

Translation / Original: German

Readers are requested to note that this is a translation for information purposes only.

The original German text is legally binding.

STATUTES

VDGH Verband der Diagnostica-Industrie e.V. (Association of the German Diagnostics Industry)

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§ 1

Name, purpose and headquarters of the Association

- I. "VDGH Verband der Diagnostica-Industrie" (in the following: "the Association") is an industry association for the defence and the promotion of common interests of the members of this Association.
- II. The purpose of VDPH is not oriented to commercial operations. The VDPH can engage in commercial operations to cover its own costs. The generating of income must not compromise the tax exemption of the association.
- III. The Association is headquartered in Frankfurt/Main. The Association is registered in the register of associations [Verbandsregister]. The location of the Association's office is decided by the general assembly and can be different from the Association's headquarters.
- IV. The business year is the calendar year.
- V. The Association is – as a sector association [Fachverband] – a corporate member of the German chemical industry association Verband der Chemischen Industrie (VCI).
- VI. The place of fulfilment and jurisdiction for all claims of the Association against its members is Frankfurt/Main.

§ 2

Membership

- I. Membership in the Association is open to all companies who are headquartered in the European Economic Area and
 - are industrial-scale manufacturers of products according to "Regulation 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices" or importers

who – exclusively or predominantly – distribute in Germany such products from companies of the same business group,

- or industrial-scale manufacturers of products according to “Regulation 2017/745 of the European Parliament and of the Council on medical devices” or importers who – exclusively or predominantly -- distribute in Germany such products from companies of the same business group if such products solely generate a measured diagnostic value,
- or offer to perform – in their own laboratory – a laboratory diagnostic service with an in vitro diagnostic medical device in the meaning of “Regulation 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices” which has been developed and manufactured inside the company but who, beyond that, do not render any laboratory diagnostic services within health care. The product which is decisive and used for the performing of the laboratory diagnostic service must have CE marking according to Regulation 2017/746,
- or industrial-scale manufacturers of reagents, consumables or instruments/machinery for applied research and basic research (life science research) or suppliers of pre-products for the diagnostic industry or importers who – exclusively or predominantly – distribute in Germany such products from companies of the same business group.

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

If a membership application is rejected, the concerned company is free to appeal - within one month – to the general assembly. The next ordinary general assembly makes the final decision.

- II. Membership in the Association terminates by
- a) withdrawal
 - b) exclusion
 - c) the initiation of bankruptcy proceedings regarding the assets of the member or the rejection of an application to initiate bankruptcy proceedings for lack of assets
 - d) no longer fulfilling the prerequisites for the acquisition of membership

Withdrawal must be declared in writing to the management of the Association, observing a period of six months to the end of a calendar year.

The board can decide to exclude a member if this member fails to meet its obligations vis-à-vis the Association irrespective of a relevant reminder or if the member engages in conduct that stands in serious contradiction to the common interests of the membership of the Association. An appeal against the board decision can be made to the next ordinary general assembly.

Until the date of termination of membership, the member remains under the obligation to pay all membership fees and possibly occurring cost contributions that become due up until that date.

§ 3

Rights and obligations of the members

- I. The members are entitled to advice and support from the Association in all questions ensuing from the purpose of the Association.
- II. The members of the Association are obliged to

- a) comply with the provisions of the statutes and with the decisions of the general assembly,
- b) support the Association and its organs in the fulfilment of their tasks,
- c) pay the membership fees and cost contributions as decided by the general assembly.

§ 4

Organs of the Association

Organs of the Association are:

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

§ 5

General Assembly

- I. The ordinary general assembly takes place once in a business year at a venue to be decided by the board. The general assembly is to be held by 1 July of any year. On behalf of the Association, invitations to the general assembly are circulated by the management at least four weeks before the day of the general assembly.

An extraordinary general assembly must be convened at the request of at least one fourth of the members.

- II. The general assembly is quorate if at least $\frac{1}{4}$ of the members are represented and entitled to vote. Each member has one vote, which is cast by an empowered delegate. If a general assembly is not quorate because the number of participants is too low, an invitation to a further general assembly must be issued; this further general assembly can take place two weeks later at the earliest. Irrespective of their number, the members attending this further general assembly can make decisions on agenda items which had been announced on the agenda of the non-quorate general assembly.
- III. The general assembly is chaired by the chairman of the board.
- IV. Decisions are made by a simple majority of votes of the attending members. Abstentions are not taken into account. If there is an equality of votes, the motion which is voted upon is deemed defeated.

Decisions on dissolution, merger, membership fees or amendments to the statutes require a majority of two thirds of those present.

- V. The ordinary general assembly elects the board and decides on the budget of the Association. If the number of candidates exceeds the number of board positions to be filled, appointments to the board are made according to the number of votes received by the respective candidates. If there is an equality of votes, a run-off election is held. Candidates, who were not elected, have the status of replacement board members during the election period and replace possibly departing board members; their sequence is determined by the number of votes which they received. If there is an equality of votes, the board decides on replacement board members. Furthermore, the general assembly decides on all matters of fundamental importance which are part of applicable legislation or of these statutes, in particular
- a) approval of the acts of the board and the management,
 - b) approval of the financial report, determination of the budget and of membership fees,

- c) election of the board members,
 - d) decision on the admission or the exclusion of members,
 - e) appointment of trusteeship,
 - f) decisions on amendments to the statutes,
 - g) election of an honorary chairman.
- VI. Beside the members and the board of the Association, the management attends the general assembly. The management takes minutes of every general assembly; in particular, the adopted decisions are minuted. The minutes need to be signed by the chair of the assembly and by the director or by another member, and they need to be sent to all members.
- VII. Motions for the general assembly must be sent to the board or to the management at least two weeks before the general assembly. The same applies for motions for the agenda, but the agenda can be extended during the assembly by a simple majority of the members present. Proposals received for the agenda must be communicated in writing to the members.

§ 6

Board

- I. The board is composed of staff from at least seven and at most nine members of the Association. At least one board member should be on the staff of a company which is a member of the technical department (Fachabteilung) Life Science Research of VDGH. The chairman of the board, the deputy chairman of the board, the treasurer and up to six further board members are elected by the general assembly, each for a term in office of two years; reelection is possible. Three months before the general assembly, upcoming board elections are announced in writing to the members, together with an appeal to potential candidates to come forward. The list of candidates is closed five weeks before the general assembly. Together with summary

- applications of the candidates, this list is attached to the invitation to the general assembly. Board elections are secret, unless the electing general assembly unanimously decides for a different form of voting. For special merits for the VDPH, the general assembly can elect – at the proposal of the board – an outgoing chairman as honorary chairman, who can attend board meetings and general assemblies in an advisory role.
- II. The board is responsible for the ongoing work of the Association, which is performed in the interest of the members. The board makes all the necessary decisions for this purpose unless such decisions are reserved for the general assembly and, in particular, the board gives the necessary instructions to the management.
- III. Meetings of the board should take place at least three times per annum. Further meetings take place if this is demanded by two board members. The board is quorate if – after an invitation in due course – at least five board members are present. The board makes decisions by a majority of votes. If there is an equality of votes, the chairman has the casting vote; in the absence of the chairman the deputy chairman has the casting vote. The board members must keep secrecy about all matters which have been deemed confidential because of their nature or by decision of the board. The management attends and minutes the board meetings.
- IV. The Association is represented by two board members, both before and outside law courts.
- V. The work of the board members is honorary and bound to the person; it is not possible to stand in for board members.

§ 7

Management

- I. The board decides who is entrusted with managing the Association.
- II. The management is in charge of the tasks which arise from the purpose of the Association, unless tasks are assigned to other organs. In agreement with the board, the management takes all the steps that become necessary to represent and defend the interests of the members of the Association. The management informs the board and the members about all matters of interest to them. Furthermore, the management carries out the decisions of the general assembly and of the board.
- III. The management performs its activities in an impartial manner and guards the secrecy of business and trade secrets of individual companies and of other confidential items of information, which come to the knowledge of the management.

§ 8

Sector departments

- I. Members, who – because of the specific nature of their products; especially under § 1 (1) sentences 4 and 5 of these statutes – require an additional representation of their specific sectoral interests, can form sector departments within the VDGH; the consent of the board is needed for this step. Specific problems, which such members intend to address, must be explained in writing to the board. In outside contacts, the sector departments are represented by the organs of the VDGH. The sector departments adopt rules of procedure for their activities, based on the "model rules of procedure for sector departments" as decided by the board. § 9 of these statutes applies accordingly to the composition of committees of the sector departments.
- II. Organs of the sector departments are their member assemblies and boards.

- III. The members of a sector department can dissolve the sector department by a majority decision. The VDPH board has the same right if there is no longer any need for a specific representation of the sectoral interests of such members.
- IV. The member assemblies of the sector departments can decide to raise extra cost contributions, in order to have an additional budget for a sector department. The rules of § 10 of these statutes apply accordingly.

§ 9

Committees

- I. The board of the Association can set up committees to perform specific tasks that need to be described precisely.
- II. The members of a committee are appointed by the board. Proposals can be made by all member companies.
- III. New members to an existing committee are to be appointed only with the consent of the committee chairperson.
- IV. Eligible for appointment as committee members are only persons who work in their principal professional occupation for member companies; only one staff member per company can be appointed. For their deliberations, the committees can consult experts who do not necessarily need to work for member companies.
- V. The committees appoint a chairperson and a deputy chairperson for a term in office of three years each; reelection is possible.
- VI. The committees report to the board as regards the execution of the tasks entrusted to them. Board members receive one copy each of the minutes of meetings.

§ 10

Membership fees

- I. In order to fund the budget as decided by the general assembly for the current business year, the members of the Association pay a membership fee. This payment needs to be made within four weeks after request by the trust agency, which is retained to collect membership fees. Every member company pays the minimum annual fee, which is determined by the general assembly. The remaining part of the membership fee is determined by a system oriented to net domestic sales, which is decided by the general assembly and can vary for diagnostic medical devices [Diagnostica] and diagnostic equipment [Diagnosticaeräte], respectively.
- II. The collection agency of the VCI or a trust agency is retained to calculate and to collect the fees; this appointment is made by the general assembly.

Members, who have further chemical sales outside the scope of the Association, must pay directly to the VCI – for such further chemical sales – the fee determined by the VCI general assembly, unless agreed otherwise with the VCI.

- III. Members, who are six months in arrears with their payment irrespective of a reminder from the board, can be excluded from membership by the board. This does not discharge them from their payment obligation.

In justified cases – e.g. economic difficulties of a member company – the treasurer can fully or partly suspend the fee collection from a member company for one year at most or the treasurer can extend the payment period to two years at most. The treasurer can also decide not to engage in the collection of outstanding membership fees if such efforts are feared to remain unsuccessful or if the treasurer holds the view that such efforts are out of proportion to the thus achieved income.

§ 11**Final provision**

In case of the dissolution of the Association, the last general assembly decides on the assets and on the appointment of liquidators. Surplus assets can be used solely to promote research in diagnostic medical devices [Diagnostica] and diagnostic equipment [Diagnosticageräte]. Any distribution to the members of the Association is excluded.

The board is entitled to adapt the statutes to the requirements of competent public authorities where such adaptations are merely of a formal nature and do not affect the contents of the statutes.

Berlin, 1 January 2018