

Technical File

TECHNICAL FILE FOR MICROBIOLOGICAL SAFETY CABINETS

The technical file for each type of microbiological safety cabinet (MSC) shall consist of the following:

B.1 Application form

Application form for a Sales Permit.

Note: The applicant shall be the manufacturer or importer of the type of MSC. The manufacturer or importer shall be established within the Republic of South Africa.

B.2 Technical specifications

A technical description supported by technical drawings of the type of MSC, indicating the following as a minimum:

- a) All component parts.
- b) Description of each component part.
- c) Material(s) used in each component part.
- d) Electrical wiring diagrams.
- e) Methods of assembly.
- f) Marking of the type of MSC as required by paragraph 8 of SANS 12469:2002.
- g) Classification of the MSC as required by paragraph 6.1 of SANS 12469:2002.

Note 1: The technical drawings shall be to scale.

Note 2: Photographic evidence may be included in the technical file in order to support the technical specifications.

B.3 Information for users

A written manual that details the operating procedures for the type of MSC as required by paragraph 9 of SANS 12469:2002.

B.4 Proof of compliance

Test report(s) demonstrating compliance with all relevant requirements of SANS 12469:2002, ensuring that all component parts have been covered.

Note 1: Only test reports from a testing authority that has been accredited in accordance with SANS 17025 by a signatory to the International Laboratory Accreditation Co-Operation's Mutual Recognition Agreement shall be acceptable. No approval certificates shall be accepted.

Note 2: Test reports shall satisfy the requirements of the latest edition of SANS 17025.

B.5 Other

Any other materials that the applicant may wish to include in the technical file in order to support the application for a Sales Permit for the type of MSC, e.g. marketing materials and photographs.
