

CONFIRMED
MARCH 1991

Specification for

Single use labelled medical specimen containers for haematology and biochemistry

UDC 615.471:621.642.1:616.15 – 074

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

BSI
Documents

AVA

Document Sharing Hub

Cooperating organizations

The Surgical Instruments and Medical Equipment Standards Committee, under whose direction this British Standard was prepared, consists of representatives from the following:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Sterilizer Manufacturers
- Association of National Health Supplies Officers
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Institute of Surgical Technologists
- British Medical Association
- British Paediatrics Association
- British Surgical Trades' Association Incorporated
- Department of Health and Social Security*
- Disposable Hypodermic and Allied Equipment Manufacturers' Association
- Institute of Purchasing and Supply
- Institution of Production Engineers
- Medical Defence Union
- Medical Protection Society
- Medical Sterile Products Association*
- Ministry of Agriculture, Fisheries and Food*
- Ministry of Defence*
- Royal College of Midwives
- Royal College of Obstetricians and Gynaecologists
- Royal College of Surgeons of Edinburgh
- Royal College of Veterinary Surgeons
- Royal Institute of Public Health and Hygiene
- Royal National Institute for the Deaf
- Scientific Instrument Manufacturers' Association

The organizations marked with an asterisk in the above list, together with the following, were directly represented on the Technical Committee entrusted with the preparation of this British Standard:

- Association of Clinical Biochemists
- Association of Clinical Pathologists
- British Laboratory Ware Association
- British Lamphown Scientific Glassware Manufacturers' Association Ltd.
- British Plastics Federation
- British Society for Haematology
- Glass Manufacturers' Federation
- Institute of Medical Laboratory Sciences
- Public Health Laboratory Service
- Plastics and Rubber Institute
- Royal College of Pathologists

This British Standard, having been prepared under the direction of the Surgical Instruments and Medical Equipment Standards Committee, was published under the authority of the Board of BSI and comes into effect on 30 July 1982

© BSI 12-1999

First published August 1972
First revision July 1982

The following BSI references relate to the work on this standard:
Committee reference SGC/29
Draft for comment 79/64277 DC

ISBN 0 580 12740 0

Amendments issued since publication

Amd. No.	Date of issue	Comments

Contents

	Page
Cooperating organizations	Inside front cover
Foreword	ii
1 Scope	1
2 Definitions	1
3 Material, capacity and design	1
4 Anticoagulants	1
5 Label	1
6 Marking	2
Appendix A Test for leakage of a complete container	4
Appendix B Colour references	4
Appendix C Test to determine the accuracy of fill line	4
Table 1 — Capacity of containers	1
Table 2 — Identification code and concentration for anticoagulants	2
Table 3 — References to suitable colours for colour coding	4
Publications referred to	6

Foreword

This revision of this British Standard, has been prepared under the direction of the Surgical Instrument and Medical Equipment Standards Committee. The standard was first published in 1972 following a request from the British Committee for Standards in Haematology to consider standardization of medical specimen containers for blood. In this revision the opportunity has been taken to align the standard with ISO 4822:1981, published by the International Organization for Standardization (ISO), although some requirements have been more tightly defined. This standard supersedes BS 4851:1972 which is withdrawn.

The test for spontaneous discharge of contents on opening has been omitted because it has proved difficult in practice to carry out the test in a reproducible and objective manner. The committee consider that the development of a satisfactory test for spontaneous discharge is important and research continues to determine the dangers of and methods of test for, spontaneous discharge. When this information becomes available, the requirements and test method will be added to this standard.

A test to determine the accuracy of fill line has been added to this revision in Appendix C while the following tests have been omitted:

- method for the determination of elutable sodium and potassium;
- screening test for iron contamination;
- test for ability to withstand sterilization by moist heat at 121 °C;
- test for ability to withstand sterilization by moist heat at 134 °C;
- test for ability to withstand sterilization by dry heat.

This standard is complementary to BS 6242 which specifies requirements for unlabelled medical specimen containers.

Certification. Attention is drawn to the certification facilities described on the inside back cover of this standard.

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.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 6, 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.