Sterility Assurance Limited

Policy on Use of Certification Claims

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Document Approval			
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1. Rules on Use of Certification Marks and/or Claims

1.1. ISO 13485 Certification Marks and/or Claims

a) SAL clients with a current, valid ISO 13485 certificate may display the certification logo detailed in clause 4.1, below, and/or make claims about being ISO13485 "certified" or "registered". Such logo use and/or certification claim may be made by the client on any their marketing literature or company stationary (e.g., letter headed paper, business cards, compliments slips, company vehicles, website, social media pages…etc.).

b) Please note that SAL do not offer accreditation, so clients should not make any such claim of being accredited to ISO13485 – see here for more information: Accreditation vs Certification: What's the difference? | UKAS)

c) The logo and/or certification claim referred to in clause 1.1a), above, shall not be displayed on any of the client's product, product packaging, labelling or instructions for use, as this would give the incorrect impression that the product itself is certified by SAL to ISO 13485.

d) Accompanying literature relating to a specific product or group of products (e.g., technical data sheet, product specification) may refer to the fact that the client's organisation is certified to ISO 13485, so long as this is displayed in an unambiguous way that does not in any way imply that the product, process or service itself is certified. Some examples of acceptable phrases are provided below:

- "[The products] are manufactured by an ISO 13485 certified quality management system."
- "[Organization name] maintain an ISO 13485 certified quality management system."
- "[Organization name] are certified to ISO 13485 [by SAL / Sterility Assurance Limited] for the manufacture of [these products]."

e) If the client's ISO13485 certificate bears the UKAS Tick & Crown logo (adjacent to the SAL logo in the bottom right of the certificate), then the client may additionally display the UKAS Tick & Crown logo. The UKAS logo, if used, should be displayed at the same proportion as the SAL logo. Typically, a minimum height of 20mm is required, unless the client can justify the reasons for it being smaller yet still understood by any external parties. The UKAS logo can only be used in conjunction with the SAL ISO13485 logo and should never be used alone.

1.2. UK Medical Devices Regulation Certification Marks and/or Claims

a) UK Medical Devices Regulation 2002, as amended ("UKMDR") refers to the use of UKCA marking as the certification mark. However, SAL is intending to maintain a restricted scope of designation by only offering certification to Regulation 14 of UKMDR which explicitly state that no person shall affix the UKCA mark that has followed this conformity assessment procedure. Therefore, no UKCA mark may be applied by any SAL client anywhere on any product, packaging, labelling, accompanying information or any other marketing or promotional materials.

b) Clients with a current valid UKMDR certificate may make certification claims on any their marketing literature or company stationary (e.g., letter headed paper, business cards, compliments slips, company vehicles, website, social media pages…etc.). Such claims may also be made on the packaging/labelling accompanying the system or procedure pack, if space permits. However, the claims shall be limited to the scope of certification, i.e., to the aspects

of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged and should not imply that the company as a whole is certified, only the processes that are used to produce the certified products. Some examples of acceptable phrases are provided below:

- [Organization name] are certified [by SAL / Sterility Assurance Limited] to annex [II or V] of UK Medical Device Regulation 2002, as amended, for [procedure pack details]. Certification is limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged."
- [Procedure pack details] are manufactured in accordance with Regulation 14 of the UK Medical Device Regulations 2002, as amended. The aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged are certified in accordance with annex [II or V] of this regulation [by SAL / Sterility Assurance Limited].

2. Client Obligations

By signing the SAL proposal form, the client formally agrees to comply with the following requirements:

a) The client will conform to the rules outlined above in clause 1 for the use of certification marks and/or claims.

b) The client will not make or permit any misleading statements to be made regarding its certification. This includes, but is not limited to, claims that its ISO13485 management system certification implies that the products/services/processes are certified, or that activities outside the scope of certification are in fact certified.

c) The client will not use or permit the use of a certification document / certificate, or any part thereof, in a misleading manner. This includes any such use that would bring SAL and/or the certification system operated by SAL into disrepute and lose public trust.

d) The client will discontinue the use of all materials that contain certification marks and/or claims within a maximum of 10 working days from the date of suspension or withdrawal of certification (see POL-02 for more details). Likewise, if the scope of certification is reduced rather than suspended or withdrawn, certification marks and/or claims shall be updated within the same timeframe.

e) The client will maintain records of any detected non-compliance with the above requirements and undertake appropriate corrections and corrective actions without undue delay.

3. SAL Processes for Ensuring Compliance with This Policy

SAL auditors will be required to check for compliance with this policy at every scheduled client audit (see POL-02 for more details).

SAL will act in accordance with POL-03 whenever a complaint is received by any interested third parties about misuse or misleading use of certification marks and/or claims by SAL clients, which will

include notification to the client to request immediate corrections and corrective actions. Where action is not forthcoming or not sufficient, certification may be suspended or withdrawn in accordance with policy POL-02. In the case of persistent misuse or misleading use of certification marks and/or claims, SAL reserve the right to take legal action against such clients.

SAL will likewise take appropriate legal action against any party not under contract with SAL that has been shown to SAL as making claims of certification by SAL.

SAL will also provide information to any interested party about the validity of any certificate claimed to be issued by SAL – refer to POL-03 for more information.

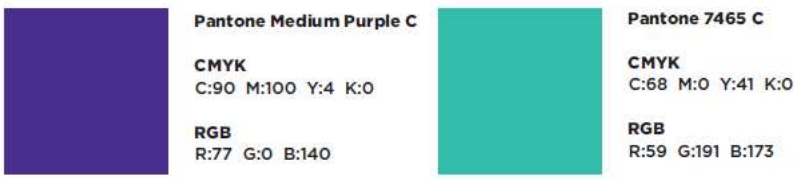
4. Certification Logo Specifications

4.1. ISO 13485

Our "ISO 13485 certified" is available in 3 colour schemes at the client's preference, as can be seen below:

These logos can be presented to clients in .jpeg, .pdf or .png format at the client's request. Font files can also be presented (the fonts used are "Gotham Black" and "Gotham Medium"). Certificate numbers may also be applied below the certification logo at the client's preference.

When printing these logos, please ensure the following colour specifications are used:



If SAL update these logos, then the issue date will correspond with the issue date of this policy (as can be seen in the header). The updated policy will be communicated will all clients with whom an active contract is in place and the client shall be given a maximum period of 12 months from the date of issue to update their documents and articles containing these logos.

Details on use of UKAS logos can be found here:
https://www.gov.uk/government/publications/national-accreditation-logo-and-symbols-conditions-for-use
Please note that the appropriate symbol to accompany the SAL "ISO 13485 certified" logo is the "Management Systems" logo.

4.2. UK Medical Devices Regulation

As detailed in 1.2, there is no approved certification logo for UK Medical Devices Regulation certification offered by SAL. Any such attempt to create a logo, or misuse the UKCA mark, will be construed as a breach of the rules outlined above in clause 2, and will be acted upon by SAL as detailed in clause 3, above.