicitly mentioned in the agenda in the convening notice to the Members and the Directors, sent four (4) weeks prior the meeting of the General Assembly.

The date on which the amendments to these Statutes shall enter into force shall be determined by the decision of the General Assembly regarding the amendments to these Statutes.

Any decision of the General Assembly relating to the amendments of these Statutes is subject to the additional requirements imposed by applicable law. In particular, when the law requires it, the amendments to these Statutes must be acknowledged by a Royal Decree or recorded in a notarial deed.

TITLE XVI. DISSOLUTION. LIQUIDATION

Article 50. Dissolution. Liquidation

The General Assembly can validly pronounce the dissolution of the Association only if (i) at least half of the Full Members are present or represented and (ii) the decision obtains a two-thirds (2/3) majority of the votes cast by the Full Members present or validly represented. Blank votes, invalid votes and abstentions shall not be counted.

If half of the Full Members are not present or represented at the first meeting, a second meeting of the General Assembly may be convened pursuant to Article 17 of these Statutes, at least thirty (30) calendar days after the first meeting of the General Assembly. The second meeting of the General Assembly shall validly deliberate, irrespective of the number of Full Members present or validly represented, in accordance with the majorities stipulated in the first paragraph of the present Article, and decide on the dissolution.

Any proposition to dissolve the Association shall be explicitly mentioned in the agenda in the convening notice to the Members and the Directors.

Upon the dissolution and liquidation of the Association, the General Assembly shall decide upon: the appointment of one or more liquidator(s), the decision-making process of the liquidators if several liquidators are appointed, and the scope of his/her/its/their powers. Failing the appointment of one or more liquidator(s), all the Directors shall be deemed to be jointly in charge of the Association's liquidation.

The General Assembly shall also decide upon the allocation of the net assets of the Association, provided however that the net assets of the Association may only be allocated to a disinterested purpose.

TITLE XVII. VARIA

Article 51. Definitions

Under these statutes, "Europe" shall be the Geographic Area which includes the countries in the European Union (EU), the European Economic Area (EEA), as well as Switzerland and for avoidance of doubt the UK. The "Extended Geographic Area" shall include those other countries where Associate Member Associations are located.

Article 52. Choice of domicile and electronic address

The Members and the Directors choose an address for service at the postal address and the email address submitted in the Membership form, except if otherwise indicated, to another postal address or email address.

For all communications arising from the execution of these statutes, between as well as towards the Association, its members, its directors, and/or those in charge of general management including as the case may be the statutory auditor shall provide in their application an electronic address in accordance with article 2:32 of the CSA. This e-mail address may not be deleted or changed by its holder except by indicating a new electronic address which can be used under the same conditions. Failing that, any communication to the old electronic address is deemed to have taken place validly.

Article 53. Varia

Anything that is not provided for in these Statutes or the internal rules, if any, shall be governed by the provisions of the CSA and in particular by Book 10. In the event there is a conflict between these Statutes and the internal rules, if any, internal procedures, or any other kind of rules of the Association, these Statutes shall prevail.

Membership of the Association does not imply or represent any endorsement by the Association of a Member or of an activity undertaken by a Member. Members shall not use the Association's name and logo(s) for any reason other than to show or signal their membership of their Association unless they received a prior and written authorisation from the CEO or the Association's Legal team to do so. In all cases this use will follow any existing guidelines on the use of the Association's logo or name. Members shall have no claim on the Association's assets.

Article 54. Language

The business of the Association shall be conducted in English, without prejudice to applicable legal obligations.

These statutes are drafted in English. In the event of a conflict between the English and French versions of these Statutes, the French version shall prevail.