BRITISH STANDARD

BS 4005 : 1996

Specification for

Single use, sterilized surgical rubber gloves

ICS 11.140; 13.340.10

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

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on
15 December 1996

First published March 1966
Second edition March 1977
Third edition June 1984
Fourth edition December 1996

The following BSI references relate to the work on this standard:
Committee reference CH/6
Draft for comment 95/562918 DC

ISBN 0 580 26739 3

Amendments issued since publication

Amd. No.	Date	Text affected

Contents

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 It supersedes BS 4005 : 1984, which is withdrawn.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 BP[1)], 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 : 1996[2)];

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

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	*Graphical symbols for use in the labelling of medical devices*

Informative references

BSI publications

BRITISH STANDARDS INSTITUTION, London

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

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Contract 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.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the responsible technical committee, the identity of which can be found on the inside front cover. Tel: 0181 996 9000; Fax: 0181 996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services, Sales Department at Chiswick: Tel: 0181 996 7000; Fax: 0181 996 7001.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library, the Standardline Database, the BSI Information Technology Service (BITS) and its Technical Help to Exporters Service. Contact the Information Department at Chiswick: Tel: 0181 996 7111; Fax: 0181 996 7048.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Customer Services, Membership at Chiswick: Tel: 0181 996 7002; Fax: 0181 996 7001.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL

ISBN 0 580 26739 3