AS 3864.1—2012

Australian Standard®

Medical refrigeration equipment—For the storage of blood and blood products

Part 1: Manufacturing requirements

This Australian Standard® was prepared by Committee HE-020, Medical Refrigeration. It was approved on behalf of the Council of Standards Australia on 18 October 2012.
This Standard was published on 23 November 2012.

The following are represented on Committee HE-020:

- Australia and New Zealand Society of Blood Transfusion
- Australian College of Nursing
- Australian Council on Healthcare Standards
- Australian Institute of Refrigeration, Air-conditioning and Heating
- Australian Red Cross Blood Service
- CHOICE
- Institute of Hospital Engineering Australia
- National Association of Testing Authorities Australia
- National Blood Authority
- Queensland Health
- Refrigeration & Air-conditioning Contractors Association of Australia
- Royal College of Pathologists Australasia (RCPA)
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS 3864.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

Australian Standard®

Medical refrigeration equipment—For the storage of blood and blood products

Part 1: Manufacturing requirements

Originally as part of AS 3864—1991.
Previous edition part of AS 3864—1997.
Revised in part and redesignated as AS 3864.1—2012.

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 1 74342 292 2

PREFACE

This Standard was prepared by the Standards Australia Committee HE-020, Medical Refrigeration, to supersede part of AS 3864—1997, *Medical refrigeration equipment—For the storage of blood and blood products.*

The objective of this Standard is to safeguard recipients of blood transfusions by ensuring that blood and blood products are properly and safely stored at the required temperature in refrigeration equipment or walk-in rooms specifically manufactured for the purpose.

The Standard consists of two parts:

Part 1: Manufacturing requirements (this Standard)

Part 2: User-related requirements for care, maintenance, performance verification and calibration

The principle differences between this edition and the 1997 edition are as follows:

(a) Separation of the Standard into two parts. Part 1 describes the requirements for manufacturers of medical refrigeration equipment used for storing blood and blood products. Part 2 is intended for the users of this type of equipment and describes the requirements for its care, maintenance, performance verification and calibration.

(b) Recognition of the variety of data management technologies available for acquisition and storage of data from temperature recording devices.

(c) Recognition of advancements in refrigeration system technology.

The term, 'normative' has been used in this Standard to define the application of the appendix to which it applies. A 'normative' appendix is an integral part of a Standard.

CONTENTS

Page

STANDARDS AUSTRALIA

Australian Standard

Medical refrigeration equipment—For the storage of blood and blood products

Part 1: Manufacturing requirements

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies requirements for the manufacture of medical refrigeration equipment used within an ambient temperature range of 10°C to 43°C (see Note 1) for the storage of the following:

(a) Blood and blood products in the temperature range 2°C to 6°C (see Sections 2 and 4);

(b) Frozen plasma and plasma products at a temperature of −25°C or lower (see Sections 3 and 5)

This Standard covers both reach-in cabinets and walk-in rooms. This Standard is intended to be read in conjunction with AS 3864.2. Where the term 'the Standard' is used it refers to both Parts 1 and 2 of AS 3864.

NOTES:

1 Where medical refrigeration equipment is intended to be used in an air-conditioned atmosphere, only the ambient temperature range of 10°C to 32°C will be applicable for satisfying the requirements of this Standard, provided there is an adequate back-up electrical supply in case of power failure.

2 In some situations equipment meeting the scope of the Standard may also be required to meet additional regulatory requirements. These requirements are outside the scope of the Standard.

1.2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

1397 Continuous hot-dip metallic coated steel sheet and strip—Coatings of zinc and zinc alloyed with aluminium and magnesium

1627 Metal finishing—Preparation and pretreatment of surfaces
1627.0 Part 0: Method selection guide

2070 Plastics materials for food contact use

3864 Medical refrigeration equipment—For the storage of blood and blood products
3864.2 Part 2: User-related requirements for care maintenance, performance verification and calibration.

60529 Degrees of protection provided by enclosures (IP Code)

AS/NZS

1677 Refrigeration systems
1677.1 Part 1: Refrigerant classification
1677.2 Part 2: Safety requirements for fixed applications

3100 Approval and test specification—General requirements for electrical equipment

