



International  
Operators  
Association

# RULES OF ASSOCIATION

For

**The Pharmaceutical BFS International Operator's Association**

Date:

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## **1 TITLE, DOMICILE**

- 1.1 The name of the association is “The Pharmaceutical BFS International Operator’s Association” (the “**Association**”).
- 1.2 These rules of association, (the “**Rules**”) constitute the bylaws of the Association. Each member of the Association (a “**Member**”) undertakes to follow the Rules.
- 1.3 The Association is a non-profit industrial interest association for companies engaged in BFS operation, companies offering Pharmaceutical Products produced by BFS technology and companies supplying certain technologies and consumables for BFS operation.
- 1.4 For the purpose of these Rules “**Pharmaceutical Products**” means a “medicinal product” cf. Article 1 of Directive 65/65/EEC, relating to Medicinal Products (1989), or any such definition that replaces the definition in the directive, but it shall additionally include such products as antiseptics, in vitro diagnostics and the like. Further, for the purpose of these Rules “**BFS**” means blow-fill-seal technology, being defined as the process by means of which a purpose built machine blow moulds, fills and seals plastic containers in one operation.
- 1.5 The Association is domiciled in Denmark. Any lawsuits against the Association must be started at the City Court of Copenhagen as court of first instance. These Rules are governed exclusively by Danish law.

## **2 OBJECTS OF THE ASSOCIATION**

- 2.1 The objects of the Association are:
- 2.1.1 To promote appropriate standards in the production and quality assurance of Pharmaceutical Products produced by BFS.
- 2.1.2 To establish and agree with the relevant bodies standards appropriate to the pharmaceutical application of BFS technology.
- 2.1.3 To provide a vehicle for conducting both the coordinated views of the Members and their requirements to the manufacturers of BFS machines, filters, plastic resin and other components forming an integrated part of the BFS process.

- 2.1.4 To provide a forum for exchange of technical information between Members using BFS technology to produce Pharmaceutical Products.
- 2.1.5 To provide means of informing Members of regulatory requirements and developments.
- 2.1.6 To facilitate lawful co-operation between the Members.
- 2.2 Each Member undertakes to carry on any activities in relation to the Association in strict compliance with applicable law, including without limitation competition and anti-trust law, pharmaceutical and healthcare law, data protection law, trade law, tax law, etc.

### **3 MEMBERSHIP**

- 3.1 All companies fulfilling the following criteria can apply for membership of the Association:
  - 3.1.1 Companies operating BFS technology in their production (“**Operators**”), either as original equipment manufacturers or contract manufacturing organisations.
  - 3.1.2 Healthcare original equipment manufacturers (“**OEM’s**”) who are product owners of products produced by BFS technology supplied by a contract manufacturing organisation.
  - 3.1.3 Manufacturers producing BFS machines, equipment integrated into BFS lines/operation, resin, components and foils used in direct contact with BFS products (“**Vendors**”).
  - 3.1.4 Consultancies, within the BFS industry, that are nominated by an Operator or an OEM (“**Consultants**”).
  - 3.1.5 Affiliated companies or exclusive sales representatives of Vendors (“**Affiliates**”).
- 3.2 Admission of Members. Application for membership may be made in accordance with the procedure laid out from time to time on the Association’s website. The Board is authorized to decide on the admission of new Members.

## 4 RESIGNATION AND EXCLUSION OF MEMBERS

- 4.1 Unless the Board decides otherwise, membership of the Association shall automatically cease, without any refund of membership fee to the Member;
- 4.1.1 if the Member is dissolved or ceases to trade,
- 4.1.2 after the receipt by the Chairman or by the Officer of Operation of written notice from the Member of its intent to resign as Member, or
- 4.1.3 if the subscription or part-subscription of any Member remains unpaid for two months after the date upon which it fell due, without further warning.
- 4.2 Further, membership of the Association may cease, without any refund of membership fee to the Member, if;
- 4.2.1 a Member acts against these Rules, commits a criminal offense or acts in a similar way, or
- 4.2.2 a Member acts disloyally, harms the Association, or behaves in an unethical manner; (examples include, but are not limited to; price fixing, misrepresentation of facts, figures, information on products or packaging and the science of BFS technology, false sales promotion where competitors are unjustly attacked, taking unlawful right of competitor's products and proprietary rights, etc).
- 4.3 If a Member acts as set out in clause 4.1 or 4.2 above, the majority of two thirds of all Officers can take a decision that the membership of the relevant Member shall cease. Prior to such decision the Board shall give the relevant Member the opportunity to state its case in such form and way as reasonably decided by the Board.

## 5 OFFICERS OF THE ASSOCIATION

- 5.1 The overall management of the Association is carried out by a board of directors (the "**Board**"), consisting of the officers ("**Officers**") as set out herein. The Board shall be composed of the following 4 Officers elected by the Members; (i) the chairman of the Board ("**Chairman**"), (ii) the officer of operation (communication and treasurer function) ("**Officer of Operation**"), (iii) the technical officer ("**Technical Officer**") and (iv) the regulatory officer ("**Regulatory Officer**"). In addition, the Board may appoint up to 2 appointed Officers ("**Appointed Officers**").

- 5.2 Candidates for Chairman, Officer of Operation, Technical Officer and Regulatory Officer shall be physical persons employed by Operators or OEM's.
- 5.3 The Officers and the Appointed Officers are unpaid by the Association but are entitled to get travel cost reimbursement for reasonable costs carried out in their capacity as Officers and Appointed Officers, in accordance with the guidelines laid out in the travel rules adopted by the Association from time to time ("**Travel Rules**").
- 5.4 Term of Office. Each Officer shall be elected by the representatives of the Members at the AGM. The Officers shall serve for a term of two years but may be re-elected. Two Officers are elected on each AGM.
- 5.5 Election of Officers. Nominations for election to a position as Officer shall be proposed and seconded in writing by the Board or by a Member. Notification of any election shall be made to the Officer of Operation as set out in clause 7.6.
- 5.6 Appointed Officers are appointed by the Board to assist the Board in performing its duties and/or for special projects. Appointed Officers are appointed for 1-year terms until the next AGM but may be reappointed.
- 5.7 The Board must meet as often as the Chairman finds it expedient or one of the other Officers requests it.
- 5.8 The Board forms a quorum when more than half of the Officers are present. A simple majority of votes of the Officers present is required for the Board to adopt a resolution. In case of an equality of votes, the Chairman has the casting vote. The Appointed Officers have no votes in the Board.
- 5.9 An Officer or an Appointed Officer may not participate in the transaction of any matter relating to any agreement between the Association and such person or of any matter in which the person has a considerable interest in which may contravene the interests of the Association.
- 5.10 The Board may further specify the duties of its members in its rules of procedure.

## **6 MANAGEMENT AND CONTROL**

- 6.1 The day to day operation of the Association is carried out by the Officer of Operation who shall seek assistance and advice from the Board in case of larger decisions

and general matters. Decisions on significant matters of policy shall be decided by the Board or at an AGM as reasonable decided by the Board.

6.2 Power to bind the Association. For larger decisions, the Association is bound by joint signatures of two Officers (for the avoidance of doubt not including the Appointed Officers) or by the joint signatures of all Officers.

6.3 Any payments executed from the Association's bank accounts shall require double signatures for electronic online banking payments as well as manual payments. The Board will nominate persons that have access to the Association's bank accounts and have right to execute payments.

## **7 MEETINGS**

7.1 Meetings of the Association shall be held at such times and locations as decided from time to time by the Board. Apart from the AGM, the Board may decide to arrange other meetings or arrangements, including without limitation training seminars, specialist workshops etc.

7.2 Guests may be invited by the Board to attend meetings of the Association (e.g. to give presentations or for other relevant purposes).

### AGM

7.3 The agenda for the AGM must include:

- a) A report from the Board of the business of the Association since last AGM.
- b) Presentation of the annual report, together with a resolution for its adoption.
- c) Election of Officers.
- d) Resolutions proposed by the Board or the Members.
- e) Any other business.

7.4 Unless the Board decides on another person, the Officer of Operation shall serve as chairman of the meeting at AGM's.

- 7.5 Notices for the AGM shall be posted on the Association's web site at least 4 weeks in advance of the meeting. Further, as a service, but not as a formal requirement, the Board shall at the same time post notices by email to Members. Members are responsible to keep the Association updated of their emails
- 7.6 Possible motions from the Board or from Members for resolution at the AGM, must be presented in writing or by email to the Officer of Operation at least 3 weeks in advance of the AGM.
- 7.7 Agenda of the business to be transacted at the AGM complete with all relevant documents shall be posted as set out in clause 7.5 at least 2 weeks in advance of the AGM.
- 7.8 In case the Board or at least 30% of the Members require a Members' decision on a certain matter, they are entitled to make a request hereof to the Board. The request must clearly state the matter that requires a Members' decision. The Board must then either (i) arrange for a written voting procedure of the matter or (ii) postpone the matter to the next AGM.

#### Voting

- 7.9 At the discretion of the Board a vote may be taken at an AGM or by written voting procedure, cf. clause 7.8. Only Members shall be allowed to vote. The Board may decide that Members that have not paid their full subscription 3 days prior to the AGM or to the conduct of written vote, as the case may be, are not entitled to vote. The Members have one vote each per membership. All motions shall, subject to any exceptions set out in these Rules, be determined by a simple majority (i) in case of an AGM of those present and entitled to vote, and (ii) in case of a written voting procedure of all Members entitled to vote.
- 7.10 A Member is entitled to grant a written power of attorney to vote at AGM's to another Member. If the power of attorney is not sent to the Board no later than 3 days prior to the AGM, the Board may at its discretion reject the power of attorney.
- 7.11 The Board may decide that a certain matter is only relevant for a specific membership group (e.g. Operators, OEM's, Vendors, Consultants or Affiliates) and that accordingly only Members within such group is entitled to vote on the matter.



## **8 FINANCE**

- 8.1 The fiscal year of the Association runs from 1 January to 31 December each year.
- 8.2 The Accounts of the Association shall be reviewed by a professional accountant elected by the Board.
- 8.3 The annual accounts of the Association for the previous year, the auditor's report on the accounts, a report as to the financial position of the Association and a budget for the coming year shall be made available to the Members as set out in clause 7.7.
- 8.4 The Board decides on the annual subscription for Members and announces it to the Members.

## **9 ALTERATION OF THE RULES**

- 9.1 No alteration to these Rules, or decision on liquidation of the Association, shall be made unless:
- a) notice calling an AGM has been given in accordance with clause 7.5 and an agenda specifying the proposed shall have been made available to the Members in accordance with clause 7.7 and;
  - b) such alteration is approved by not less than three quarters of the votes of registered Members present and entitled to vote at the AGM.

## **10 LIQUIDATION**

- 10.1 In the event of liquidation of the Association, any properties, funds or monies or securities remaining in the treasury of, or to the account of, or otherwise belonging to the Association, shall be used by first to pay any lawful indebtedness of the Association. Any sums thereafter remaining shall be distributed to charity by the Board as per guidelines adopted by the Members. In no case shall any sum or any security, or any credit, or any pecuniary benefit be paid to, or accrue to, or inure to the benefit of, any Member and any Officers or Appointed Officers, save and except for payment of any proper expense incurred by such person, persons or organization on behalf of the Association.

**11 INDEMNIFICATION**

11.1 None of the Officers or Appointed Officers shall be personally liable for their conduct of business as Officer or Appointed Officer, except in case of fraud, a criminal offense or other comparable offense. The Association shall indemnify the Officers or Appointed Officers in respect of all actions, claims and demands whatsoever made against them in respect of any act, thing or matter lawfully done or omitted to be done by them in their conduct of business as Officer or Appointed Officer, except in case of fraud, a criminal offense or other comparable offense

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So adopted at the AGM held on \_\_\_\_\_

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