

Translation for information purposes only

The German original version of the VDPH Statutes is legally binding

Statutes**VDGH – Verband der Diagnostica-Industrie e.V.****Version based on the general assembly decision of 25 June 2021****Content**

- §1 Name, purpose and registered office of the association
- §2 Membership
- §3 Rights and obligations of the members
- §4 Organs of the association
- §5 General assembly
- §6 Board (Vorstand)
- §7 Management (Geschäftsführung)
- §8 Specialist departments (Fachabteilungen)
- §9 Committees
- §10 Membership fees
- §11 Final provisions

§1 Name, purpose and registered office of the association

- (1) The "VDGH - Verband der Diagnostica-Industrie e.V." (in the following: "the association") is an industry association that represents and promotes the common interests of the association members.
- (2) As its purpose, the VDPH does not pursue economic business operations. The VDPH can engage in economic business operations to cover its own costs. The tax exemption of the association must not be put at risk by generating income.
- (3) The registered office of the association is Frankfurt/Main. The association is entered in the register of associations. The business office of the association is determined by the general assembly and can be different from the registered office of the association.

- (4) The business year is the calendar year.
- (5) The association is a corporate member of the German chemical industry association (Verband der Chemischen Industrie / VCI).
- (6) The place of performance and jurisdiction for all claims of the association against its members is Frankfurt/Main.

§2 Membership

- (1) Membership in the association is open to any company which has its registered office in Europe and
 - is a manufacturer of products on an industrial scale according to Regulation 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices or, as an importer, exclusively or predominantly distributes in Germany such products of the companies belonging to its company group, or
 - is a manufacturer of products on an industrial scale according to Regulation 2017/745 of the European Parliament and of the Council on medical devices or, as an importer, exclusively or predominantly distributes in Germany such products of the companies belonging to its company group if these products exclusively generate a diagnostic measured value, or
 - offers the performance of a laboratory diagnostic service with an in vitro diagnostic product developed and manufactured in the company in the meaning of Regulation 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices in its own laboratory but does not provide any other laboratory diagnostic services in healthcare. The product relevant to and used for the provision of the laboratory diagnostic service in this sense must be CE-marked according to the said Regulation. Or
 - is a manufacturer on an industrial scale of reagents, consumables or instruments/equipment for applied and basic research in life sciences (life science research) or a supplier of preliminary products for the diagnostics industry or, as an importer, exclusively or predominantly distributes in Germany such products of the companies belonging to its company group, or

- is a manufacturer of veterinary diagnostic products or, as an importer, exclusively or predominantly distributes in Germany such products of the companies belonging to its company group, or
- is a manufacturer of digital health applications according to § 33a SGB V (German Social Code V).

Membership is acquired by written application and acceptance of the application by the board.

If an application for membership is rejected, the entity concerned can appeal to the general assembly within one month. The next ordinary general assembly makes the final decision.

(2) Membership in the association is terminated

- a) by withdrawal,
- b) by exclusion,
- c) by the opening of insolvency proceedings against the assets of the member or the dismissal of an application for the opening of insolvency proceedings for lack of assets,
- d) if the conditions for acquiring membership are no longer given.

The withdrawal must be declared in writing to the management of the association, observing with six months' notice to the end of a calendar year.

The board can decide to exclude of a member if a member, after prior threat of exclusion by the management, fails to fulfil its obligations towards the association or if the member seriously acts against the common interests of the association membership. An appeal against the decision of the board can be brought before the next ordinary general assembly.

Until the date of termination of membership, the member remains liable to pay all membership fees and all possibly due shares in costs.

§3 Rights and obligations of the members

- (1) The members of the association are entitled to advice and support from the association in all matters arising from the purpose of the association.
- (2) The members of the association are obliged to
 - a) to comply with the provisions of the statutes and the resolutions of the general assembly,
 - b) to support the association and its organs in the fulfilment of their legal and statutory tasks,
 - c) to pay the membership fees and shares in costs determined by the general assembly.

§4 Organs of the association

The organs of the associations are

- a) the general assembly
- b) the board
- c) the management

§5 General assembly

- (1) The ordinary general assembly is held once in each financial year at a place to be determined by the board and shall be held by 1 July each year. Invitations to the general assembly are sent out on behalf of the association by the management no later than four weeks before the date of the general assembly. An extraordinary general assembly is convened at the request of at least one quarter of the members.
- (2) The general assembly constitutes a quorum if at least one quarter of the members are represented with voting rights. Each member has one vote, which is cast by an authorised representative. If a quorum is not achieved due to insufficient attendance, an invitation to a new general assembly must be sent out which can be held two weeks later at the earliest. Irrespective of their number, the members present at this general

assembly can pass resolutions on the items announced on the agenda of the general assembly that was not quorate.

- (3) The general assembly is chaired by the chairperson of the board.
- (4) In voting, the members present decide by a simple majority. Abstentions are not taken into account. In the event of a tie, the motion is deemed rejected. A majority of two thirds of those present is required for resolutions on dissolution, merger, determination of membership fees or amendments to the statutes.
- (5) The ordinary general assembly elects the board and decides on the budget of the association. If there are more candidates than board positions to be filled, the board is filled according to the number of votes a candidate receives. In the event of a tie, a run-off election takes place. Candidates who are not elected are considered as replacement board members for the duration of the election period; they replace any board members who leave the board prematurely in the order in which they received their votes. In the event of a tie, the board decides on the replacement. Furthermore, the general assembly decides on all matters of fundamental importance that are listed in the legislation or in these statutes, in particular:
 - a) Approval of the acts of the board and the management,
 - b) approval of the treasury report and determining the budget and the membership fees,
 - c) election of the members of the board,
 - d) admission or exclusion of members,
 - e) election of the auditor,
 - f) decisions on amendments to the statutes,
 - g) election of an honorary chairperson.
- (6) Beside the members and the board of the association, the management attends the general assembly. Minutes of each general assembly, in particular of the resolutions passed, are drawn up by the board, signed by the chairperson of the assembly and the director (Geschäftsführer) or another member and sent to all members.

- (7) Motions for the general assembly must be submitted to the board or to the management at least two weeks before the general assembly. The same applies to motions for the agenda, however, the agenda can be extended during the assembly with the consent of a simple majority of the members present. Proposals received for the agenda must be communicated in writing to the members.

§6 Board

- (1) The board is composed of staff from at least seven and at most nine members of the association. At least one member of the board is to be from the staff of a company that is a member of the life science research department of the VDGH. Board membership is limited to one person per member company. The board members are elected by the general assembly for a period of two years; re-election is permitted. The chairperson of the board, the deputy chairperson of the board and the treasurer are elected by the general assembly from among the elected board members, on the proposal of the board. If an elected function holder without a deputy leaves the board during the election period, the board decides on a replacement until the next general assembly.
- (2) Elections to the board are announced to the members in writing three months before the general assembly with the request to declare a candidacy. The list of candidates closes five weeks before the general assembly. It is attached to the invitation to the general assembly together with a short application of the candidates. Elections to board are by secret ballot unless the electing general assembly unanimously decides on another form of election. In recognition of special services to the VDGH, the general assembly can, upon proposal of the board, elect a departing chairperson as honorary chairperson, who can attend board meetings and general assemblies in an advisory capacity.
- (3) The board is responsible for the day-to-day work of the association which safeguards the interests of the membership. The board makes all decisions necessary for this, insofar as such decisions are not reserved for the general assembly and, in particular, the board gives the necessary instructions to the management.

- (4) Board meetings are to be held at least three times a year. Additional meetings take place if this is requested by two board members. The board constitutes a quorum if at least five board members are present after an invitation with reasonable notice. The board passes resolutions by a majority of votes. In the event of a tie, the vote of the chairperson or, in his/her absence, the vote of his/her deputy is decisive. The board members are bound to secrecy with regard to all matters which by their nature are confidential or which have been designated as confidential by a resolution of the board. The management attends the board meetings and takes minutes thereof.
- (5) The association is represented in and out of court by two board members.
- (6) The activity on the board is honorary and in a personal function; deputizing on the board is excluded.
- (7) If a board member leaves his/her company during the election period and this board member does not subsequently take up employment with another member company, the participation in the board ends on the day of his/her departure from the company according to his/her contract. Notwithstanding the foregoing, the board can, at the request of a board member, decide by a two-thirds vote that the board member remains on the board for the elected term of office, provided that this board member does not take up employment with a company outside the membership.

§7 Management

- (1) The board decides whom to entrust with the management of the association.
- (2) The management is responsible for the tasks arising from the purpose of the association, unless these are assigned to other bodies. In consultation with the board, the management does everything that is necessary to safeguard the interests of the association membership. The management informs the board and the members of all matters of interest to them. Furthermore, the management carries out the decisions of the general assembly and the board.
- (3) The management conducts its activities in an impartial manner and keeps secret the business and trade secrets of individual companies and other confidential information coming to its knowledge.

§8 Specialist departments

- (1) Members who, because of the specific nature of their products and in particular those according to §2 (1) letter d) of these statutes, require additional representation of their particular specific interests, can – with the consent of the board – form themselves into specialist departments within the VDPH. The specific problems they intend to deal with must be explained in writing to the board. In external contacts, the specialist departments are represented by the organs of the VDPH. The specialist departments adopt for themselves rules of procedure, based on model rules of procedure for specialist departments as adopted by the board. §9 of these statutes applies accordingly to the composition of the committees of specialist departments.
- (2) The organs of the specialist departments are their general assemblies and boards.
- (3) The members of a specialist department can dissolve the specialist department by majority vote. The VDPH board has the same right if there is no longer a need for special representation of the specific interests of these members.
- (4) The general assembly of the specialist departments can decide to adopt an additional budget for the specialist department by charging an extra contribution. The rules of §10 of these statutes apply accordingly.

§9 Committees

- (1) The board of the association can form committees to deal with special, precisely defined tasks.
- (2) The members of a committee are appointed by the board. Proposals can be made by any member company.
- (3) New members to an existing committee can only be appointed in agreement with the committee chairperson.
- (4) Only staff working in their main professional activity for member companies can be appointed as committee members, and only one staff per company. The committees are authorised to consult experts, who do not necessarily have to belong to a member company, in their deliberations.

- (5) The committees elect a chairperson and a vice-chairperson for a period of three years; re-election is possible.
- (6) The committees answer to the board for the fulfilment of the tasks assigned to them. The members of the board each receive a copy of the minutes of the meetings.

§10 Membership fees

- (1) In order to cover the budget decided by the general assembly for the current business year, the members of the association pay a membership fee which is payable within four weeks following the request for payment from the trustee retained for fee collection. Each member company pays the minimum annual fee, which is determined by the general assembly. As for the rest, the membership fee is apportioned according to a scale based on net domestic sales, which is determined by the general assembly.
- (2) The calculation and collection of the fees is carried out by the collecting agency of the VCI or mandated to a trustee agency to be appointed by the general assembly. Members who have other chemical sales beside those covered by the association must – unless otherwise agreed with the VCI – pay directly to the VCI the contribution determined by the VCI general assembly on such other chemical sales.
- (3) If members are in arrears with their payment obligations for six months despite reminder from the board, the board can exclude them from membership without forfeiting the right to payment. In justified cases – for example, economic difficulties of a member company – the treasurer can suspend the collection of the membership fee of a member company in whole or in part for a maximum of one year or defer it for a maximum of two years. The board can also refrain from collecting outstanding membership fees if there is reason to fear that this might be unsuccessful or if, in the opinion of the board, the necessary effort is not in adequate proportion to the proceeds.

§11 Final provisions

- (1) In the event of dissolution of the association, the last general assembly decides on the assets and the appointment of liquidators. Surpluses can only be used for the promotion of research in the field of IVD and LSR. There must be no distribution to the members of the association.

- (2) The board is authorised to adapt the statutes to the requirements of the competent public authorities, as far as this concerns only the form and not the factual content.

Berlin, 25 June 2021