

Specification for

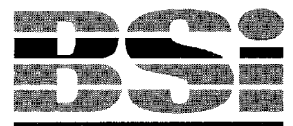
**Single use, sterilized
surgical rubber gloves**



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ICS 11.140; 13.340.10

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/6, Rubber products for hospital use, upon which the following bodies were represented:

- Association of Clinical Pathologists
- British Rubber Manufacturers Association Ltd.
- British Surgical Trades Association
- Department of Health
- Guild of Hospital Pharmacists
- Infection Control Nurses' Association
- Malaysian Rubber Producers' Research Association
- Medical Sterile Products Association
- National Association of Glove Manufacturers
- National Association of Theatre Nurses
- Co-opted members

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Amendments issued since publication

Amd. No.	Date	Text affected

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Foreword

This British Standard has been prepared under the direction of the Health and Environment Sector Board and is the fourth edition of BS 4005. This edition introduces technical changes but it does not reflect a full review or revision of the Standard, which will be undertaken in due course. It supersedes BS 4005 : 1984, which is withdrawn.

The principal differences from the third edition are as follows:

- a) requirements for freedom from holes, dimensional requirements and physical properties are addressed by cross-reference to BS EN 455 : Parts 1 and 2;
- b) requirements for type designation, materials, cuff termination, thickness and shelf life have been deleted.

This British Standard does not include requirements to ensure that the chemical formulation of surgical rubber gloves is such that the gloves do not contain any substance known to be harmful to the wearer or to any person with whom the gloves may come into contact.

Attention is drawn to BS EN 30993 which comprises various Parts describing screening tests for assessing biological hazards in medical devices.

The gloves may be coated with a surface lubricating material to assist the user in putting them on. This material, if not bonded to the surface of the gloves, should be capable of absorption by the body; surface lubricating materials, such as maize starch BP¹⁾, should be removed prior to undertaking operative procedures in order to minimize the risk of any adverse tissue reaction.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing product surveillance which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS EN ISO 9000.

Enquiries as to the availability of third party certification schemes are forwarded by BSI to the Association of British Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

¹⁾ Sterilizable maize starch conforming to the British Pharmacopoeia monograph 1993.

Specification

1 Scope

This British Standard specifies requirements for gloves made from natural or synthetic rubber and intended for use in surgical work. It is applicable to single use gloves, supplied sterilized ready for use, which are each worn once and then discarded.

2 References

2.1 Normative references

This Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are made at the appropriate places in the text and the cited publications are listed on the inside back cover. For dated references, only the edition cited applies; any subsequent amendments to or revisions of the cited publication apply to this standard only when incorporated in the reference by amendment or revision. For undated references, the latest edition of the cited publication applies, together with any amendments.

2.2 Informative references

This Standard refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

3 Dimensions

The dimensions of gloves shall conform to BS EN 455-2.

4 Freedom from holes

Gloves shall conform to BS EN 455-1.

5 Physical properties

The physical properties of gloves shall conform to BS EN 455-2.

6 Packaging

The gloves shall be supplied double wrapped, the outer wrappers of unit packs being sealed before sterilization. The unit packs shall contain an individual glove or a pair of gloves, shall facilitate the aseptic extraction of the contents and shall not be capable of easy reclosure.

NOTE. The outer wrapper should serve as a microbiological barrier and should be sufficiently robust to maintain the sterility of its contents, under conditions of handling and storage normally encountered in hospitals and in medical practice, for at least the period of the shelf life.

7 Marking

7.1 Each glove shall be marked with its size and the name, trade mark or recognized symbol of the manufacturer.

7.2 The inner wrapper for each individual glove or pair of gloves shall be legibly marked with:

- a) the size of glove;
- b) if gloves have been treated with sterilizable maize starch BP or similar material, a warning to the effect that surface powder should be removed prior to undertaking operative procedures in order to minimize the risk of adverse tissue reaction.

7.3 The outer wrapper for each individual glove or pair of gloves shall be legibly marked with the following information:

- a) the manufacturer's name, trade mark or recognized symbol;
- b) size of glove;
- c) month and year of manufacture;
- d) the number and date of this British Standard, ie. BS 4005 : 1996²⁾;
- e) the words 'for single use only' or equivalent, and/or the symbol for 'do not reuse' specified in EN 980 : 1996;
- f) the manufacturer's identifying lot number and the word 'STERILE', prominently displayed.

NOTE 1. Marking the outer wrapper with the word 'STERILE' means that the pack and contents have been subjected to a sterilization process.

NOTE 2. The information in c) and f) may be presented using the relevant symbols specified in EN 980 : 1996.

7.4 The multi-unit shelf container shall be legibly marked with items a) to f) of 7.3 and instructions for storage.

NOTE. Recommendations for storage of vulcanized rubber are given in BS 3574.

²⁾ Marking BS 4005 : 1996 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is solely the claimant's responsibility. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

List of references (see clause 2)

Normative references

BSI publications

BRITISH STANDARDS INSTITUTION, London

BS EN 455 :	<i>Medical gloves for single use</i>
BS EN 455-1 : 1994	<i>Specification for freedom from holes</i>
BS EN 455-2 : 1995	<i>Specification for physical properties</i>

CEN and CENELEC publications

EUROPEAN COMMITTEE FOR STANDARDIZATION (CEN) and EUROPEAN COMMITTEE FOR ELECTROTECHNICAL STANDARDIZATION (CENELEC), Brussels. (All publications are available from Customer Services, BSI.)

EN 980 : 1996	<i>Graphical symbols for use in the labelling of medical devices</i>
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Informative references

BSI publications

BRITISH STANDARDS INSTITUTION, London

BS 3574 : 1989	<i>Specification for the controlled storage and packaging of vulcanized rubber and rubber products</i>
BS EN 30993	<i>Biological evaluation of medical devices</i>



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