

General Terms and Conditions for the Operation of Presafe Denmark A/S

1. 1 TERMS AND CONDITIONS

- 1.1 The terms and conditions shall apply to all tasks carried out by Presafe Denmark at the request of clients, within the fields of certification or approval of products or systems (hereinafter referred to as tasks).
- 1.2 The terms and conditions are those agreed for the performance of all tasks as described above, unless specific agreement in writing has been made stating clearly and unambiguously the deviations for specified items.

2 Definitions

- 2.1 Certification is the activity addressing pre-evaluation, audit (including sampling, if relevant) and the issue of certificates covering products, systems or personnel.
- 2.2 Approval consists in activities such as type inspection (including design approval) and product verification provided by law or any other recognized basis.

3 Basis of agreements

- 3.1 Tasks are initiated based on a written agreement or, in the case of certification and approval tasks, based on an application lodged with Presafe Denmark. Presafe Denmark carries out the task based on the information and specifications contained in the agreement or application.
- 3.2 The client/applicant (hereinafter called the client) undertakes to provide Presafe Denmark with truthful and relevant information, which is of importance for the task. The client undertakes to accept the conduct of audits within the timeframes stipulated by Presafe Denmark, and to give duly authorized Presafe Denmark representatives access to all relevant premises and information. Aspirants and/or observers affiliated to e.g. accreditation authorities shall upon request be provided with equal access to all relevant premises and information at no cost for the client.
- 3.3 The client undertakes to give Presafe Denmark, on a current basis, a report, either orally or in writing, on any material changes to the information disclosed to Presafe Denmark at the time of the agreement, at the time of application or subsequently in connection with cases in progress.
- 3.4 The client undertakes to supply Presafe Denmark with vigilance reports & FSCA reports related to its certified products at the same time as the client informs the competent authority according to current rules and deadlines in force. The documentation submitted to Presafe Denmark must be equivalent to the information submitted to the competent authority.
- 3.5 No deviations from legislation, requirements, stipulations, terms and conditions can be made by agreement, unless an exemption has been granted by the relevant authority.
Presafe Denmark will inform the client of changes to the terms and conditions (or interpretation of these). The client is given a period of 6 months to adapt to new or changed requirements of which he/she has been notified. After this period, Presafe Denmark cannot undertake to issue or maintain certificates or approvals in conformity with the obsolete rules.
- 3.6 Presafe Denmark accepts to consider application material presented only in Danish (or Norwegian or Swedish) or in English. German or French are subject to special agreement, provided that the client accepts to cover Presafe Denmark's costs of additional time for handling the case and/or translation services.
- 3.7 Presafe Denmark is entitled to carry out audits of certified clients with no (or short) notice in order to examine complaints, as follow up on suspended/withdrawn/cancelled certificates and/or in case of significant changes

to the products or quality system etc. The client is obliged to give the audit team access and assist the audit team during the audit.

- 3.8 Presafe Denmark is entitled to carry out unannounced audits of the client and its critical subcontractors and suppliers without any underlying reasons. All costs in relation to unannounced audits will be charged to the client. The client is obliged to ensure that Presafe Denmark has access to perform unannounced audits, and the client's contracts with critical subcontractors and suppliers shall ensure that Presafe Denmark has access to carry out announced as well as unannounced audits of the critical subcontractors and suppliers in question. Furthermore, the client is obliged to provide Presafe Denmark with the relevant information needed to plan audits. E.g. undated invitation letters, production schedules and plans etc. During unannounced audits Presafe Denmark may collect device/s for testing, either at the client's premises or from the market. The cost of the devices and the testing will be invoiced to the client. When testing has been finalized, the device will be returned to the client, provided that the testing is non-destructive. All costs related to the testing will be charged to the client. Clause 10.10 of these Terms and Conditions does not apply to devices collected for testing during unannounced audits.

4 Schedule

- 4.1 Unless otherwise stipulated unambiguously in the agreement, schedules, deadlines, etc. specified by Presafe Denmark are always estimates, without regard to the fact that the task may prove to be more complicated or more time-consuming than anticipated, or that the progress of the work may be influenced by outside factors.
- 4.2 Presafe Denmark cannot be held liable in the event of delays, unless specific agreement has been made to that effect.

5 Fees and terms of payment

- 5.1 Unless otherwise agreed, tasks are carried out and invoiced in conformity with the hourly rates applicable at the time in question, with the addition of travelling costs, if any, and other expenses.
- 5.2 Where Presafe Denmark has provided the client with a rough calculation of the costs (estimate) or an estimated number of hours for performing the task, Presafe Denmark will inform the client in the event of the estimated price or number of hours being exceeded by a considerable amount, to allow the client to decide whether the task shall be modified or discontinued, cf. clauses 6.1 to 6.3.
- 5.3 The client undertakes to pay the fee charged by Presafe Denmark and originally agreed between the parties, even when the tasks performed result in an undesirable outcome from the point of view of the client.
- 5.4 Payment shall be effected within 30 days from the date of invoice. If the time of payment of the balance due to Presafe Denmark is exceeded, an interest of 1½% for each commenced month is charged, the interest being added to the amount including interest accrued at any time.
- 5.5 Presafe Denmark is entitled to request the client to provide a bank guarantee or a surety, or to request that the client makes a prepayment or pay a deposit, if necessary in the form of a cash payment or a bankers' draft, before the task is initiated.
- 5.6 Presafe Denmark is entitled to invoice on account or invoice part of the balance due at the end of each month.

6 Right to modify, cancel and discontinue tasks

- 6.1 The client is entitled to request the approval work to be discontinued or postponed at any time.
- 6.2 Where the client requires the work to be discontinued or postponed, he/she is obliged to pay Presafe Denmark any fee corresponding to the time consumed, costs and expenses incurred, as originally agreed. Furthermore, Presafe Denmark can claim compensation from the client for any documented additional costs incurred in connection with the cancellation.
- 6.3 Where a task is discontinued, or postponed by the client, Presafe Denmark cannot be held liable for any deficiencies or errors in connection with work already performed, nor may the names, trademarks or approval marks of Presafe Denmark be used in such way as to associate them with the products or systems subject to the task, cf. clause 9.
- 6.4 The client is entitled at any time to cancel current certification or approval or approval agreements made with Presafe Denmark, giving three months' notice in writing of cancellation. Presafe Denmark can claim full compensation from the client for any documented costs incurred in connection with his/her cancellation. Cancellation by Presafe Denmark shall be presented in writing giving at least six months' notice.
- 6.5 Presafe Denmark is entitled to discontinue on-going agreements for certification or surveillance audits with a notice of six months. In case of misconduct or a situation when the client does not fulfil his/her obligations, Presafe Denmark is entitled to terminate the cooperation with immediate effect.

7 Confidentiality and independence of staff

- 7.1 Presafe Denmark and its staff shall observe the deepest professional secrecy with regarding the tasks which are carried out. With regard to all information gained in performing their tasks, see also clauses 7.2 and 8.2.
- 7.2 By derogation from the professional secrecy obligation stipulated above, Presafe Denmark, and its personnel as required by law, can at any time disclose information required by the relevant administrative authorities in connection with certification or approval services. Presafe Denmark will inform the client about any disclosure of information required by relevant authorities unless prohibited by law – exempt hereof is information submitted to the competent authority/Accreditation organization(s).
- 7.3 The client can, by notice in writing, absolve Presafe Denmark from the secrecy obligation, if the client in cases of dispute or similar cases requests Presafe Denmark to make a public statement of or to disclose to a third-party information about the client.
- 7.4 The staff of Presafe Denmark is free from any commercial, financial and other pressures which might influence their judgement, and the staff shall not, within a three-year period prior to the assessment, have been involved in any consultancy, design or other preparatory services related to the task to be carried out.

8 Publication of results and documentation of tasks performed

- 8.1 Presafe Denmark undertakes to establish and maintain a publicly available list of certified products or systems, giving information on certificate holders and scopes of certification. Identical provisions apply to other approvals and licences.
- 8.2 Issued certificates or inspection reports and related annexes are the property of the paying client, see also clause 8.3, and a copy shall not be handed over to any third party without the written consent of the client. The documents may, however, without the consent of the client, be handed over to the authorities mentioned in clause 7.2 for the purpose of their supervision or accreditation.
- 8.3 Presafe Denmark can withdraw certificates or approvals in the event of the licensee no longer conforming to the conditions which apply to the maintenance of the certificate or approval, or in the event of misuse of the certificate or approval. Certificates and approvals may be withdrawn in the following specific cases:
 - a. where the client provides incomplete or incorrect information;
 - b. where non-compliance with relevant requirements is of a serious nature;

- c. where information on changes of control systems or other circumstances decisive for the issue of the certificate is withheld;
 - d. where there is a claim of validity not covered by the certificate;
 - e. in the event of bankruptcy, sale or any other form of winding up of the business of the client;
 - f. where any balance due to Presafe Denmark has not been paid;
 - g. where supplies or services covered by the certificate have not been provided for a long period of time;
 - h. in the event of misuse of the trade marks, approval marks or the name of Presafe Denmark.
- 8.4 When a certificate is withdrawn, suspended or cancelled, it shall be returned to Presafe Denmark upon request as soon as possible. Presafe Denmark has the right to make the withdrawal, suspension or cancellation public and to notify the relevant authorities. In such cases the client:
- shall refrain from promoting the certification
 - is not allowed to use the certification documents
 - undertakes to give primary clients written notification.
- 8.5 Certificates are not transferable.

9 Trade marks, approval marks, etc.

- 9.1 The holder of a certificate or an approval is entitled to use the Presafe Denmark trade mark and other approval marks for business purposes, if the marks can be directly associated with the management systems covered by the certificate. The Presafe Denmark logo shall not be used for marking of products, however it is accepted that the logo is used on product packaging when it relates to the management system only.
- 9.2 The holder of the certificates is not allowed to use the Presafe Denmark trade mark and other approval marks for laboratory test, calibration or inspection reports
- 9.3 Companies may not use the DANAK mark/logo.
- 9.4 The use of the Presafe Denmark trade mark and other approval marks shall be discontinued without delay if Presafe Denmark withdraws or suspend the certificate, the approval or if it is stopped for other reasons.
- 9.5 The trade mark and the approval marks shall not be used in places from which it cannot be removed in the event of the certification or approval being withdrawn (e.g. in telephone directories or the like).

10 Limitation of the responsibility of Presafe Denmark

- 10.1 Pursuant to the general provisions of indemnity in Danish law, Presafe Denmark shall only be liable for substantiated default and negligence on the part of Presafe Denmark, subject to the specifications or limitations set forth in clauses 10.2 to 10.17.
- 10.2 Subject to any rule of law which cannot be dispensed with, the liability of Presafe Denmark for personal injury or damage to things and/or property cannot exceed USD 200.000 per claim, unless otherwise agreed in writing at the time of conclusion of the contract, or if stipulated by the relevant authorities.
- 10.3 Presafe Denmark shall not be held liable for any damage resulting from products or systems of the client, or caused by the staff of the client, unless the defect or deficiency originate in the tasks carried out by Presafe Denmark, and in this case the financial limitation specified above shall apply.
- 10.4 Presafe Denmark disclaims all responsibility for any consequential loss, loss of profit, loss of time or any other indirect loss.
- 10.5 Presafe Denmark disclaims all responsibility for actions or omissions on the part of other parties. Presafe Denmark cannot be held liable, neither wholly nor in part, for delays, omissions or loss due to circumstances which can be ascribed to the client - e.g. deficient finishing of products or systems, deficient preparation, suspension of operation, lack of attendance on the client's part, missing documentation, incomplete, misleading or incorrect information, failure to reply to requests etc. from Presafe Denmark, Circumstances at Presafe Denmark subcontractors' which Presafe Denmark has not or could not have been able to anticipate are force majeure, cf. clause 10.6nd, consequently, exempt from liability. Correspondingly, Presafe Denmark shall not be held liable if any third party fails to recognize or only recognizes in part the certificates issued by Presafe Denmark.

- 10.6 Presafe Denmark shall not be held liable for delays or loss owing to the weather, strikes, catastrophes of nature, fire or other force majeure circumstances.
- 10.7 Any deficiency resulting from services provided by any other party and having a bearing on the certification or the approval is no concern of PresafeDenmark's.
- 10.8 The liability of Presafe Denmark is conditional on the client lodging his/her complaint in writing as soon as the client becomes or should have become aware of errors and deficiencies in the services provided by Presafe Denmark.
- 10.9 In the event of Presafe Denmark being held liable by a third party for circumstances for which the liability of Presafe Denmark in relation to the client is restricted, cf. clauses 10.2 to 10.17, the client shall indemnify Presafe Denmark, including indemnification in full for legal costs.
- 10.10 Presafe Denmark is responsible for samples, materials, prototypes etc. received only if an agreement has been made for their storage and/or return. The liability of Presafe Denmark is limited to an amount corresponding to the value of the samples, materials, prototypes etc. received or as indicated in 10.2 whichever is the less. A requirement for storage will apply only for a six-month period, unless otherwise agreed.
- 10.11 In addition to these present terms and conditions, the provisions of DANAK applicable at any time shall apply as regards the placing of the liability for the accredited technical test or calibration subcontracted to a third party by Presafe Denmark, as considered necessary, for the purpose of certification or approval tasks.
- 10.12 Presafe Denmark cannot be held liable for any direct or indirect loss suffered by the client (e.g. termination of certification or approval) as a result of Presafe Denmark's notification and/or accreditation being withdrawn, Presafe Denmark ceasing the operation as a notified and/or accredited body or due to changes in regulatory requirements.
- 10.13 Tasks shall be performed as commissioned by the client and on the basis of the knowledge and facilities available to Presafe Denmark at the time of the performance of the task. Presafe Denmark shall not be liable where subsequent development proves that the knowledge and facilities of Presafe Denmark are inadequate or incorrect.
- 10.14 Presafe Denmark shall not be liable for any damage or loss for which claims have not been made within three years after the performance of the task.
- 10.15 Presafe Denmark shall not be liable for any damage or loss resulting from the use of statements in documents indicating that the statements are based on an estimate.
- 10.16 The limitations specified in clauses 10.2 to 10.17 shall not apply in the event of gross negligence or intent on the part of Presafe Denmark or any employee of Presafe Denmark.
- 10.17 Presafe Denmark shall not be liable for any loss of certification or market access (include withdrawal of products from the market) due to
- a. changes in the Competent Authority's interpretation of the Directive.
 - b. The enforcement of own areas of responsibility by the Competent Authority

11 Reporting obligation

- 11.1 Specific provisions concerning the obligation to submit reports may oblige the client to inform Presafe Denmark of deviations from or changes of the quality, or other properties, of the item being certified or approved.

12 Subcontractors

- 12.1 Presafe Denmark is entitled to subcontract the whole task or part of the task on Presafe Denmark's own responsibility. The subcontractor is, however, required to have obtained the appropriate accreditation, and in all respects the subcontractor is subject, by contract, to the conditions applying to Presafe Denmark.

13 Provisions for complaints and appeals

- 13.1 Complaints shall be presented in writing to Presafe Denmark at the latest four weeks after the cause of the complaint has been ascertained "**Contact details** below". As a general rule complaints against Presafe Denmark are handled internally. Where the client cannot agree to the result of the consideration of the complaint the case or incident may be lodged as an appeal. An appeal shall be lodged to Presafe Denmark no later than 20 days after receipt of the consideration of the complaint. Appeals are considered by the Presafe Denmark Expert Committee. In the event of a dispute between the client and Presafe Denmark as a result of the application of the product classification rules, the matter will be brought before the Danish Medicines Authority for final decision. Upon request, clients will receive a copy of Presafe Denmark's procedure for dealing with complaints and/or appeals.
- 13.2 The client has the right to appeal the decisions of the Presafe Denmark expert committee to the Danish competent authority.
- 13.3 Where Presafe Denmark considers the complaint and/or appeal to be unjustified, the complainant shall pay all costs incurred by Presafe Denmark in connection with the consideration of the complaint/appeal and resumption of the task. This cost includes costs for consultations with relevant authorities.
- 13.4 Appeals against decisions made by Presafe Denmark regarding complaints shall be submitted for legal decision, the Sø- og Handelsretten (the Maritime and Commercial Court) serving as the independent court of appeal.

Contact details:

- Address: Tuborg Parkvej 8, DK-2900 Hellerup, Denmark
- Phone: +45 3945 4999
- E-mail: presafedk@presafe.com

14 Disputes

- 14.1 Disputes shall be subject to Danish law. The venue shall be the Sø- og Handelsretten (the Maritime and Commercial Court of Copenhagen, Denmark).