AS 3787.1—1997

Australian Standard®

General requirements for single-use, sterile, plasticized polyvinyl chloride (PVC) packs for human blood

Part 1: Single blood packs

This Australian Standard was prepared by Committee HT/6, Transfusion Equipment for Medical Use. It was approved on behalf of the Council of Standards Australia on 17 January 1997 and published on 5 May 1997.

The following interests are represented on Committee HT/6:

Australian Chamber of Commerce and Industry

Australian Red Cross Society

Australian Society of Anaesthetists

Commonwealth Department of Health and Family Services

Department of Public Works and Services, N.S.W.

Health Department of Western Australia

Medical Industry Association of Australia

N.S.W. Health Department

Queensland Health

Royal College of Pathologists of Australasia

South Australian Health Commission

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Part 1: Single blood packs

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PREFACE

This Standard was prepared by the Standards Australia Committee HT/6, Transfusion Equipment for Medical Use to supersede AS 3787.1— 1990, *General requirements for single-use, sterile, plasticized polyvinyl chloride (PVC) blood packs for whole blood and blood components*, Part 1: *Single blood packs*.

This Part of AS 3787 deals with single blood packs whereas Part 2 of the Standard deals with multiple blood pack systems.

The committee was aware of the importance for manufacturers to demonstrate the overall system performance of the blood packs in relation to blood product viability, e.g. red cell viability *in vivo* or *in vitro*. This edition does not specifically address this need.

The Standard was originally developed by the Commonwealth Therapeutic Goods Standards Committee's Subcommittee on Blood Bags and submitted to Standards Australia as the basis for the development of an Australia Standard suitable for adoption as an Order under the Therapeutic Goods Act 1966.

The objective of this Standard is to ensure that the quality of blood collection packs is such that blood and blood components are maintained at the highest possible level.

The principal differences between this Standard and the 1990 edition are as follows:

(a) The design of the outlet port will need to be such that the risk of the closure-piercing device of an infusion (giving) set puncturing the wall of the blood collection pack is minimized.

(b) Appendices C, F, I, P, M, R and AA have been modified.

(c) Labelling requirements have been altered.

(d) Requirements for testing for haemolytic effects have been modified.

The principal difference between this Standard and ISO 3826—1993, *Plastics collapsible containers for human blood and blood components*, are as follows:

(i) Chemical tests and biological requirements are inadequate in the ISO Standard. For example, chemical testing is carried out on a water extract, which is not appropriate for a blood pack.

(ii) The labelling requirements in this Standard for single blood pack systems refer to the Therapeutic Goods Order (TGO)—*General requirements for labels for therapeutic devices*, and the Australian Red Cross Blood Service—*Guidelines for blood and blood component labels*.

(iii) The physical tests are not specific enough in the ISO Standard. Also, there is no test for particulate contamination.

Alternative validated test methods to those given in this Standard may be used, provided that equivalent or comparable results are obtained.

A more modern test for alkylene oxide, alkylene chlorohydrin and alkylene glycol residues (Appendix AC) is under investigation.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

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Part 1: Single blood packs

1 SCOPE This Standard specifies requirements for sterilized, non-vented, collapsible, plasticized polyvinyl chloride (PVC) single blood packs for the collection, storage, transportation and administration of whole blood.

The Standard does not apply to blood bag systems used for the freezing of red cells.

2 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS
1386 Cleanrooms and clean workstations
2103 Dial gauges and dial test indicators (metric series)
2134 Recommended practice for chemical analysis of materials by atomic absorption spectrometry
2134.1 Part 1: Flame atomic absorption spectrometry
2134.2 Part 2: Graphite furnace spectrometry
2145 Hypodermic equipment—Hypodermic needle tubing
2385 Single-use (sterile) infusion sets for general medical use

ISO
10993 Biological evaluation of medical devices
10993.4 Part 4: Selection of tests for interactions with blood
10993.10 Part 10: Tests for irritation and sensitization

British Pharmacopoeia (BP), Vol. 2
European Pharmacopoeia (EP)
United States Pharmacopoeia (USP), Monograph 85
United States Pharmacopoeia (USP), Monograph 87
United States Pharmacopoeia (USP), Monograph 161
Australian Red Cross Blood Service—Guidelines for blood and blood component labels
Guideline on validation of the *Limulus amoebocyte* lysate test as an end-product endotoxin test for human and animal parenteral drugs, biological products and medical devices, F.D.A., 1987
NHMRC Report, 81st Session, Appendix XV.
Therapeutic Goods Order (TGO)—Standard for sterile therapeutic goods (Commonwealth of Australia)
Therapeutic Goods Order (TGO)—General requirements for labels for therapeutic devices (Commonwealth of Australia)

3 DEFINITIONS For the purposes of this Standard the definitions below apply.

3.1 Collection tube—the tube through which blood is collected from the donor and a means by which blood from the blood collection pack can be sampled.