**USE OF CE MARK, PRESAFE LOGO AND CERTIFICATES**

This document provides information and requirements in relation to the use of certificates, PRESAFE DENMARK logos, CE mark and conformity declarations. The requirements apply beyond and above the requirements given in “General Terms and Conditions for the Operation of Presafe Denmark A/S”.

**CE certificates and ISO 9001/13485 certificates.**

Certificates issued by Presafe Denmark are controlled documents, why the following rules apply:

* Photocopies of your certificate may be made.
* Obsolete versions of the certificate shall be marked “invalid”, “obsolete” or it shall through similar identification be obvious that the certificate is no longer valid.

The above requirements also apply to electronic versions.

If you need additional copies of your certificate, at request Presafe Denmark can provide controlled copies.

**CE Mark:**

* The CE mark shall be used as per the requirements of the relevant directive i.e. on the device/ packaging as well as the IFU.
* Specific requirements for size etc. are given in the relevant directive.
* For devices covered by Presafe Denmark CE certificates the CE mark shall be accompanied by the Notified body ID number of Presafe Denmark A/S, 0543. The height of the digits in the NB number shall be at least 1/3 of and not larger than the height of the letters in the CE mark and the NB number it is to be placed after the CE mark (horizontally or vertically) or below the CE mark.
* The CE mark may be used in marketing material provided that it is directly associated with the CE marked products. There shall be no doubt as to which product is CE marked. Also the CE mark with the notified body ID shall not be placed in such a way that it could be interpreted as applying to class I devices that are neither sterile nor have a measuring function.

**Reference to certification/registration statements:**

Certified companies may claim being certified, however the following rules apply.

* Reference to certification shall always be associated with the standard(s) (or directive and annex/es) your company/product has been certified to.
* Specific for ISO certifications:
	+ References shall not be misleading, shall reflect the certification as well as any limitations in the certification. (e.g. if not all processes are covered by the certification)
	+ If not all parts or sites of your organization are certified, or if not all services or activities provided are covered, the reference shall reflect this.
	+ References shall not state, indicate or give the impression that the products, processes or services are certified.
	+ References are not allowed to be used on products, product packaging or in any other way that can be interpreted as denoting product conformity.
	+ A statement on the product packaging or in the accompanying information that the certified client has a certified management system is accepted.( NB Type labels or identification plates are considered as part of the product)

The statement shall in no way imply that the product, process or service is certified by this means.

The statement shall include reference to identification (e.g. brand or name) of the certified client, and the type of management system (e.g. quality, environment)

* Specific for certification according to the MDD directive or to the IVDD directive:
	+ Reference to being CE certified is only allowed for legal manufacturers of the devices
	+ Any reference to being MDD or IVDD certified shall be specific to the products covered by the MDD/IVDD certification if not all devices manufactured is covered.

**Presafe logo**

* The Presafe logo should be reproduced in black and white or in the original colors of the logo.
* The Presafe logo may be used in marketing material, including letterheads, provided that it is used together with a reference to compliance, as given above
* The Presafe logo shall only be used in association with certifications provided by Presafe Denmark A/S
* The Presafe logo shall not be used on a product or product packaging provided to or shown to actual or potential customers or in any other way that could be interpreted as denoting product certification.
* The Logo may not be applied to laboratory test, calibration or inspection reports or certificates.

**DANAK Logo.**

The DANAK logo shall not be used.