

# Bylaws of Medical Devices and Diagnostics Sector Committee

A Sector Committee of the European  
Chamber of Commerce in Vietnam



*Adopted on September 27<sup>th</sup>, 2018*

## TABLE OF CONTENTS

Definitions and Frequently Used Terms .....	3
ARTICLE I – Name and Statement of Purpose .....	5
ARTICLE II – Organizational Bodies and Administration .....	5
ARTICLE III – Meetings .....	6
ARTICLE IV – General Assembly Voting .....	8
ARTICLE V – MDDSC Board .....	8
ARTICLE VI – Member Qualifications and Application.....	10
ARTICLE VIII – Member Rights and Responsibilities .....	11
ARTICLE IX – General Provisions .....	14

## DEFINITIONS AND FREQUENTLY USED TERMS

<b>Alternate Representative</b>	Representatives from company members to join meetings without voting rights.
<b>Authorised Representative</b>	Representatives from company members to join meetings on behalf of Member Representatives and have proxy to vote
<b>Annual Meeting</b>	as defined in Art. III §1
<b>Membership Fee</b>	the annual fee owed by members of MDDSC, as proposed by the Treasurer and approved by the General Assembly each year for the upcoming year
<b>Board</b>	the MDDSC executives, as defined in Art. II §2
<b>Board Meeting</b>	as defined in Art. III §5
<b>Board Members</b>	as defined in Art. V
<b>Casting Vote</b>	the deciding vote by the Chairperson in a case of an equality of votes on a decision of the Assembly General
<b>Chairperson</b>	as defined in Art. V §5(b)
<b>Code of Ethics</b>	MDDSC internal document
<b>Conflict of Interest</b>	as defined in Art. VII §2(b)
<b>EuroCham</b>	the European Chamber of Commerce
<b>Foreign Company</b>	any company established outside of Vietnam or any company established within Vietnam, in which any non-Vietnamese citizen owns the majority of the charter capital or interests.
<b>General Assembly</b>	as defined in Art. II §1
<b>Government</b>	the Government of the Socialist Republic of Vietnam
<b>Inter-Company Dialogue</b>	a good faith, genuine discussion, orally or in writing, between Members or between Members and non-Members to resolve any disputes or complaints arising from participation in MDDSC as a Member or from breach of obligations under these Bylaws or Code of Ethics prior to resorting to official MDDSC channels of dispute or complaint settlement.
<b>Member</b>	a paid-up member company of MDDSC
<b>Member Representative</b>	the duly appointed official representative of a Member to MDDSC with voting right.

<b>MDDSC</b>	the Medical Devices and Diagnostics Sector Committee of EuroCham
<b>Proxy</b>	a Representative duly authorized to vote on behalf of another Member Representative that is absent from a vote at a meeting of the General Assembly
<b>Regular Meeting</b>	as defined in Art. III §2
<b>Related Person</b>	as defined in Art. VII §2(b)
<b>Represented</b>	in respect to the requirement for quorum at meetings of the General Assembly, a Paid-up Member shall be considered Represented when they are in attendance at the meeting either through their Member Representative, Alternate Representative, or duly appointed Proxy. Participation by means of video- or tele-conference or equivalent is permitted.
<b>Staff</b>	as defined in Art. II §3
<b>Treasurer</b>	as defined in Art. V §5(c)
<b>Vice-Chairperson</b>	all elected Board Members who do not hold the position of Chairperson
<b>Vote</b>	a formal indication of choice between two or more possible options. A Paid-up Member may vote through their Member Representative or duly appointed Proxy. Voting by means of video- or tele- conference or equivalent is permitted
<b>WFOE</b>	an enterprise established in Vietnam in which 100% of charter capital or interest is owned by a foreign person or entity

## ARTICLE I – NAME AND STATEMENT OF PURPOSE

**Section 1. Name.** The name of the group is Medical Devices and Diagnostics Sector Committee. It exists as a sector committee of the European Chamber of Commerce in Vietnam and operates in line with EuroCham’s Statutes and EuroCham’s Sector Committee Rules and Regulations. The Medical Devices and Diagnostics Sector Committee shall be henceforth referred to in this document as MDDSC

**Section 2. Statement of Purpose.**

- a) Objectives. MDDSC is organized for the purposes of engaging with governments, regulators, payers, healthcare providers and others to advocate good practices, promote high industry standards and help developing policies which will shape the future of healthcare in Vietnam.
- b) Collaboration. To fulfill its mission, MDDSC shall work together with the Government and its agents, as well as with Vietnamese and foreign companies, organizations, and other stakeholders. MDDSC shall work in a manner that enables it to fulfill its mission, taking into account the interdependence of the issues raised by its Members and the sector.
- c) Organizational Stance. MDDSC shall be strictly non-political. It shall be neither a trading, nor a distribution organization. It is not formed for acquisition or gain. It shall not concern itself in any way with the domestic matters or internal policies of its Members, provided these do not conflict with the MDDSC Bylaws.

## ARTICLE II – ORGANIZATIONAL BODIES AND ADMINISTRATION

**Section 1. General Assembly.** The General Assembly shall consist of the Member Representatives of all Members of MDDSC. The General Assembly shall convene at least annually at Regular Meetings, and from time-to-time at Extraordinary Meetings, for the purposes of remaining informed about, and participating in, matters relating to MDDSC.

**Section 2. MDDSC Board.** The Board shall consist of six (6) Board Members with full voting rights, chosen by a vote of the General Assembly from among the Member Representatives of the General Assembly. The Board shall elect, from among the Board Members, a Chairperson and a Treasurer for maximum two-year (2) terms, with the possibility of re-election [*see Art. V herein*].

## ARTICLE III – MEETINGS

### Section 1. Annual Meeting.

- a) Timing and Purpose. There shall be one (1) Annual Meeting, held in the last quarter of the year, with timing to be determined by the Board. The General Assembly may, among other things:
  - (1) Approve the budget and Membership base fee for the following year;
  - (2) Elect new Board Members at the frequency mentioned here above;
- b) Quorum. For the Annual Meeting to be valid, two-thirds (2/3) of Members must be represented in person or by Proxy.

### Section 2. Regular Meetings.

- a) Timing and Purpose. Regular Meetings shall occur quarterly, with one (1) meeting being held in the last quarter of the year, which shall be designated as the Annual Meeting. Regular Meetings shall be open to all General Assembly Members in order to:
  - (1) Hear activity reports, including updates on the budget and any working groups.
  - (2) Discuss and vote on any other matters as may be required; and
  - (3) At one (1) meeting, approve the audited financial report.
- b) Quorum. For a Regular Meeting to be valid, a majority of Members must be represented in person or by Proxy.

### Section 3. Extraordinary Meetings.

- a) Timing and Purpose. Extraordinary Meetings shall occur at the discretion of the Chairperson or the Board in case any critical issue arises. Extraordinary Meetings shall be open to all General Assembly Members.
- b) Quorum.
  - (1) There is no quorum requirement for an Extraordinary Meeting where no Vote is to be taken.
  - (2) For an Extraordinary Meeting in which any vote is to be taken, a majority of Members must be Represented in person or by Proxy, and Members shall be provided advance notice of a vote at least 48-hours in advance.

### Section 5. Board Meetings.

- a) Timing and Purpose. Board meetings shall occur at the discretion of the Board.
- b) Quorum. There is no quorum requirement for a Board meeting to be valid.
- c) Decisions. For a decision of the Board to be valid, the majority of voting Members must have voted, with a minimum of 4 Members having voted in favor.
- d) Voting Procedure. At any meeting of the Board, every decision shall, unless otherwise provided herein, be determined by a majority of the votes cast on the decision.
- e) Casting Vote. In the case of an equality of votes on a decision, the Chairman has the right but not the obligation to cast the Casting Vote.

### Section 6. Representation and Voting Powers.

- a) Member Representatives and Alternates. Members must submit to EuroCham Secretariat the names of three (3) persons who may represent its interests to MDDSC: one (1) Member Representative, and up to two (2) Alternate Representatives. [see Art. VIII §1 herein]
- b) Meeting Attendance. Only Member Representatives or their Alternate Representatives may attend MDDSC meetings.
- c) Voting Power. Only Member Representatives may cast votes at MDDSC meetings. If a Member Representative cannot attend a meeting but wants to vote, his or her voting power must be transferred via Proxy authorization to his or her Alternate Representatives. Proxy authorization can be done for 1 year.

**Section 7. Notice Requirements.**

- a) General Rule. All Members shall finalize in writing (including e-mail) the date, time, and location of all upcoming Regular Meetings, and Extraordinary Meetings of the General Assembly at least one (1) week in advance of such meetings, unless otherwise proscribed herein.
- b) Annual Meeting. All General Assembly Members shall finalize the date, time, and location of the Annual Meeting at least two (2) weeks in advance of the meeting.

**Section 8. Internal Meeting Minutes.**

- a) Responsibility for Minutes.
  - (1) For all meetings minutes shall be recorded by the EuroCham Secretariat.
  - (2) For other internal MDDSC meetings, minutes may be recorded by either the EuroCham Secretariat, or any other MDDSC Member, at the discretion of Chairperson.
- b) Effective Date. Generally, the minutes of a given meeting shall become effective upon approval of the Chairperson or the chair of the given meeting.
- c) Ability to Comment. Meeting attendees may make comments or dispute the minutes per email. After SC coordinator sends out the meeting minutes, attendees have 03 working days to review. Any valid comments or disputes shall be added to the minutes as notes attributed by the submitting Member.
- d) Availability of Minutes. All minutes shall be made available to all members in attendance at the relevant meeting upon request. Meeting minutes shall be available to non-attending members at the sole discretion of the Chairman, as the case may be.

**Section 9. External Meetings and Communications.**

- a) General Meeting Requirements.
  - (1) In order to qualify as an official MDDSC meeting, any meeting between MDDSC and a Government official, international intra- governmental organization, or international non-governmental organization, must:
    - A. be approved by the Chairperson, a Vice-Chairperson designated by the Chairperson, and
    - B. at least one (1) Board Member and one (1) MDDSC representative must be present.
  - (2) In order to qualify as an official MDDSC meeting, any meeting between MDDSC and any third-party not designated in Art. III §9(a)(1) herein, must:
    - C. be approved by a Board Member, and

D. at least one (1) MDDSC member must be present.

Special Appointees. In certain circumstances, the General Assembly may appoint suitable individuals to act on behalf of MDDSC.

- b) Meeting Minutes. Meeting minutes shall be held by the EuroCham Secretariat or MDDSC Staff.
- c) External Communications. Any letter, paper, press release external or communicable or other document addressed to any government department, agency, or representative, or other third party on behalf of MDDSC must have the prior approval of MDDSC Board.

## ARTICLE IV – GENERAL ASSEMBLY VOTING

**Section 1. Votes Required to Pass a Measure.** Passage of a measure by the General Assembly requires a two-thirds (2/3) vote in support of such measure.

### **Section 2. Quorum.**

- a) General Rule. For votes of the General Assembly to be valid, a majority of Paid-up Members must be Represented.
- b) Exceptions. For votes related to the following matters to be valid, two-thirds (2/3) of Paid-up Members must be Represented:
  - (1) Annual Budget and Member Fees;
  - (2) Election of new Board
  - (3) Changes to the Code of Ethics; and
  - (4) Changes to Bylaws.

**Section 3. Remote Voting.** In certain cases, the Chairperson may select to conduct voting by means of written submissions. In such cases, the same quorum and voting requirements described in §1-2 of this Article apply, and only those Members providing written submission would qualify as Represented for purposes of satisfying quorum requirements.

**Section 4. Proxy Voting.** Any company with voting rights may authorize any other authorised company Representative to vote on its behalf at any meeting of MDDSC. Notice of Proxy authorization must be received in writing by the EuroCham Secretariat no later than 24-hours prior to the time and date of the meeting at which such Proxy is to vote, unless otherwise agreed to by Chairperson. Proxy authorization can be valid for 1 year.

## ARTICLE V – MDDSC BOARD

**Section 1. Election of Board Members.** The Board for the upcoming year shall be elected at the Annual Meeting and shall begin its term immediately following the announcement of the election results or at any other time determined by General Assembly. Nominations must be received by the Chairperson at least 48-hours prior to the Annual Meeting.

### **Section 2. Seat Types and Selection.**

- a) Seats and Voting Rights. The Board shall be comprised of Member Representatives with full voting rights on the Board.



- b) Selection of Voting Board Members. The voting Members of the Board shall be chosen by a vote of the General Assembly consistent with the provisions of this Article.

**Section 3. Replacement.** If a Member appoints a new Member Representative, any seat held by the former representative shall not be transferred to the new representative. The vacated seat shall be decided in the next General Assembly meeting.

**Section 4. Board Roles.**

- a) Board Roles. The Board shall have one (1) Chairperson and one (1) Treasurer, and all other elected Board Members shall hold the position of Vice- Chairpersons.
- b) Chairperson.
  - (1) Election. The Chairperson shall be elected by a majority vote of the Board from among the voting Board Members. Each voting Member shall cast one (1) vote for one (1) candidate per round of voting. The first candidate to achieve the support of a majority of the voting Members shall be the Chairperson for the upcoming year.
  - (2) Duties. The Chairperson shall, among other things:
    - A. Preside over all meetings of MDDSC and execute all decisions taken by it;
    - B. Direct and oversee the activities of MDDSC;
    - C. Act as the first point of contact for the Chairperson of EuroCham; and
    - D. The chairperson shall have the right but not the obligation to have the Casting Vote when necessary [*see Art. III §5(e) herein*].
- c) Vice-Chairpersons.
  - (1) Election: all elected Board Members, other than Chairperson and Treasurer shall hold the position of Vice- Chairpersons, in accordance to §1 of this Article
  - (2) Duties: With the approval of the majority of the Board, a Vice-Chairperson may be appointed to exercise all the powers, and perform all the duties, of the Chairperson in the case of the Chairperson’s absence, including providing the Casting Vote in Board decisions.
- d) Treasurer.
  - (1) Election. The Treasurer shall be elected by a majority vote of voting Board Members from among the voting Board Members. Each voting Board Member shall cast one (1) vote for one (1) candidate per round of voting. The first candidate to achieve the support of a majority of the voting Board Members shall be the Treasurer for the upcoming year.
  - (2) Duties. The Treasurer shall, among other things:
    - A. Prepare the annual budget and ensure that MDDSC, to the greatest extent possible, remains within budget;
    - B. Propose the annual base fee and any other financial changes as may be required, to the Board for review prior to the Annual General Assembly or Extraordinary Meeting.

**Section 6. Board Powers.**

- a) The Board shall act in the interests of MDDSC and administer MDDSC's accounts and represent MDDSC at meetings with Government departments or other related organizations.
- b) The Board may establish any committees or working groups, or sub-committees or sub-working groups, as deemed necessary by a majority vote of the Board, and delegate duties or powers as needed.

**Section 7. Removal of Board Members.**

- a) A Board Member may be removed from the Board by a unanimous vote of the other voting Board Members.
- b) A Board Member absents from Board meeting more than 03 times in a row shall be removed by a unanimous vote of the other Board Members.
- c) In the case that a Board Member's status is evaluated for removal due to a Conflict of Interest, their voting rights, and the voting rights of their company, on the Board, in relation to any decisions regarding removal of the conflicting Board Member, shall be invalid.

**ARTICLE VI – MEMBER QUALIFICATIONS AND APPLICATION**

**Section 1. Qualifications for Membership.** To be eligible for membership in MDDSC, a company must meet both of the following criteria:

- 1. Be a foreign company, i.e., one in which non—Vietnamese persons or entities own a majority of the company's shares [Note: If the applicant has a parent company, the parent company must also be a foreign company];
- 2. Either
  - a. Have a worldwide consolidated Medical Devices and Diagnostics revenue of more than USD 100 Millions yearly; or
  - b. Be a Vietnam—licensed enterprise, wholly owned by foreign investors (a "Wholly Foreign Owned Enterprise" or "WFOE") with an approved license to work with Medical Devices and Diagnostics products in Vietnam and representing at least one international Medical Devices and Diagnostics company meeting the requirements of (a) above.

**Section 2. Membership Application and Approval.**

- a) Application Form. Any company applying for membership must complete and sign the MDDSC application form and Code of Ethics. Membership applications must be addressed to MDDSC Board.
- b) Conflict Disclosure. Any company applying to be a Member must disclose their interest in any matter in which the company, or Related Person<sup>1</sup>, has any actual, apparent, or reasonably foreseeable, current or future interest or obligation that

---

<sup>1</sup> Comprised of organizations and individuals that have direct or indirect relationships with such enterprise. With regard to a subsidiary company, "Related Person" means the parent company, a manager of the parent company or any person who has the power to appoint such managers. With regard to parent company, "Related Person" means any subsidiary company; (a) A person or a group of persons being able to control the decision-making process and operations of enterprise through the management bodies of enterprise; (b) A manager of an enterprise; (c) Husband, wife, father, adoptive father, mother, adoptive mother, child, adopted child or sibling of any manager of the enterprise, or of any Member holding capital contribution or controlling shares; (d) An individual who is authorized to act as representative of a person stipulated; (e) An enterprise in which a person stipulated herein holds shares to the level that they are able to control the decision-making process of the management bodies of enterprise.

influences or affects, or may influence or affect, Member's decision on any matter presented to the General Assembly. For the avoidance of doubt, this includes membership in any other regional or national organization or association in the Medical Devices sector. Failure to make disclosure may result in suspension or termination of Member, or denial of application.

- c) Application Review. MDDSC Board, in coordination with the EuroCham Secretariat, shall review the eligibility of the application based on the criteria described in §1 of this Article.
- d) Approval by MDDSC Board. New Members may be elected when passed a two-thirds (2/3) vote of the MDDSC Board, provided that a quorum is present.
- e) Notification of Decision. Applicants for membership shall be informed in writing about the decision of MDDSC by the EuroCham Secretariat within two (2) weeks of the MDDSC Board vote.

## ARTICLE VIII – MEMBER RIGHTS AND RESPONSIBILITIES

### Section 1. Member Representatives and Alternates.

a) Appointment.

Member Representative. Each Member shall appoint a Member Representative who must be the company's medical devices operation General Manager or Chief Representative in Vietnam, or an executive of equivalent or more senior rank.

- b) Replacement. A Member may appoint a new Member Representative at any time, but the new representative would not assume any committee, working group seat vacated by the previous representative.

### Section 2. Membership Fee.

a) Annual Membership Fee.

- (1) Members shall pay an annual membership fee.
- (2) The membership fee for the upcoming year shall be calculated based on the budget for the upcoming year and presented by the Treasurer to the General Assembly at the Annual Meeting.
- (3) The membership fee is fixed for all members.

b) Increase of Membership Fee.

- (1) The Treasurer shall submit a budget for the upcoming year each November, or at any other time as designated by the General Assembly;
- (2) The budget shall be approved by the General Assembly by majority vote;
- (3) Depending on the budget requirements, the Treasurer may propose to increase the membership fee; and
- (4) The increase must be approved by the General Assembly.

c) Payment of Membership Fee.

- (1) The membership fee invoices to Members should be issued in January, or at any other time as designated by the General Assembly;

- (2) Members must pay their required fees within 60 days after receipt of the invoice;
- (3) The Membership fee shall be paid into an account that is opened or made available by EuroCham for MDDSC.

**Section 3. Member Rights.** Members shall have the right,

- a) Through their Member Representative or Alternate Representatives, to participate in the deliberations and meetings of MDDSC;
- b) Through their Member Representatives, to vote at General Assembly meetings (may also be done on the authorised Representative's behalf by a duly appointed Proxy); and
- c) Through their Member Representatives, to be eligible for any elective or appointed position in MDDSC.

**Section 4. Member Duties.** Members must:

- a) Be acquainted with and abide by the EuroCham statutes, and Code of Ethics and Bylaws;
- b) Fully and accurately respond to information requests from the General Assembly, unless complying with such requests conflicts with a Member's internal rules;
- c) Pay the annual membership fee within 60 days following receipt of the fee invoice;
- d) Attend General Assembly meetings;
- e) Before being able to attend meetings, submit a roster of three (3) permitted representatives [*see §1 of this Article*] to the Chairperson, and the EuroCham Secretariat;
- f) Keep confidential all information shared during General Assembly meetings. For clarity, this does not preclude Members from sharing information disclosed to the General Assembly among Members of MDDSC;
- g) Not disclose to any party information about a Member without that Member's express consent; and
- h) Provide timely disclosure to the General Assembly of any potential Conflict of Interest which arises and may conflict with Member's existing obligations, or any Conflict of Interest not disclosed at the time of application which has become apparent to Member since application. Failure to make disclosure of reasonably apparent potential Conflict of Interest may result in disposition, suspension, or termination of Member as stipulated in §8 of this Article.

**Section 5. Suspension of Membership.**

- a) General Conditions of Suspension. The General Assembly, by a majority vote, may suspend a Member if:
  - (1) The Member fails, for two (2) consecutive years, to meet the requirements detailed in Art. VII §1 herein;
  - (2) The Member fails to pay its membership fee within 60 days of receipt of the fee invoice;
  - (3) The Member fails to submit a signed statement of compliance with MDDSC Code of Ethics and bylaws; or

- (4) The Member's Member Representative has been absent from four (4) consecutive Regular Meetings, regardless of whether its Alternate Representative has been present.
- b) Emergency Suspension. The General Assembly may suspend a Member or Member Representative if it determines, by a majority vote, that the action(s) of that company, its affiliates, or its representative are so detrimental to MDDSC or EuroCham that it must take emergency action to protect the association from risk.
- c) Implications of Suspension.
  - (1) A suspended Member may not send representatives to meetings, cast votes, or take part in any organized activities of MDDSC.
  - (2) A suspended Member Representative may not attend meetings, cast votes, or take part in any organized activities of MDDSC.
- d) Reinstatement. A suspended Member shall be reinstated upon a majority vote of the General Assembly in favor of reinstatement.

#### **Section 6. Termination of Membership.**

- a) Request for Resignation. The Chairperson, based on a majority vote of the General Assembly, may invite by written notice a Member to resign its membership in MDDSC.
- b) Reasons for Termination. A Member shall be terminated from MDDSC if: (1) It is dissolved or ceases to carry on business in Vietnam;  
(2) The General Assembly, by a two-thirds (2/3) vote, determines that it should be removed; or  
(3) Member has been suspended for one (1) calendar year and a reinstatement vote [see Art. VIII §5(f) herein] has not been scheduled.
- e) Termination without Prejudice. Terminated Members may re-apply for membership after one (1) calendar year.

#### **Section 7. Withdrawal of Membership.**

- a) Withdrawal Procedure. A Member may withdraw its membership from MDDSC at any time by sending a written resignation to the Chairperson and EuroCham secretariat.
- b) Effective Date. Termination of Membership shall be effective from the date stated in the notice, and may not have any retroactive effect. If there is no date stated in the notice, membership shall end on the date that such notice is received by the Chairperson.
- c) Non-Refundable Fees. No portion of a Member's membership fees shall be refundable.

**Section 8. Disposition, Suspension, or Termination of Member due to Conflict of Interest.** Disposition, Suspension, or Termination of a Member as a result of a Conflict of Interest shall be carried out in accordance with the following procedures:

- a) if a potential Conflict of Interest arises during the course of a Members' tenure, the matter is to be brought to the General Assembly for consideration as soon after disclosure as reasonably possible. The General Assembly may:
  - (1) note the Conflict of Interest in their records and request the Member to provide updates regarding the Conflict of Interest at designated intervals;
  - (2) select to engage suspension or termination procedures in §§5-6 of this Article;
  - (3) revoke Member's rights immediately; or
  - (4) take any reasonable action to resolve the Conflict of Interest.
  
- b) Members shall be suspended or terminated due to a conflict of interest only by a majority vote of the General Assembly.
  - (1) Suspension or termination of Member will equally affect Member's rights as a Board Member.
  - (2) In the case that a Member is evaluated for a Conflict of Interest, their voting rights, and the voting rights of their company, in relation to any decisions regarding suspension or termination of said Member, shall be invalid.
  
- c) Members disposed, suspended, or terminated as a result of a Conflict of Interest shall have the right to make a written appeal presented to the General Assembly at the next valid General Assembly meeting. The appeal shall be decided by a vote in accordance with article IV.

## ARTICLE IX – GENERAL PROVISIONS

**Section 1. Operating Year.** The operating year shall be January 1 to December 31.

**Section 2. Governing Law.** In the case of a conflict of interpretation between provisions in these bylaws and the EuroCham statutes and/or the EuroCham sector committee rules and regulations, the prevailing interpretation shall be based on the highest listed source, as follows:

- (1) EuroCham statutes;
  - (2) EuroCham sector committee rules and regulations; (3)
- MDDSC bylaws.

**Section 3. Definitions and Qualifications.** Definitions of all terms in the Definitions and Frequently Used Terms section of these bylaws shall apply to all capitalized terms as printed, and any capitalized terms with changes to tense, plurality, type, or form, and abbreviations of those terms, throughout the text of these bylaws. Article and section headings and titles are merely organizational and not binding or enforceable.

**Section 4. Internal Dispute Resolution and Inter-Company Dialogue**

- a) The first step of resolving any complaint between MDDSC Members or between a MDDSC Member and non-MDDSC members (excluding the health authorities, HCP, professional organizations, patients or patient groups) should be through Inter-Company Dialogue.
  
- b) MDDSC recommends that Inter-Company Dialogue is done at the level of Country Representative and may take the form of written or verbal communication and shall be considered as non-official. In order to ensure this interpretation, any communication should be clearly labelled as Inter-Company Dialogue (either in the title of the email or letter or clearly stated in any verbal communications).

- c) If the Inter-Company Dialogue is not successful, a formal complaint should be filed with the EuroCham Secretariat or, where the complaint relates to a breach of the Code of Ethics, follow the Code of Ethics dispute resolution process as defined in the Code of Ethics (articles 19.3-20.2). However, before such procedure is engaged, MDDSC shall confirm whether genuine efforts to resolve the dispute through the Inter-Company Dialogue has been undertaken.
- d) Every effort should be made to resolve disputes through the Inter-Company Dialogue before escalating and involving the MDDSC bylaws or the Code of Ethics procedures.

#### **Section 5. Review of the By-Laws.**

- a) These by-laws must be reviewed at least every five years. The General Assembly, or a subcommittee appointed by the General Assembly, must perform a full review of these by- laws and, if necessary, propose amendments to the MDDSC's General Meeting. The General Meeting will then confirm or reject the new revision of the by-laws in accordance with the voting procedures and protocols detailed in Article IV.
- b) (b) At any time, the General Assembly, based on input from any Member, a change in applicable law, or on its own accord, may decide to initiate a revision to these by-laws. Under such circumstances, the General Assembly, or a subcommittee appointed by the General Assembly, must perform a review of the relevant provisions in these by-laws, and, if necessary, propose amendments during any of the General Meeting. The General Meeting will then confirm or reject the new revision of the by-laws in accordance with the voting procedures and protocols detailed in Article IV.

These Internal Rules were adopted on **September 27<sup>th</sup>, 2018** by the General Assembly of MDDSC:

**Fabrice Leguet**

Chairman of Medical Devices and Diagnostics Sector Committee

---