



TEAM-PRRC 38 rue des Mathurins
75008 PARIS - FRANCE

STATUTES OF THE ASSOCIATION

TEAM-PRRC

(EUROPEAN ASSOCIATION OF PERSONS
RESPONSIBLE FOR REGULATORY
COMPLIANCE OF MEDICAL DEVICES)

The founding signatory members and all persons who have adhered to these statutes hereby form a non-profit association in accordance with French law of 1st July 1901 and the decree of 16 August 1901, and establish the statutes of the next way.

Only the version of the statutes written in French is legal.

ARTICLE 1 - DENOMINATION

The Association's name is: TEAM-PRRC (European Association of Persons Responsible for Regulatory Compliance of Medical Devices), also called hereinafter "TEAM-PRRC" or "Association."

Persons responsible for regulatory compliance are referred to as "PRRC" in accordance with the English acronym for their designation in the European Regulations.

ARTICLE 2 - PURPOSE

TEAM-PRRC's purpose is:

- 1: Bringing together persons responsible for regulatory compliance (PRRC) of medical devices as defined by European regulations.
- 2: Discuss the problems faced by PRRC in their activities, propose and exchange solutions.
- 3: To establish, maintain, develop a high level of professionalism of PRRC.
- 4: Exchange with the health authorities in charge of national, european and international regulations.
- 5: Act at the request of a PRRC as mediator in the challenges encountered in its activity.
- 6: Working for the betterment of Public Health.
- 7: Work for help among the members of the association.

TEAM-PRRC has no political, union or denominational affiliation.

ARTICLE 3 - HEADQUARTERS

The association's headquarters are located at 38 rue des Mathurins 75008 PARIS (France).

The Board of Directors may transfer it, including to another department or country, after approval of the location envisaged by the General Assembly.

ARTICLE 4 - DURATION

The duration of the Association is unlimited.

ARTICLE 5 – MEANS OF ACTION

The Association's means of action include:

- the publication of an Association website;
- the organisation of meetings, conferences, debates;
- attending exhibitions;
- the publication of a professional directory, newsletters, notes, various communications;
- dialogue and participation in debates, discussions, meetings, with national, european and international regulators;
- the creation of professional documentation;
- active participation in ad 'hoc committees outlining the purpose of the Association

as well as any other means directly related to the purpose of the Association as expressed in Article 2.

ARTICLE 6 - COMPOSITION – ANNUAL FEES

The Association consists of:

1) Founding members

Those that are listed by name at the foot of these statutes are considered to be such.

2) Active members

These are considered to be those who will join these statutes and paid the annual dues set by the General Assembly.

3) Honorary members

They are appointed by the General Assembly on the proposal of the Board of Directors and chosen from among the individuals who render or have rendered services to the Association or whose participation would benefit the Association purpose.

4) Supporting members

These are people who wish to help the Association pursue its purpose, but cannot be active members. They cannot take part in deliberations or votes, and do not count in quorums. They pay an annual fee set by the General Assembly.

ARTICLE 7 – REQUIREMENTS MEMBERSHIP

To be a member of the Association under Article 6-2 (active members), one must meet the conditions set out in Article 15 of the Regulation 2017/745 on medical devices of the European Parliament and European Council, specifying the conditions of training and/or professional experience necessary to practice the profession of "Person responsible for regulatory compliance" (PRRC).

Active members must represent at least two-thirds of the total membership of the Association, excluding supporting members.

Those who do not meet these conditions can still apply to the Board of Directors, which will decide.

Applications for membership are made in writing and addressed to the Association's headquarters by mail or email and are reviewed by the Board of Directors, which, if refused, will not have to disclose its reasons to the candidate.

The signing of the Ethical Charter of TEAM-PRRC members is mandatory to become a member of the Association.

ARTICLE 8 - LOSS OF MEMBERSHIP

The membership of the Association is lost:

- 1) by resignation;
- 2) by writing off for non-payment of the annual dues;
- 3) by striking out for serious reasons.
- 4) by death.

The terms and conditions for the loss of membership are specified in the Internal Regulations.

ARTICLE 9 - RESOURCES

The Association's resources consist of:

- contributions from its active members and support members. The amount of the first annual contribution is included in the Internal Regulations. Subsequently, the assessment is set by the General Assembly on the proposal of the Board of Directors;

- grants that could be granted to it by European states, or regional, national or European public authorities;
- the income of his property;
- sums collected in return for the services provided by the Association;
- donations or allowances from contributors;
- all other resources authorized by legislation and regulations.

The Association may not receive remuneration for any business activity.

To finance its expenses, the Association may, on the decision of the Board of Directors, call on individual or legal lenders (including banking institutions).

Each loan will be the subject of a written document detailing the identities of the parties, the amounts and the terms of repayment. It will be detailed in the financial report presented by the Treasurer to the Board of Directors and then to the nearest General Assembly.

ARTICLE 10 - HERITAGE

The Association's heritage includes:

- buildings assigned to the operation of the Association;
- capital from the annual budget savings.

The Association's heritage is solely responsible for the commitments made on its behalf, and none of the association's members, regardless of title or function, can be made personally liable for it.

ARTICLE 11 - ORDINARY GENERAL ASSEMBLY

The Association's Ordinary General Assembly includes founding members, active members and honorary members of the Association. Active members must be up to date with the payment of their annual membership fee to participate.

It meets at least once a year, and must be convened by the President, at his initiative, or at the request of the majority of the members of the Board of Directors, or at the written request of at least twenty members (none of them supporting member).

Convocations are sent at least one month in advance and specify the agenda and the modalities for representation. Summonses can be sent by email with a request for an accused of reading.

Each member may be represented by another member with written proxy. This proxy may be handwritten or written by email and addressed at least a fortnight before the General Assembly to the Office and jointly to the member receiving the written proxy. The latter must accept it in the same form.

The same member cannot be given more than three proxies.

The Office of the Ordinary General Assembly is that of the Board of Directors.

In order to deliberate validly, the Ordinary General Assembly must be composed of at least a quarter of the members of the Association, whether they are present or represented, excluding from this account the supporting members of the Association.

All decisions of the Ordinary General Assembly are taken by an absolute majority of the members present or represented.

The Ordinary General Assembly:

- Check attendances and powers and sign an emanating sheet.
- hears reports on the activity of the Board of Directors and on the moral and financial situation of the Association since the previous General Assembly;
- examines membership movements (requests, acceptances, refusals);
- appoints honorary members;
- takes note of the warnings issued by the Board of Directors;
- rules on appeals in case of disbarment of members;
- approves accounts including loans made, votes on the next year's budget, and may appoint any auditor and report on the holding of the accounts;
- vote the amount of dues on the proposal of the Board of Directors
- provides, if necessary, for the renewal of the members of the Board of Directors;
- authorizes membership in a union or federation;
- gives the Board of Directors or certain members of the Bureau all permissions to carry out the operations that fall within the association's purpose and for which statutory powers would be insufficient;
- deliberates on any issue on the agenda at the request of at least five members of the Association, and proposed by email at least fifteen days before the Ordinary General Assembly;
- decides on a change of address of the headquarters;
- deliberates on any proposed amendments to the Internal Regulations.
- deliberates on any issue relating to the Ethical Charter.

The decisions of the General Assembly are required for all members, including absentees or representatives.

It is held minutes of each Ordinary General Assembly. The minutes will be published in the space of the Association's members website, and the Association Secretary will attach it to the statutory register.

ARTICLE 12 - EXTRAORDINARY GENERAL MEETING

The General Assembly has an extraordinary character:

- when it decides on any changes to the statutes,
- when it follows the request to the President for the Ordinary General Assembly by at least half of the members of the Board of Directors or by at least twenty members up to date with their dues and that this request has not been followed up two months,
- when it decides on the removal of a founding or honorary member or a member of the Board of Directors or the Office of the Association
- when it is to declare the dissolution of the Association.

The Extraordinary General Assembly must be convened:

- by the President, at his initiative or at the request of at least half of the members of the Board of Directors.
- by at least half of the members of the Board of Directors when their request to the President to hold a General Assembly has not been followed up within two months;
- by at least twenty members of the Association up to date with the payment of their dues, when their written request to the President to hold an Ordinary General Assembly was not followed up within two months.

The summonses are sent at least one month in advance and must specify the extraordinary nature of the General Assembly and the agenda containing the text of the resolutions to be adopted. There can be no "various issues" on the agenda.

Summonses can be sent by email with a request for an accused of reading.

The Association's Extraordinary General Assembly includes all members of the Association except support members. Active members must be up to date with their annual membership fee to participate.

The representation of the members of the Association is identical to those defined for the Ordinary General Assembly.

Any founding member can speak, including publicly, on the issues on the agenda in the event of an Extraordinary General Assembly.

The Office of the Extraordinary General Assembly is that of the Board of Directors.

The Extraordinary General Assembly must be composed of at least a quarter of the members of the Association, the supporting members not counting.

The deliberations must strictly respect the agenda on summonses.

All decisions of the Extraordinary General Assembly are taken by a two-thirds majority of the votes of the members present or represented.

If the quorum is not reached at the Meeting of the Extraordinary General Assembly, and no challenge signed by at least five members of the Association has reached by email or recommended

letter to one of the members of the Bureau in the thirty days after the minutes of the Extraordinary General Assembly are posted online, the decisions are deemed definitively adopted.

Otherwise, the Extraordinary General Assembly will be reconvened, with a minimum period of one month between the sending of the summonses and the holding of the second Assembly. At this new Extraordinary General Assembly, it may be validly deliberated, regardless of the number of members present.

It is held minutes of each Extraordinary General Assembly. The minutes will be deposited in the space of the Association's members website, and will be attached to the Association's statutory register by the Secretary.

ARTICLE 13 – BOARD OF DIRECTORS

The Association is governed by a Board of Directors.

The first Board of Directors is appointed by the founding members and its composition detailed at article 19 of these statutes.

The Board of Directors will then be elected by the General Assembly of the Association, whose first meeting will be held within one year of the date of publication in the Journal Officiel de la République Française the Association's statement.

The General Assembly sets the number of Directors and elects them for one year.

Members of the Board of Directors are eligible for re-election.

In the event of a vacancy of one or more directors, the Board of Directors provisionally provides for its replacement among the members of the Association (except among the supporting members). The Board of Directors submits the final nomination of the replacement to the next General Assembly.

Members of the Board of Directors who have not attended or have not been represented at at least half of the Board of Directors meetings held during the term of office for which they have been elected are automatically excluded from the Board of Directors, unless there is a justification presented to the Board of Directors which will decide whether or not to exclude the member concerned in light of that justification.

The Board of Directors reports on its mandate and the attendance of its members at the General Assemblies.

1) Powers of the Board of Directors

The Board of Directors has the broadest powers to authorize all acts that are not reserved for the General Assembly, including:

- it decides on memberships of the Association, addresses the Warnings and undertakes the delisting of members;
- it proposes the holding of the General Assemblies;

- it monitors the management of the members of the Bureau and is held accountable for their actions;
- it authorizes all purchases, disposals or rentals, loans necessary for the operation of the Association, with or without mortgages or other guarantees;
- it authorizes any transaction, any release of a mortgage or guarantee with or without payment;
- it may grant a member of the Association any delegation of powers for a specific issue and a limited time;
- it sets the amount of any representation allowances exceptionally awarded to certain members of the Bureau;
- it sets the amount that the Treasurer can commit without the permission of the President or another member of the Bureau.

The Board of Directors will be able to consult with the members of the Association by mail or email. The text of the proposed resolutions will be addressed to all members (except support members) with the indication of the deadline for publicizing their vote. The answers will be stripped at a meeting of the Board of Directors and the results will be proclaimed by the President; at all it will be prepared minutes.

2) Board meetings

The Board of Directors meets quarterly, and if the President summons it or at the request of one third of its members.

Meetings can be held through video conferencing.

The Board of Directors also meets at least fifteen days before a General Assembly to consider the moral and financial reports that will be presented there.

The Board of Directors must be composed of at least two-thirds of its members (present or represented) for the decisions taken at its meetings to be valid.

A member of the Board of Directors who cannot be present may be represented by sending a written proxy to the member of the Board of Directors who will represent him:

- by mail;
- by email with a copy to the other members of the Board of Directors.

Proxys will be attached to the reports.

Decisions are taken by an absolute majority. In the event of a split, the President's vote is preponderant.

It is held minutes of the meetings.

The minutes of the physical meetings must be signed by name by at least two members of the Board of Directors.

The minutes of the meetings by video conference include the printing of a screen copy of the members present, to serve as an emanation sheet, the minutes of the meeting and the powers that may be given.

Minutes of Board meetings are sent to each member of the Board of Directors by mail or email, and a copy must be attached to the Association's statutory register.

ARTICLE 14 - BUREAU

The General Assembly appoints among the Board of Directors a Bureau consisting of:

- a President;
- a Secretary and, if necessary, an Assistant Secretary;
- a Treasurer and, if applicable, an Assistant Treasurer;
- if necessary, one or more Vice-Presidents.

The founding members have set the composition of the first Bureau, detailed at article 20 of these statutes.

The Board of Directors may appoint a Director. This decision must be taken by two-thirds of the members of the Board of Directors. The Board of Directors will have to specify the responsibility and possible remuneration of the Director of the Association according to the legal provisions in force.

1) The President

The President convenes General Meetings and Board of Directors meetings.

He represents the Association in all acts of civil life and is vested with all powers to do so. It may delegate some of its responsibilities to a member of the Board of Directors. This delegation will be submitted for approval to the Board of Directors.

He has standing to sue on behalf of the Association, both in application and in defence, if the Ordinary General Assembly has given him special power.

In case of absence or illness, he is replaced by the oldest member of the Board of Directors, or by any other member specially delegated by the Board of Directors.

2) The Secretary

The Secretary is responsible for all matters relating to correspondence and archives.

He shall be responsible of keeping the list of members of the Association up-to-date, with their postal addresses and e-mail and the validity of their dues.

He sends calls for dues to members, records renewals, in coordination with the Treasurer.

He writes the minutes of the deliberations and transcribes them on the Association's statutory register.

It includes the minutes of the General Assemblies in the private space reserved for members of the Association on the Association's website.

It informs the administrative structures of changes to the representation and operation of the Association and updates the Association's file with these structures.

3) The Treasurer

The Treasurer is responsible for all matters relating to the management of the Association's assets.

He makes all payments provided that it has a supporting document and collects all revenue sets under the supervision of the other members of the Board of Directors.

However, expenses above an amount set by the Board of Directors must be ordered by the President or, failing that, by any other member of the Board

Purchases and sales of securities that make up the equity are made with the approval of the Board of Directors.

It maintains a regular day-to-day accounting of all transactions and keeps supporting documentation of payments made.

He submits a financial report to the Board of Directors one month before the General Assembly, which will decide on the management.

The financial report must include a chapter tracing all payments made to each member of the Board of Directors, with details of their constituent elements.

The financial report includes the amount of the main items of revenue and expenditure, including borrowings, bank balances, transactions awaiting bank reconciliation.

ARTICLE 15 - FREE MANDATE

Members of the Association may not receive any remuneration because of the duties entrusted to them.

They will, however, be able to obtain reimbursement for expenses incurred for the direct needs of the Association, along with physical evidence of the payment of these expenses, after the President's agreement. If it is to reimburse the President, the agreement of two other members of the Board will have to be obtained.

ARTICLE 16 - INTERNAL REGULATION – CODE OF ETHICS

An Internal Regulation determines the details of the implementation of these statutes.

The first Internal Regulation takes effect at the same time as these Statutes.

Its amendment must be submitted to the General Assembly.

A Code of Ethics for TEAM-PRRC members represents the commitments of the members of the Association. Signing is required to become a member of the Association.

It takes effect at the same time as these Statutes.

Its amendment must be submitted to the General Assembly.

ARTICLE 17 - DISSOLUTION

The dissolution of the Association can only be pronounced by the Extraordinary General Assembly, which is specially convened for this purpose and which rules on the terms of Article 12.

The General Assembly appoints one or more commissioners responsible for the liquidation of the Association's assets, whose powers it will determine.

It assigns net assets to any associations declared with a similar purpose or to any public or private institutions recognized as a public utility of its choice.

ARTICLE 18 – FOUNDING MEMBERS

The founding members of the Association are:

- Elem AYNE,
- Jean-Louis DIVOUX,
- Denys DURAND-VIEL,
- Anne JURY,
- Daniel PETIT,

ARTICLE 19 – BOARD OF DIRECTORS

The first Board of Directors is composed in accordance with Article 13 of these statutes as follows :

- Elem AYNE;
- Jean-Louis DIVOUX;
- Anne JURY;
- Daniel PETIT;

ARTICLE 20 - BUREAU

In accordance with Article 14 of these Statutes, the founding members set the composition of the first Bureau as follows:

- **Elem AYNE , President;**
- **Anne JURY, Vice-President;**
- **Jean-Louis DIVOUX, Secretary;**
- **Daniel PETIT, Treasurer.**

ARTICLE 21 - FORMALITIES

The President, on behalf of the Board of Directors, is responsible for completing all the reporting and publication procedures required by the current legislation. All powers are given to the wearer of an original copy to carry out these formalities.

Made in as many originals as interested parties, plus two originals for the Association, one of which will be at the top of the statutory register, and one intended for legal filing.

Paris, February 24, 2020