### INTERNATIONAL STANDARD



First edition 1995-08-01

Corrected and reprinted 1996-02-01

# Single-use containers for venous blood specimen collection

Récipients non réutilisables pour prélèvements de sang veineux



### Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bedies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the rechnical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the Nember bodies casting a vote.

International Standard ISO 6710 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.* 

Annexes A, B, C, D and E form an integral part of this International Standard. Annex F is for information only.

© ISO 1995

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization

Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

## Single-use containers for venous blood specimen collection N:500

#### Scope 1

This International Standard specifies requirements and test methods for evacuated and non-evacuated single-use venous blood specimen containers.

It does not specify requirements for blood collection needles or needle holders.

This International Standard replaces the require-NOTE 1 ments for non-evacuated containers previously specified in ISO 4822, Single use blood specimen containers up 25 ml capacity, which has been withdrawn.

### Normative references 2

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.

ISO 3696:1987, Water for analytical laboratory use ---Specification and test methods.

ISO 7000:1989, Graphical symbols for use on equipment — Index and synopsis.

#### Definitions 3

For the purposes of this International Standard, the following definitions apply.

3.1 container: Vessel to contain a blood specimen, with closure in place.

3.2 evacuated container: Container intended for blood collection by means of evacuation either already induced by the manufacturer (i.e., pre-evacuated containers) or induced by the user before blood is taken.

3.3 tube: That part of the container, without the closure, that contains the specimen.

3.4 closure: Component by which the container is closed.

Óh primary pack: Smallest package of containers. 3.5

36 container interior: Inside surface of the con-

additive: Any substance (other than inside sur-3.7 face treatments designed to be irremovable) that is placed in the container in order to allow the intended analysis to be performed.

3.8 nominal capacity: Volume of whole blood with which the container is intended to be filled.

3.9 free space: Extra capacity, or head space, which is provided to allow adequate mixing of the contents of a container, as determined by the minimum free space tests laid down in annexes A and B.

3.10 fill line: Line marked on a tube or its label to indicate the nominal capacity of a container.

3.11 draw volume: Nominal capacity of an evacuated container.

3.12 expiry date: Date after which the manufacturer does not claim that a container complies with the requirements of this International Standard.