**The Certification Process in Presafe Denmark A/S**

Presafe Denmark A/S is a provider of certification services for the medical device industry.

Presafe Denmark A/S offers certification according to:

* The Medical Device Directive (MDD) and the In Vitro Diagnostic Directive (IVD)
* (EN) ISO 13485 and (EN) ISO 9001:2008

Furthermore, Presafe Denmark A/S offers the following services:

* ISO 13485 audits under CMDCAS, the CMDCAS audits are carried out on behalf of SAI Global ltd. a SCC recognised registrar[[1]](#footnote-1).
* Audits according to the Taiwanese requirements. The registration process of your product(s) in Taiwan is eased[[2]](#footnote-2) by having Presafe Denmark A/S carry out audits incl. the Taiwanese requirements.

# How to obtain MDD, IVDD, ISO 13485 and/or ISO 9001 certification

The process involved in obtaining certification varies according to your requested certification type.

The certification process for MDD, IVD directive, ISO 13485 and/or ISO 9001 certifications is described below in the section *System Certification Process*.

For IVD and MDD certifications, the requirements given in “product approval” apply as well.

# System Certification Process

The certification cycle for quality management system certifications(E.g. ISO 13485, 9001) is three years, MDD/IVD certifications has a certification cycle of 5 year, but the audit cycle follows that of quality management system certifications(E.g. ISO 13485, 9001)

You start with the certification phase followed by 2 years of annual surveillance audits.

A recertification audit is required to take place at the latest 3 years after the certification audit. The re-certification audit initiates a new 3year cycle and is followed by 2 years of annual surveillance audits.

Subsequent cycles follow the same model, i.e. a recertification initiates the cycle and is followed by 2 of annual surveillance audits.

## Certification

The certification consists of 3 phases:

### *Pre-assessment of your quality management system*

This assessment is carried out at Presafe Denmark A/S or at your facility.

Presafe Denmark A/S evaluates your implemented quality system against the requirements and your product information (your technical file/s or design dossiers) before an audit can take place[[3]](#footnote-3).

### The result of the pre-assessment, including any existing or potential non-compliance, is reported to you in a pre-assessment report. Depending on the severity and number of (potential) non-compliances, we determine if we need to have documentation for the correction of the problems identified prior to performing the stage 1 audit[[4]](#footnote-4).

### *Evaluation, is your company ready for a certification audit?*

When the pre-assessment report recommends that a stage 1 audit can take place we visit your facility in order to verify that the system is in place and to ensure that we allocate the right resources for the upcoming audit. Included in this is evaluation of the need for Presafe Denmark A/S, to audit any significant suppliers or subcontractors.

A successful stage 1 audit recommends that the stage 2 (the certification audit) may take place.

### *Certification audit*

The certification audit is the actual audit on site; based on an audit program sent to you well in advance of the audit, we carry out a full audit of your quality management system and your products to verify that you comply with the requirements.

During the audit we will compile objective evidence of your compliance by interviewing personnel, look at procedures, products and the general implementation of the quality system etc.

In case of significant outsourced processes or significant supplier, where Presafe Denmark A/S has identified a need for auditing them, this will be conducted.

Based on the objective evidence compiled we will make our conclusions, as to which parts of the quality system/products that are in compliance and which are not. The result of the audit is reported to you at the closing meeting, including any non-conformities. An audit report summarizing the audit is sent to you after the audit.

Non-conformities represent areas which must be addressed by you to ensure compliance. Evidence that you are in compliance must be documented, submitted to and accepted by our auditor. If some of the issued non-conformities are serious or many non-conformities have been issued, we reserve the right to carry out an on-site follow-up of the closing of the nonconformities.

After the audit and the closing of the nonconformities, should any have been identified, a final review of the audit documentation is made (“verification”). After this verification has taken place your certificate is issued and sent to you.

### *Surveillance audits*

In order for you to maintain your certification, Presafe Denmark A/S has to verify your company’s continued compliance with the requirements. This verification is usually carried out annually for 2 years, in the form of surveillance audits.

Surveillance audits are conducted according to the audit program sent to you prior to the audit, and the audit typically covers certain areas of the quality system and/or your products. Please note that the duration of a surveillance audit is shorter than the certification audit.

As with the certification audit, the result of your audit (incl. non-conformities, should there be any) is reported to you at the closing meeting, and the audit report is sent to you subsequent to the audit.

Once the audit is finalized, any nonconformities have been closed, and the closure is accepted by Presafe Denmark A/S, we confirm the continued validity of your certification. If some of the issued non-conformities are serious or many non-conformities have been issued we reserve the right to carry out an on-site follow-up of the closing of the nonconformities.

Presafe Denmark A/S also offers you the possibility of having surveillance audits performed every 6 months which may be relevant for a “young” quality system, if your company is undergoing changes or perhaps just because you want to maintain focus on the system[[5]](#footnote-5).

### *Recertification audit*

Every third year the surveillance audit is replaced by a recertification audit. The recertification is, as the certification phase, however, less time consuming than those of the certification audit.

Step one of the recertification is a renewed pre-assessment of the quality manual, this step may be waivered if Lead Auditor deems a renewed pre-assessment redundant.

If step one is carried out, an evaluation of your quality system documentation, and once again the evaluation is reported to you in a pre-assessment report sent to you prior to the audit. The pre-assessment is performed in order to document that the changes made since the certification has not impacted your quality system in such a way that it is no longer compliant with the requirements. It also ensures that the system is up to date with the interpretation of the regulatory setting.

Should Presafe Denmark A/S find any issues during the pre-assessment, these shall be solved and the evidence documented to Presafe Denmark A/S at the latest at the opening meeting of the recertification audit. In certain cases Presafe Denmark A/S may require that these issues are documented closed to Presafe Denmark A/S prior to the recertification audit and/or require a visit to your facility (please see “Evaluation, is your company ready for a certification audit?”)

Step two is the recertification itself. The audit and the subsequent activities (please see “Certification Audit“) are carried out like the certification audit, and subsequent to the independent review your certificate is reissued.

### *Recertification (MDD and IVDD)*

The MDD/IVDD recertification requires that the product approval processes described in a later section has been finalized and that the audit processes and cycles for Quality system certification are followed. Recertification (MDD and IVDD) are conducted every 5 year (which also is validity period for CE certificates)

# Product Approval

Products approvals require certification of the quality system manufacturing the devices, why the requirements given in *system certification process* applies in addition to the approval of the devices.

As a designated notified body Presafe Denmark A/S also carries out technical file assessments, design and type examinations of medical and in vitro diagnostic devices according to the MDD and IVDD respectively[[6]](#footnote-6).

Devices must be approved and the approval type depends on the risk class of the device as well as the quality system approval (annex of the MDD/IVDD).

For High Risk devices, and in certain cases for lower risk of devices, a design or type examination is required. For lower risk devices a representative sample of the technical files for the devices to be covered by the certification are subject to technical file assessment.

In all cases the product approval must be finalized before a certification audit may take place, as the purpose of the audit, in relation to CE certification, is to ensure the capability of the system to manufacture devices which are identical to the approved products.

***Type or design examination***

The certification of a product is based on an evaluation and acceptance of the design dossier/technical file of your product(s).

Presafe Denmark A/S evaluates the design dossier/technical file and reports the result to the company. If observations are issued compliance cannot be established based on the submitted design dossier/technical file. These observations represent non-conformities which are to be addressed in order to establish compliance with the requirements and Presafe Denmark A/S has to verify this compliance. Please note that some high risk devices require involvement by a competent authority or EMA e.g. medicinal substance, human blood derivative.

The type or design examination certificate of the device is issued at the same time as the certificate for the quality system and has a validity of 5 years. If the certification is to be extended, the design dossier/technical file, and/or any changes to it, has to be re-evaluated.

***Technical file assessment.***

Representative technical files for MDD class IIb devices covered by an annex II certificate and all class IIa devices are evaluated for compliance to the requirements, The Number of devices and their categories (GMDN code categories for IIb devices; MD categories for Class IIa devices) determines the number and type of technical file to be assessed

If, during the assessment, lack of compliance is identified nonconformities or observations are issued. These are to be addressed in order to establish compliance with the requirements and Presafe Denmark A/S has to verify this compliance. Nonconformities need to be closed before certification, whereas observations have to be addressed before the next surveillance audit.

During subsequent audits Presafe Denmark A/S will perform further technical file assessments according to a sample plan established by Presafe Denmark A/S. The sample plan is specific to each manufacturer and the number and types of technical files to be assessed depend on the Number of devices and their categories (GMDN code categories for IIb devices; MD categories for Class IIa devices

# Changes to the Certification

No system remains the same forever and changes of a significant nature are often implemented to a company’s quality system, the company itself or its products, e.g.: New quality system, extended scope of the services provided by your company, outsourcing/change of processes, new or changed products etc. Any such changes must be reported to Presafe Denmark A/S. We then evaluate the changes and conduct the activities needed for us to maintain the certification. The coverage of the activities depends on the nature of the change; these can range from a simple acceptance from us to an extra audit or a full technical file assessment. Depending on the nature of the change and the certification issued, it may or may not be acceptable to conduct the change prior to our acceptance.

Likewise, Presafe Denmark A/S may need to change the certification or conduct additional activities. This typically occurs if there are changes to the regulatory requirements or the standards.

# Cancellation, Suspension and Withdrawal of Certificates

As the certifications by Presafe Denmark A/S document the compliance of companies or products, Presafe Denmark A/S has the ability to withdraw a company’s certificate if the company or the product(s) no longer comply with the requirements.

In most cases Presafe Denmark A/S and the company agree on an action plan for resolving any non-compliance/nonconformities, however, if Presafe Denmark A/S and the company cannot come to an agreement or if the non-compliance(s) is of a significant nature, Presafe Denmark A/S may be forced to withdraw the certification. Should the company request certification again, it is normally required that the certification cycle starts over.

The customer can cancel the certification agreement with Presafe Denmark A/S and/or any certifications provided that a reasonable notice (3 months) is given. Presafe Denmark A/S also has the right to cancel the certification agreement with a company – again provided that a reasonable notice (6 months) is given. Should the company request certification again, it is required that the certification cycle starts over i.e. starting at the certification phase.

As a customer in Presafe Denmark A/S you also have the right to suspend a certification for up to 3 months. This option allows you to put the certification on hold, without having to start the certification cycle all over.

Once a certificate is withdrawn, the certification terminated or the certification suspended the company must refrain from using the certificates and from promoting the certification.

# Quotes and Applications

## Quotes

At your request Presafe Denmark A/S provides a quote for your chosen certification.

In order for Presafe Denmark A/S to issue a quote for your company, we ask you to fill in and submit the Presafe Denmark A/S questionnaire, which you can download from Presafe Denmark A/S’s websites: [www.presafe.dk](http://www.presafe.dk)

## Applications

Once you have selected Presafe Denmark A/S as your registrar/notified body, you submit a signed application form (which you have received with your quote for certification) and the documentation requested in this form.

Presafe Denmark A/S then reviews your application and upon approval of the application we will send you a signed contract accompanied by an order confirmation with information regarding where on our website you can find various documentation and templates that will assist you in the certification process and which Lead Auditor is to be your future point of contact to Presafe Denmark A/S.

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1. The processes explained here cover the most common conformity assessment routes to obtain CE marking of medical or in vitro diagnostic devices. Alternative routes (may) exist depending on class of the device in question. Please contact Presafe Denmark A/S for further information. [↑](#footnote-ref-1)
2. The processes explained in this document do not apply to audits according to the Taiwanese requirements, please contact Presafe Denmark A/S for information. The audit of manufacturers to Taiwanese requirements can only be used for devices manufactured in EU. [↑](#footnote-ref-2)
3. For further information about product approval please see section ”Product Approval” on page 4. [↑](#footnote-ref-3)
4. For further information about product approval please see section *Product Approval* on page 4. [↑](#footnote-ref-4)
5. Please note that two annual audits will not double the cost for the audit as the nominated audit time per year is split in two and only the travel expenses for the auditor will increase. [↑](#footnote-ref-5)
6. Please note that design and/or type examinations are not an option for all classes of devices. [↑](#footnote-ref-6)