

Specification for

Paper bags for steam sterilization for medical use

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Packaging and Freight Containers Standards Policy Committee (PKM/-) to Technical Committee PKM/566, upon which the following bodies were represented:

- British Aluminium Foil Rollers' Association
- British Paper and Board Industry Federation
- Department of Health and Social Security
- Institute of Sterile Services Management
- Medical Sterile Products Association
- Ministry of Defence
- Packaging and Industrial Films Association
- Pira (Research Association for the Paper and Board, Printing and Packaging Industries)
- Pharmaceutical Society of Great Britain
- Retail Bag Manufacturers Association
- Sterilisation Packaging Materials Association
- United Kingdom Sugar Industry Association

This British Standard, having been prepared under the direction of the Packaging and Freight Containers Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 30 March 1990

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Foreword

This revision of BS 6257 has been prepared under the direction of the Packaging and Freight Container Standards Policy Committee, at the request of the Sterilization Packaging Materials Association. It supersedes BS 6257:1982 which is withdrawn.

The principal changes from the previous edition are as follows:

- a) the standard includes gusseted and non-gusseted bags;
- b) dimensional tolerances are consistent irrespective of the bag size;
- c) a greater latitude is allowed in positioning the heat-seal strip closure;
- d) for lipped bags, the lip depth is specified;
- e) the colour change for the steam sterilization indicator is now a requirement;
- f) changes to the marking requirements.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This British Standard specifies requirements for materials, construction, performance, packaging and marking for single web, paper sterilization bags for steam sterilized dressings, instruments, or other items of medical equipment.

Non-heat-seal closure and heat-seal closure bags are covered by the standard.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Materials

The bags shall be manufactured from paper complying with BS 6256.

Only materials recognized by the appropriate authority¹⁾ as non toxic shall be used in the manufacture of the bags.

3 Construction and design

3.1 Construction

The bags shall be manufactured from single web paper.

3.2 Design

Bags shall be of the following designs:

- a) unlippped, plain top with thumb cut (see Figure 1);
- b) unlippped, heat seal closure with thumb cut (see Figure 2);
- c) lippped, plain top (see Figure 3);
- d) lippped, heat seal closure (see Figure 4);
- e) gusseted or non-gusseted.

NOTE "Plain top" in this context means non-heat-seal closure.

3.3 Bottom seal formation

The bottom seal formation shall be one of the following types:

- a) double folded with each fold bonded with a suitable non-corrosive adhesive;
- b) sealed across the entire width of the bottom of the bag by means of a heat-seal or other suitable non-corrosive adhesive bond, not less than 6.5 mm in depth;
- c) sealed across the entire width of the bottom of the bag by means of a heat-seal or other suitable non-corrosive adhesive bond, and then folded once or more, each fold being bonded with a suitable non-corrosive adhesive or heat-sealed.

3.4 Back seam

The seam shall be made at the back with a double line of water resistant non-corrosive adhesive.

4 Dimensions and tolerances

4.1 Dimensions

For ordering and package marking purposes dimensions shall be quoted in the following order:

- a) gusseted bags: width, gusset, length;
- b) non-gusseted bags: width, length.

NOTE 1 The length measurement is internal and is from the bottom of the bag to the top of the lip or thumb cut.

NOTE 2 Where the bag has a serrated cut-off the measurements are taken from the bottom of the serration.

4.2 Tolerances on dimensions

The tolerances on the stated dimensions shall be as follows:

- a) bag widths ± 3 mm;
- b) bag gussets ± 3 mm;
- c) bag lengths ± 10 mm.

4.3 Heat-seal strip

For bags with a heat-seal closure the heat-seal adhesive shall be applied as a continuous horizontal strip across the front, gussets (if gusseted) and back of the bag. The width of the heat-seal strip shall be 25 ± 3 mm on bags 150 mm or less in width, and 40 ± 3 mm on bags wider than 150 mm.

The top edge of the heat-seal strip shall be positioned not less than 2 mm and not more than 10 mm from the lower lip or bottom of the thumb cut.

4.4 Thumb cut

Unlippped bags shall incorporate a thumb cut 9 ± 3 mm deep and not less than 15 mm wide for ease of opening.

4.5 Lip

Lippped bags up to and including 500 mm in length shall have a lip not greater than 20 mm deep.

Lippped bags over 500 mm in length shall have a lip not greater than 25 mm deep.

5 Performance

NOTE A summary of performance requirements and test methods is given in Table 2.

5.1 pH of the water extract

The pH of the water extract of the paper and adhesive sandwich shall be not less than 4.5 and not greater than 8.0 when tested in accordance with Appendix A.

5.2 Chloride content

The chloride content of the paper and adhesive sandwich, calculated as sodium chloride (NaCl), shall not exceed 0.05 % when tested in accordance with Appendix A.

¹⁾ For further information contact Enquiry Section at BSI, Linford Wood, Milton Keynes MK14 6LE.