

**STATUTES OF THE  
EUROPEAN DIAGNOSTIC MANUFACTURERS ASSOCIATION**

**1. DEFINITION**

The undersigned Associations and Companies belonging to the In Vitro Diagnostic Industry in various countries of Europe have decided to found an international organisation under the name of:

**European Diagnostic Manufacturers Association (EDMA)**

and to assign to this organisation a mainly scientific purpose, by promoting the common technological, regulatory and economic interests of the European medical in vitro diagnostic products industry.

The European in vitro diagnostic industry is engaged in the research, development, manufacture and distribution of reagents, reagent products, kits, instruments or systems which are intended for in-vitro use in the examination of materials derived from the human or animal body for the purpose of providing information ancillary to the diagnosis, monitoring or screening of a state or states of health or disease.

To this end, they have decided to create an international association with a scientific purpose in conformity with Belgian law.

**2. TITLE, HEAD OFFICE, OBJECTIVES, DURATION**

**Article 1**

An international non-profit association has been formed (governed by the provisions of Title III of the law of 21 June 1921 on non-profit associations, international non-profit associations and foundations) entitled European Diagnostic Manufacturers Association, in abbreviated form "EDMA" and hereinafter referred to as "the Association".

**Article 2**

The head office of the Association is established in Belgium, in the Brussels area; it is at present situated at rue Joseph II, 40, 1000 Brussels.

The head office of the Association may be transferred anywhere in Belgium by means of an ordinary resolution adopted by the Board of Directors and published in the *Moniteur belge* (Belgian official journal).

**Article 3**

The Association is a non-profit making organisation and its objective shall be the study and eventual solution of all problems of relevance in the widest possible sense to the medical in vitro diagnostic industry, in particular those of a scientific, technical, documentary and institutional nature, together with problems relating to international collaboration, such as :

- to ensure permanent contact among its Members,
- to study and deal with all matters of common interest, for example in the fields of health legislation, science, technology and research,
- to promote and encourage among its Members such common ethical principles and practices as can be voluntarily agreed upon,

- to contribute expertise to and to co-operate with national, European and international organisations, governmental and non governmental, having aims and objectives similar to those of the Association or whose activities affect the interests of the Members of the Association,
- to gather and disseminate scientific, technical and other information of interest to the Members of the Association,
- to co-ordinate the efforts of its Members towards the realisation of the above goals,
- to collaborate within the framework of Europe.

The Association may also represent and defend the material and ethical interests of its members, on a secondary basis and without prejudice to its main scientific and educational character.

The Association may take any measures or steps and initiate any course of action capable of promoting the achievement of the above objectives.

The Association proposes to organise working meetings with its members in order to achieve its objectives.

#### **Article 4**

The Association shall be formed for an unlimited period.

### **3. MEMBERSHIP**

#### **Article 5**

The Association shall be composed of full members and non-voting associate members, who shall be natural persons or legal entities duly constituted in accordance with the laws and customs of their country of origin:

- a) National Member Associations (NMA) being non-governmental associations representing the in vitro diagnostic industry in European countries, but there shall not be eligible for Membership of EDMA more than one such association in one country. In the case where more than one such association in the same country seeks Membership of the Association, the Executive Committee shall decide on the basis of their membership the one which it regards as being the most representative of the interests of the in vitro diagnostic industry in that country.
- b) Corporate Associate Members (CAM) being companies which, satisfy all of the following criteria that is to say that they are :
  - In membership of all those NMAs for which they or their affiliated companies are eligible and where they have significant sales of IVD;
  - themselves or through affiliated companies engaged in research, development, manufacture or distribution of in vitro diagnostic products in Europe;
  - are willing to accept the Statutes, general policies and decisions of the Association.

(An “affiliated company” is one that is controlled by or under common control with a given company).

- c) The following entities are eligible for associate membership of EDMA:
  - Organisations whose activities will contribute positively to and are aligned with the overall strategies and ambitions of EDMA, both short- and long-term. To easily distinguish which organisations would be compatible with EDMA goals and aims, the

following definition can be utilised: “Organisations that are outside of EDMA’s direct industry interests, but in some way contribute towards the development of or the advocacy for the IVD industry.”

- Organisations which would fit this definition are Venture Philanthropy organisations and relevant NGOs which make a positive contribution to healthcare, and associations representing diagnostic start-ups and SMEs
- Industry candidates for association status should have approximately 50 to 100 employees in total. Thus, these candidates would primarily consist of SMEs or start-ups.
- The inclusion of distinguished academic figures and institutes, who would receive a free membership, should also be considered

Associate members have the following rights and obligations/restrictions:

- Once a thorough case-by-case assessment has been carried out on a received application, the Executive Committee will vote by simple majority on whether to admit the candidate organisation to associate status. Furthermore, EDMA will determine which Task Forces the Associate Member can join and, on a case by case basis, will approve of the designated representative
- Associate members would not possess voting rights in the EDMA General Assembly and would not have the right to submit nominations for election to the Executive Committee
- A consultation on creating a new Committee focusing on the interests of start-ups and SMEs should be held as part of determining changes to EDMA’s structure in order to accommodate the new membership status
- Associate members would be given full access to EDMA publications, the members’ only pages on the EDMA website that are relevant to their work within the Association and related conferences/ events
- Associate members would have the right to receive notice of all General Assembly meetings of EDMA and to attend as an observer
- To confirm an upgrade to full membership, a simple majority vote would be taken by the Executive Committee following an eligibility investigation
- The Executive Committee would also retain the right to eject an associate member from EDMA, again through a simple majority vote
- the obligation to pay a yearly fee
- the obligation to act in compliance with Article 8 of these Statutes

An associate member is not entitled to take part in the administration or policy making of EDMA

## **Article 6**

All applications for admission to Membership of the Association shall be submitted to and decided by the Executive Committee which is under no obligation to justify its decision and whose decisions shall be final.

## **Article 7**

Any NMA or CAM wishing to resign from Membership of the Association may do so at any time by giving notice in writing to the President at least one full financial year in advance. Any Member giving such notice shall continue to be liable to pay its Membership Fee until the expiration of the period of notice.

## **Article 8**

Any Member who does not comply with the Statutes of the Association or decisions of the General Assembly can be expelled by a special majority vote of the General Assembly. The Member concerned shall have the right in every case to present its case to the General Assembly in person and/or in writing.

By accepting the membership of the Association, each member also commits itself to acting in compliance with the EDMA Code of Ethics, as revised from time to time. The EDMA Code of Ethics includes the EDMA Guidelines on the Interaction with Healthcare Professionals and on Competition Law Compliance.

## **Article 9**

Any Member who ceases to be a Member of the Association through resignation, expulsion or any other cause shall have no claim on the Association's funds but shall remain liable to pay its full fee for the current financial year or, in the case of resignation, for the whole period of resignation notice in accordance with Article 7.

## **4. ORGANS AND OFFICERS**

### **Article 10**

The Association shall comprise the following Organs and Officers;

#### **Organs**

- A General Assembly
- An Executive Committee
- An Assembly of the Corporate Associate Members (ACAM)

#### **Officers**

- A President
- Two Vice-Presidents
- A Treasurer

## **5. GENERAL ASSEMBLY**

### **Article 11**

There shall be a General Assembly having full powers enabling the objectives of the Association as set out in Article 3 to be achieved.

The General Assembly shall in particular:

- a) determine the general policy of the Association;
- b) decide on the exclusion of Members, in accordance with Article 8 of the Statutes;
- c) decide on amendments to the Statutes and on the dissolution of the Association, as well as on the method of liquidation and the destination of the Association's funds, in accordance with Article 26 of the Statutes;
- d) elect seven members of the Executive Committee from among those of its own Members representing the NMAs. The eligible members should be members representing IVD company within the NMA. Such election is made only on the votes of its NMAs and in such a way that no two or more of members of the Executive Committee shall either represent the same country or be employed by the same company

- e) elect the President, the two Vice Presidents and the Treasurer of the Association from among the members of the Executive Committee;
- f) approve the annual report of the Executive Committee on the activities of the Association during the past year;
- g) make decisions as to the appointment of an independent auditor to verify the accounts of the Association;
- h) approve the accounts of the previous year, approve year to date and estimate of current year expenditure, and approve the budget for the following year, all by a special majority vote of the General Assembly;
- i) fix the Membership Fees in accordance with Article 22;
- j) exercise control over the management of the Association's property.

Meetings of the General Assembly shall be chaired by the President or in his absence by one of the Vice-Presidents (hereinafter referred to as "the Chairman").

## **Article 12**

The General Assembly shall be composed of:

- a) The delegates of the NMAs. Each NMA shall have one vote and may be represented by one or two delegates. At each meeting of the General Assembly, the name of the delegate with the voting power shall be notified to the EDMA Office.
- b) The delegates of the CAMs. Each CAM shall have one vote and may be represented by one or two delegates.

## **Article 13**

The voting representatives shall have one vote on all matters, except that the CAM representatives shall not be entitled to vote at elections for any of the representatives of the NMAs to the Executive Committee in accordance with Article 11 (d).

Votes may be cast at meetings of the General Assembly either in person or by written proxy but representation by proxy is only permitted by NMAs to NMAs and by CAMs to CAMs. One member may hold a maximum of two proxies.

Except as provided elsewhere in the Statutes, decisions of the General Assembly are taken by a simple majority of the votes cast in person and by proxy, provided that half the members are present or represented. In case of a split decision, the Chairman's vote shall be the deciding vote.

Where in these Statutes it is provided that a decision of the General Assembly shall be taken by a "special majority vote", such a decision requires:

- a) that at least half of all the voting Members of the General Assembly are present in person or represented and
- b) that at least three quarters of the votes of the Members of the General Assembly present at that meeting in person and by proxy are cast in favour of the decision and
- c) that, where the decision in question relates to Membership Fees, the Budget of the Association or to changes in the Statutes of the Association, the three quarters votes cast in favour of the decision must include the vote of at least one representative of the CAMs.

Postal voting may be used in a duly reasoned emergency on an exceptional basis and is only permitted upon unanimous decision by the Executive Committee. Furthermore, members must be informed in advance of such postal voting so that they can decide in full knowledge of the facts. Postal votes must be ratified by the next plenary session of the General Meeting. Postal voting may take place by e-mail.

The agenda for each meeting of the General Assembly shall be prepared by the Executive Committee and shall be communicated to each Member of the Association at least four weeks before the date of the respective meeting.

No decision can be taken at a meeting of the General Assembly on any matter which does not appear on the circulated agenda, unless all the voting Members of the General Assembly are present in person and are unanimous in the vote on the decision.

#### **Article 14**

An Ordinary Meeting of the General Assembly shall be held at least once a year on a date proposed by the Executive Committee.

The General Assembly will be convened by means of a letter sent by ordinary mail, fax, e-mail or any other means of communication, at least four weeks before the meeting. The convening notice will include the agenda and a registration form.

The President is obliged to convene an Extraordinary Meeting if at least five Members of the General Assembly request it.

Minutes of meetings of the General Assembly shall be prepared for and signed by the Chairman of the respective meeting and shall be recorded in a register. They will be kept by the general management body, which will make them available to members at the head office of the Association.

## **6. ASSEMBLY OF CORPORATE ASSOCIATE MEMBERS (ACAM)**

#### **Article 15**

There shall be an Assembly of Corporate Associate Members (the ACAM). Each CAM shall have one vote and may be represented by one or two delegates. The name of the delegate with voting power shall be notified in writing to the EDMA Office.

Meetings of the ACAM shall be:

- a) convened by the President of the Association
  - i. immediately prior to the annual meeting of the General Assembly and at other times
  - ii. at the initiative of the president or
  - iii. at the request of at least three Members of the ACAM
- b) chaired by the President of the Association or, in the absence of the President, by one of the two Vice-Presidents who shall not have a right to vote at meetings of the ACAM, unless nominated as a CAM delegate with voting power
- c) attended by the Director General who will not be entitled to vote.

It shall be the responsibility of the ACAM to elect six CAM Members to the Executive Committee.

The ACAM shall have the right to discuss and formulate views on any matter affecting the Association or relating to its objectives and to make these views known to the other Organs and to the Officers of the Association, as described in Article 19.

## 7. **EXECUTIVE COMMITTEE**

### **Article 16**

There shall be an Executive Committee to conduct the affairs of the Association in accordance with decisions and general policies of the General Assembly. The Executive Committee shall be composed of maximum thirteen members:

- maximum seven elected by the NMA Members of the General Assembly from among those of its own Members representing the NMAs, and
- maximum six elected by the ACAM.

Members of the Executive Committee are elected for two years but may be re-elected for further terms of two years.

If a member of the Executive Committee resigns before the end of the normal term, the NMA or CAM who originally nominated the resigning member for election shall be entitled to nominate a replacement member to the Executive Committee. The Executive Committee shall vote on such nomination and in the absence of any dissenting votes, the nominee shall become a member of the Executive Committee until the next Ordinary General Assembly. Said replacement member shall not be replaceable upon resignation.

Members of the Executive Committee are expected to participate in all meetings of the Committee and if at any time a member fails to participate in two consecutive meetings of the Committee then, unless either of those absences was for a reason which in the opinion of the Executive Committee was acceptable, that member shall forthwith resign his membership of the Committee or, failing such resignation, shall be deemed to have resigned his membership of the Committee and the NMA or CAM who originally nominated the resigning member for election shall be entitled to nominate a replacement member to the Executive Committee. The Executive Committee shall vote on such nomination and in the absence of any dissenting votes, the nominee shall become a member of the Executive Committee until the next Ordinary General Assembly. Said replacement member shall not be replaceable upon resignation.

Each Executive Committee member will have one substitute who has to be from the same company for a CAM and is chosen for the NAMs within its board members or can be the Managing Director of the association.

### **Article 17**

The Executive Committee shall have at least three meetings per year. It must be convened if at least three of its members request it. It is convened and chaired by the President or in his absence by one of the Vice-Presidents.

The convening notice will be sent by ordinary mail, fax, e-mail or any other means of communication.

The quorum of the Executive Committee is 7 members present in person or, in exceptional circumstances, on conference telephone.

Each member of the Executive Committee shall possess one vote. A member who is not able to attend may in writing appoint another member of the Executive Committee who is present in person at the meeting to be its proxy and to vote on any or all matters on the Agenda. For decisions of the Executive Committee, a simple majority of the votes of the members present in person or by proxy is required.

No member of the Executive Committee can hold more than two proxies.

Any proxies shall be communicated to the members of the Executive Committee at the opening of the meeting.

Postal voting is not permitted.

In case a split vote, the chairman shall have the deciding vote.

The minutes of Executive Committee meetings shall be recorded in a register. This register, which will contain the decisions taken by the Executive Committee, will be kept at the disposal of members of the Association at its head office.

### **Article 18**

The Executive Committee is responsible for selecting the Director General (Article 21) and the Director.

The Executive Committee shall be empowered to set up Committees and determine the composition, the mandate and the duration of such Committees. These Committees have a purely advisory mission.

The chairman of the Committees shall be approved by the Executive Committee from among persons nominated by Members of the Association. All categories of members may take part in these Committees. As regard the composition of the Committees and Task Forces, EDMA management must ensure a balanced representation of all members of the Association. The Executive Committee is entitled to supervise the balance of Membership within the Association with regard to nationality and Membership category.

## **8. OFFICERS**

### **Article 19**

The General Assembly shall elect a President, two Vice-Presidents and a Treasurer of the Association from among the members of the Executive Committee.

The President, the Vice-Presidents and the Treasurer shall be elected for two years and their mandates may be renewed.

These Officers of the Association shall not be entitled to receive any fee or other reward from the Association and shall be entitled to receive only such reimbursement of expenses incurred in the performance of the office as the General Assembly may from time to time decide in advance.

### **Article 20**

The President or either one of the either Vice-Presidents of the Association who do not have to account for their powers to third parties shall sign documents which legally bind the Association with regard to such third parties and which:

- a) do not relate to day-to-day administrative matters or
- b) do relate to day-to-day administrative matters but which involve an amount in excess of such sum as is from time to time determined by the General Assembly.

The Association shall be represented in law by the President or one of the Vice-Presidents of the Association.

## **Article 21**

The Director General shall be responsible for the day-to-day affairs of the Association in accordance with his/her job description as issued from time to time by the Executive Committee and shall be responsible to the Executive Committee.

The Directors shall assist the Director General and shall be responsible to him.

The Director General of the Association will attend the meetings of the General Assembly, the ACAM and the Executive Committee, but without voting rights.

## **9. MEMBERSHIP FEES, BUDGET, ACCOUNTS**

### **Article 22**

Each Member of the Association shall pay the Membership Fee fixed annually by special majority vote of the General Assembly for its category of Membership - and based on a factor as defined below - but shall not incur any individual responsibility as regards the commitments entered into in the name of the Association.

The fees shall be fixed annually by the General Assembly, taking into account, for the Member Associations, the size of their respective markets and for the Corporate Associate Members, their turnover. The General Assembly shall set the amount of the fees every year.

As an introductory measure to encourage membership, the Executive Committee may reduce the annual fee paid by a new CAM during the first year of membership.

As an introductory measure to encourage membership, the Executive Committee may reduce the annual fee paid by a new NMA during the first three years of membership.

All fees shall be paid by 31<sup>st</sup> March in each year.

### **Article 23**

Pending the confirmation by the General Assembly of the budget and Membership Fees for the current financial year, the Director General is empowered to ask from the Members an instalment in proportion to the fee for the preceding year

### **Article 24**

The financial year shall extend from 1<sup>st</sup> January to 31<sup>st</sup> December.

### **Article 25**

The Executive Committee shall submit every year for the approval of the General Assembly:

- the audited accounts of the past financial year and a proposed budget for the following financial year.
- an updated budget for the current financial year
- a short report from two auditors chosen at a General Assembly from among its Members

## **10. AMENDMENTS TO THE STATUTES AND DISSOLUTION**

### **Article 26**

In the case of a proposed amendment to the Statutes, the text of the proposed amendment shall be attached to the notice convening the General Assembly at which the amendment will be considered.

Decisions by the General Assembly to amend the Statutes or to dissolve the Association can only be taken by a special majority vote of the General Assembly. Amendments to the Statutes must be submitted to the Minister for Justice and be published in the Annexes to the Moniteur belge.

The General Assembly shall decide on the method of liquidation of the Association and the destination of the Association's funds and such decisions shall require three-quarters of the votes of all the Members of the Association.

After liquidation, the net assets shall be allocated to a disinterested purpose.

## 11. **GENERAL PROVISIONS**

### **Article 27**

All matters which are not covered by the present Statutes, and in particular the publication to be placed in the Moniteur Belge, shall be settled in accordance with the provisions of the law.

**Signed in Brussels**  
October 2011  
EDMA President