**Application for certification in accordance with:**

* **Medical Device Directive (Council Directive 93/42/EEC, as amended)**
* **In Vitro Diagnostic Device Directive (Council Directive 98/79/EC, as amended)**
* **Quality system standard(s)**

***Guidance on the use of this application form:***

* ***Use the TAB keys to jump between the typing fields.***
* ***Help topics are associated with most of the fields. When the field is selected double click and help information is shown.***
* ***Please fill in all relevant sections before signing and returning.***

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| --- | --- | --- | --- |
| 1. **Company Information** | | | |
| Company name: |  | Phone: |  |
| Legal address (Street & No.): |  | Fax |  |
| Postal code & Town/City |  | PO Box No.: |  |
| Region/state: |  | Homepage: | www. |
| Country: |  | E-mail: |  |
| Managing Director: |  | E-mail: |  |
| Contact person: |  | CVR/VAT No.: |  |
| Date: | YYYY-MM-DD | Quote No.: | *To be filled in by Presafe Denmark* |

***Please complete the B section(s) relevant for your application:***

***B1) for MDD certification***

***B2) for IVD certification***

***B3) for Quality Management system certification***

| **B1) MDD**  ***The Medical Device Directive (Council Directive 93/42/EEC, as amended)***  ***Danish Statutory Order No. 1263 of 15. December 2008*** | |
| --- | --- |
| ***Conformity assessment route applied for*** | |
|  | Annex II Full Quality Assurance |
|  | Annex II section 4 Design Examination |
|  | Annex V Production Quality Assurance |
|  | Annex VI Product Quality Assurance |

| B2) IVD  ***The In Vitro Diagnostic Device Directive (Council Directive 98/79/EC, as amended)***  ***Danish Statutory Order No. 1269 of 12. December 2005*** | |
| --- | --- |
| ***Conformity assessment route applied for*** | |
|  | Annex IV Full Quality Assurance |
|  | Annex IV section 4 Design Examination |
|  | Annex V EC Type Examination |
|  | Annex VII Production Quality Assurance |
|  | Annex III section 6 EC Design Examination (for self-test devices) |

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| B3) Quality Management System Standards | |
| ***Quality Management System Certification applied for*** | |
|  | EN ISO 13485:2012 |
|  | EN ISO 9001:2008 |
|  | ISO 13485:2003 |
|  | DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016 |

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| **C) Additional Information**  ***Changes to already submitted information or additional information needed to evaluate the certification scope. E.g. :***   * ***company information including the address(es) of site(s)*** * ***processes and operations performed*** * ***human and technical resources, functions relationships and any relevant legal obligations.*** * ***outsourced process/devices*** ***that will affect conformity to requirements;*** * ***types of devices***   ***Please specify below:*** |
| **Specify:** |
| *IMPORTANT!*  *If the MDD/IVD questionnaire has not been forwarded prior to submission of this application, please enclose information about company, site(s) and device(s) (equivalent to the information requested in the MDD/IVD questionnaire) with this application.*  *Please bear in mind that your application for certification cannot be processed without submitting the information as requested in the IVD/MDD questionnaire.* |

***The following documentation is requested enclosed with this application:***

* Copy of articles of association/Certificate of incorporation.
* Any certificates from the manufacturer and/or companies/sites related to the products to be certified.

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| 1. **Signatures:** | | | |
| Applicant  ***CEO or equivalent is to sign the application*** | | Presafe Denmark A/S | |
|  |  | *Hellerup* | *201* |
| *Place* | *Date* | *Place* | *Date* |
|  | |  | |
| ***Signature*** *and printed name* | | ***Signature*** *and printed name* | |

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| **General conditions with respect to this application** |
| The applicant has acquainted himself with the “General terms and conditions” for the operation of Presafe Denmark A/S and agrees to comply with these rules and, unless other agreements have been made, to pay all fees/rates specified in the quote or according to Presafe Denmark A/S’ valid Pricelist as relevant. After Presafe Denmark A/S’ approval of this application the applicant will receive a signed copy with information about the schedule for the approval and checklists for the conformity assessment.  Presafe Denmark A/S reserves the right to cancel this agreement in case insufficient or incorrect information has been given. The applicant hereby declares:   * To inform Presafe Denmark A/S of any significant change made to the approved product and the approved quality system. * To keep the approved quality management system adequate and effective *(only relevant for MDD/IVD quality system certification).* |

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| **General conditions with respect to application for CE marking according to the MDD/IVD and quality management system certification** |
| The applicant hereby declares as relevant:   * That no application has been lodged with any other notified body than Presafe Denmark A/S for the same product-related quality system and/or the same type(s)/product(s) as covered by this application. * To fulfill all the obligations imposed by the IVD and/or the MDD with respect to the quality system/devices approved (as covered by this application). * That no application for certification to EN ISO 9001 and/or EN ISO 13485 has been lodged with any other registrar and that any present ISO 9001/13485 certification agreements with other registrars are to be cancelled. * To institute and keep up-to-date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in MDD, Annex X, and to implement appropriate means to apply any necessary corrective action. * To accept the obligation to notify the competent authorities and Presafe Denmark A/S of the following incidents immediately on learning of them:   + Any malfunction or deterioration in the characteristics or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;   + Any technical or medical reason connected with the characteristics or performance of a device leading to the reason referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.   + To have taken all the measures necessary to ensure that the manufacturing process produces products, that conform to the type described in the EC Type-Examination certificate and to the requirements of the Directive, which apply to them (IVD Annex VI). Before start of manufacture the applicant / manufacture~~r~~ must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC Type-Examination certificate and with the requirements of this Directive which apply to them. (IVD Annex VI). * To ensure that Presafe Denmark A/S has access to audit any critical subcontractors and/or suppliers *(only relevant for MDD/IVD quality system certification).* * To include all documentation needed to assess the conformity of the representative sample of the production in question with the requirements of this Directive. The applicant must make a “type” available to Presafe Denmark A/S (MDD Annex III, IVD Annex V). |

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

# 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 on the basis of a written agree­ment or, in the case of certification and ap­proval tasks, on the basis of an application lodged with Presafe Denmark. Presafe Denmark carries out the task on the basis of 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 regard to 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 with regard to 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 two-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 10.6, and, 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 Presafe Denmark’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. 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.

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).