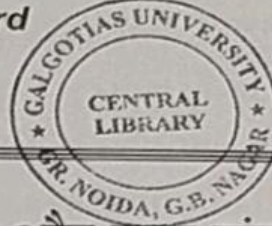


भारतीय मानक
Indian Standard

IS/ISO 3826-2 : 2008
(Superseding IS 15102 : 2002)



मानव रक्त और रक्त संघटकों के लिए
प्लास्टिक के संकोच्य आधान

भाग 2 लेवल और निर्देश पुस्तिकाओं पर उपयोग के लिए
ग्राफिकल चिह्न

Plastics Collapsible Containers for
Human Blood and blood components

Part 2 Graphical Symbols for Use on Labels and Instruction Leaflets

ICS 01.080.20; 11.040.20

© BIS 2018



भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDARDS

मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली-110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002

www.bis.gov.in www.standardsbis.in

January 2018

Price Group 6

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

NATIONAL FOREWORD

This Indian Standard (Part 2) which is identical with ISO 3826-2 : 2008 'Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Hospital Equipment and Surgical Disposable Products Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was earlier published as IS 15102 : 2002 by adopting ISO 3832 : 1993 identically under dual number. On revision of ISO 3826 in three parts, the committee also decided to adopt this standard in three parts under a single number series as IS/ISO to make pace with the latest international practice. On publication, these three parts supersede IS 15102 : 2002 'Plastics collapsible containers for human blood and blood components'.

This standard is published in three parts. Other two parts in this series are:

- Part 1 Conventional containers
- Part 3 Blood bag systems with integrated features

This standard has been prepared to:

- Reduce the need for multiple translations of words into national languages.
- Simplify and rationalize the labelling of blood treatment and transfusion devices which are medical devices used in critical situations, thereby reducing risk of misidentification, promoting safety for the patient and reducing the amount of training required by healthcare personnel.
- Promote the movement of blood treatment and transfusion devices across national boundaries.
- Support the essential requirements of relevant EU Directives.

The meaning of many of these graphical symbols should be self-evident. The meaning of others will become clear with use or when viewed in the context of the device itself. If appropriate, the meaning of symbols should be explained in accompanying literature when provided. Annex A provides examples of how the symbols specified in this standard can be used. These are illustrative only and do not represent the only ways in which requirements of this standard can be met.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex A.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

(Continued on third cover)

Indian Standard

PLASTICS COLLAPSIBLE CONTAINERS FOR HUMAN BLOOD AND BLOOD COMPONENTS

PART 2 GRAPHICAL SYMBOLS FOR USE ON LABELS AND INSTRUCTION LEAFLETS

1 Scope

This part of ISO 3826 addresses symbols that may be used to convey certain items of information related to medical devices dedicated to blood collection processes and storage. The information may be required on the device itself, as part of the label, or provided with the device. Many countries require that their own language be used to display textual information with medical devices. This raises problems to device manufacturers and users.

The symbols specified in this part of ISO 3826 do not replace current national regulatory requirements.

Manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This results in a major problem of translation, design and logistics when multiple languages are included on a single label or piece of documentation. As other medical devices, blood medical devices, labelled in a number of different languages, can experience confusion and delay in locating the appropriate language. This part of ISO 3826 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined meanings.

This part of ISO 3826 is primarily intended to be used by manufacturers of medical devices dedicated to the blood collection, process storage and distribution, who market identical products in countries having different language requirements for medical device labelling.

This part of ISO 3826 may also be of assistance to different stages of the blood supply chain, e.g.:

- distributors of blood collection devices (manual or automated) or other representatives of manufacturers;
- blood centres and distribution centres to simplify and secure the operating procedures.

The use of these symbols is primarily intended for the medical device rather than the therapeutic product.

This part of ISO 3826 does not specify requirements relating to the size and colour of symbols although the symbols specified have been specially designed so as to be clearly legible when reproduced in the space typically available on the labels of blood treatment and transfusion devices, and also so as to be suitable for on-line printing.

Several of the symbols specified in this part of ISO 3826 may be suitable for application in other areas of medical technology.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IS/ISO 3826-2 : 2008

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

basic symbol

graphical representation of a particular object or feature

3.2

compound symbol

graphical representation of a concept formed by the combination of two or more basic symbols

4 Requirements for graphical symbols and their use

4.1 Use of symbols

In use, the graphical representation of symbols shall comply with that given in Table 1 and Table 2, especially with respect to dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.

NOTE ISO and IEC jointly maintain an on-line database of graphical symbols for use on equipment, which contains the complete set of graphical symbols included in ISO 7000 ^[1] and IEC 60417 ^[2], ^[3]. In that database, each graphical symbol is identified by a reference number and contains a title (in English and French), a graphical representation in GIF and vectorized PDF format, and some additional data as applicable. Various search and navigation facilities allow for easy retrieval of graphical symbols. Information on how to access this database is available through the ISO Store ^[4], the IEC Web Store ^[5] or by contacting your local national standards body.

At a distance that takes into account the specifics and size of the product and its packaging, the symbols and associated information shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary.

4.2 System of symbols



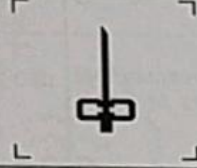
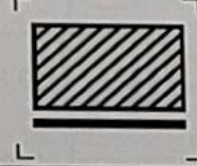
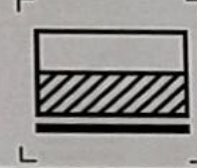
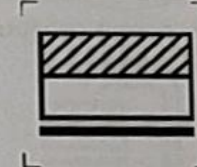
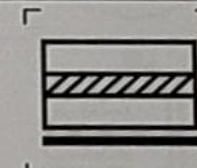
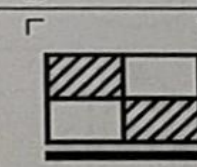
The system of symbols shall comprise basic symbols (see 4.3) that may be combined to form compound symbols (see 4.4).

NOTE Illustrative examples of labels for blood treatment and transfusion medical devices, showing the use of this system of symbols, are given in Annex A.

4.3 Basic symbols

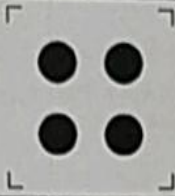
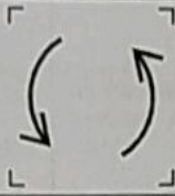
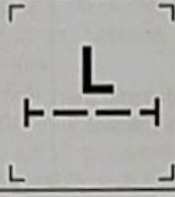

Basic symbols can be used alone, or in combination, to form compound symbols (see 4.4).

Table 1 — Basic symbols to convey information essential for proper use

No.	Symbol	Title and description	ISO 7000 registration number
4.3.1		Blood or blood component container <i>On medical devices or blood process application: to indicate that the processing or final container is used for the purpose of whole blood or blood component storage.</i>	ISO 7000-2703
4.3.2		Double needle apheresis protocol <i>On medical devices or blood process application: to indicate that the medical device is for use by double needle apheresis protocol.</i>	ISO 7000-2753
4.3.3		Single needle apheresis protocol <i>On medical devices or blood process application: to indicate that the medical device is for use by single needle apheresis protocol.</i>	ISO 7000-2754
4.3.4		Whole blood <i>On medical devices or blood process application: to indicate the presence of whole blood before any stage of processing.</i>	ISO 7000-2718
4.3.5		Red blood cell concentrate <i>On medical devices or blood process application: to indicate the presence of red blood cells concentrate obtained after centrifugation of whole blood.</i>	ISO 7000-2712
4.3.6		Plasma <i>On medical devices or blood process application: to indicate the presence of plasma obtained after centrifugation of whole blood.</i>	ISO 7000-2707
4.3.7		Buffy coat <i>On medical devices or blood process application: to indicate the presence of buffy coat. (Buffy coat is the combination of leukocyte and platelets obtained after centrifugation of whole blood.)</i>	ISO 7000-2704
4.3.8		Platelets concentrate <i>On medical devices or blood process application: to indicate the presence of platelets concentrate.</i>	ISO 7000-2709

IS/ISO 3826-2 : 2008

Table 1 (continued)







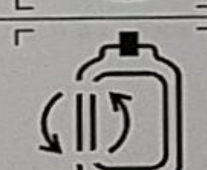
No.	Symbol	Title and description	ISO 7000 registration number
4.3.9		Anticoagulant <i>On medical devices or blood process application: to indicate the presence of anticoagulant.</i>	ISO 7000-2701
4.3.10		Processing <i>On medical devices or blood process application: to indicate a process. The symbol shall be used in conjunction with other symbols which identify the type of process.</i>	ISO 7000-2706
4.3.11		Leukocyte filter <i>On medical devices or blood process application: to indicate that the filter is dedicated to the reduction of leukocytes in whole blood or blood components.</i>	ISO 7000-2720
4.3.12		Pathogen reduced <i>On medical devices or blood process application: to indicate the reduction of pathogen agents.</i>	ISO 7000-2716

4.4 Compound symbols

Compound symbols are formed by combination of two or more basic symbols (see 4.3).



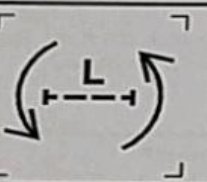
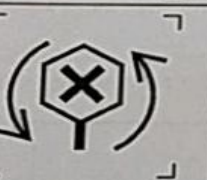
Where necessary, symbols shall be reversed, i.e. white to black and vice-versa, to permit construction and reproduction of the compound symbol.

Table 2 — Compound symbols to convey information essential for proper use

No.	Symbol	Title and description	ISO 7000 registration number
Compound symbols for "solutions"			
4.4.1		Additive solution <i>On medical devices or blood process application: to indicate that the container shows the presence of a type of solution to be mixed with other components.</i>	ISO 7000-2700
4.4.2		Anticoagulant solution <i>On medical devices or blood process application: to indicate that the container shows the presence of anticoagulant solution.</i>	ISO 7000-2702
4.4.3		Saline solution <i>On medical devices or blood process application: to indicate that the container shows the presence of saline solution to be mixed with other components.</i>	ISO 7000-2714
Compound symbols for "blood or blood component containers"			
NOTE 1 The compound symbols specified in 4.4.4 to 4.4.9 comprise basic symbol 4.3.1 combined with basic symbols 4.3.4, 4.3.5, 4.3.6, 4.3.7, 4.3.8 and 4.3.10.			
NOTE 2 The difference of density and count of lines within the basic blood symbols compared to the lines within the relevant blood symbol within the compound symbols is intended due to the expected same size of use. Using the same density and count of lines would lead to a coverage of lines within the compound symbols.			
4.4.4		Buffy coat container <i>On medical devices or blood process application: to indicate that the container is used for the purpose of final or temporary storage of buffy coat. (Buffy coat is the combination of leukocyte and platelets obtained after centrifugation of whole blood.)</i>	ISO 7000-2705
4.4.5		Plasma container <i>On medical devices or blood process application: to indicate that the container is used for the purpose of final or temporary storage of plasma.</i>	ISO 7000-2708
4.4.6		Platelets container <i>On medical devices or blood process application: to indicate that the container is used for the purpose of final or temporary storage of platelets concentrate.</i>	ISO 7000-2710
4.4.7		Processing container <i>On medical devices or blood process application: to indicate that the processing of final container is used for the achievement of a process.</i>	ISO 7000-2711

IS/ISO 3826-2 : 2008

Table 2 (continued)

No.	Symbol	Title and description	ISO 7000 registration number
4.4.8		Red blood cell container <i>On medical devices or blood process application: to indicate that the container is used for the purpose of final or temporary storage of red blood cells.</i>	ISO 7000-2713
4.4.9		Whole blood container <i>On medical devices or blood process application: to indicate that the container is used for the purpose of final or temporary storage of whole blood.</i>	ISO 7000-2719
Compound symbols for "processes for blood and blood components"			
NOTE and 4.3.12. The compound symbols specified in 4.4.10 and 4.4.11 comprise basic symbol 4.3.10 combined with basic symbols 4.3.11			
4.4.10		Leukocyte filtration <i>On medical devices or blood process application: to indicate a process of leukocyte filtration applied on whole blood or blood components.</i>	ISO 7000-2721
4.4.11		Pathogen reduction processing <i>On medical devices or blood process application: to indicate that the processing action is leading to reduction of pathogen agents.</i>	ISO 7000-2717

4.5 Other symbols

Where additional graphical symbols are utilized in the labelling of medical devices for blood treatment and transfusion, they shall be in accordance, as appropriate, with ISO 15223-1.

Annex A (informative)

Illustrative examples of symbols used in the labelling of medical devices used for blood treatment and transfusion

A.1 Blood and blood components containers: individual label

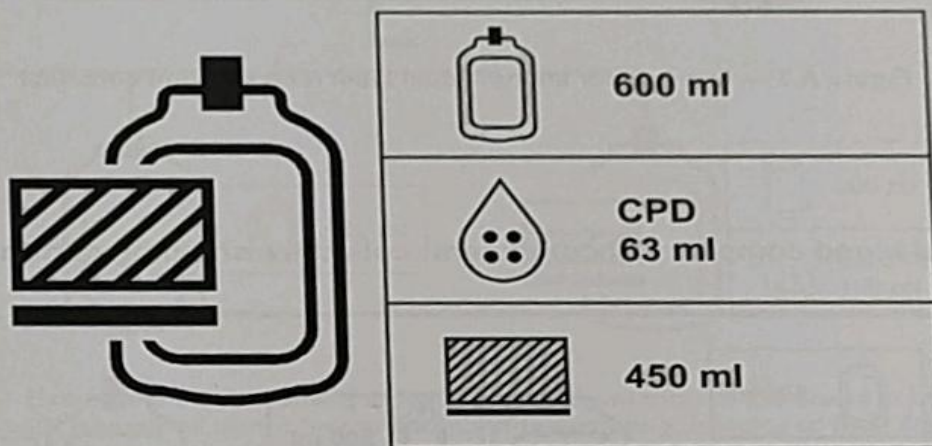


Figure A.1 — Example 1 of an individual label for a blood and blood components container

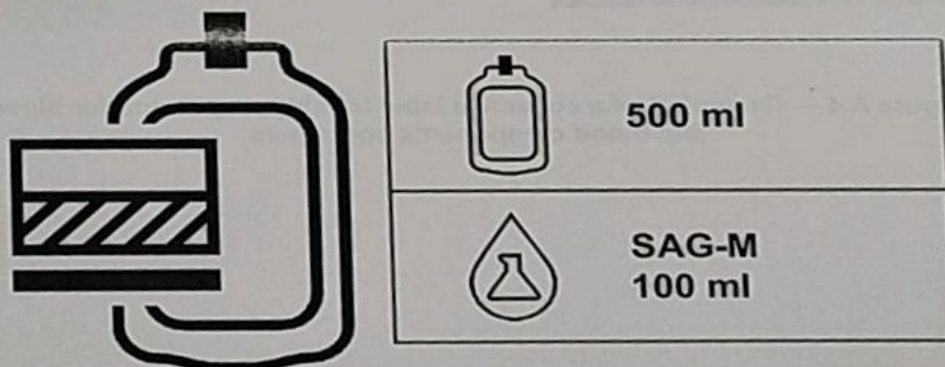


Figure A.2 — Example 2 of an individual label for a blood and blood components container

IS/ISO 3826-2 : 2008

A.2 Solution container: individual label

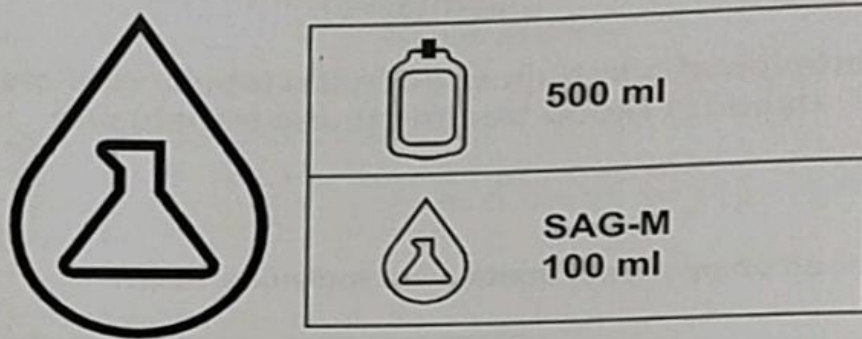


Figure A.3 — Example for an individual label for a solution container

A.3 Blood and blood components containers: collective shipping carton label

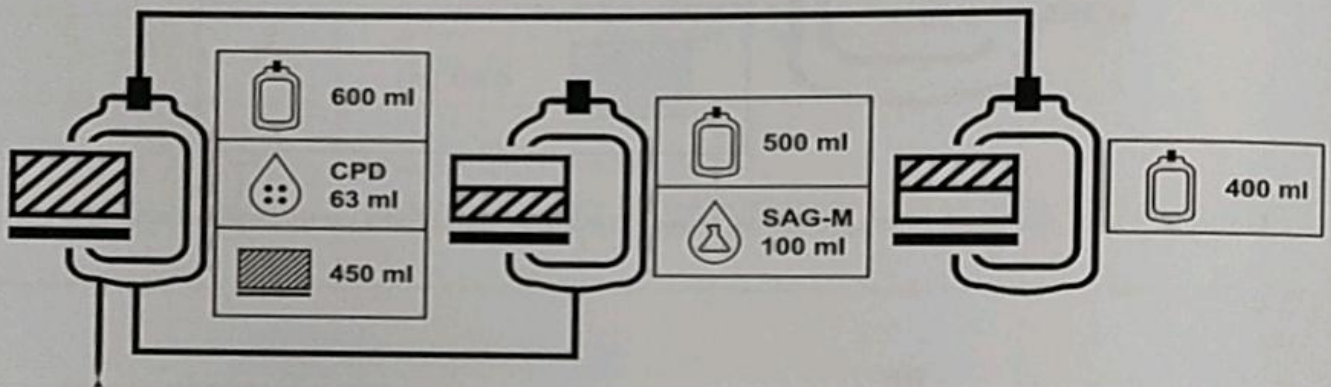


Figure A.4 — Example 1 of a collective label for shipping carton for blood and blood components containers

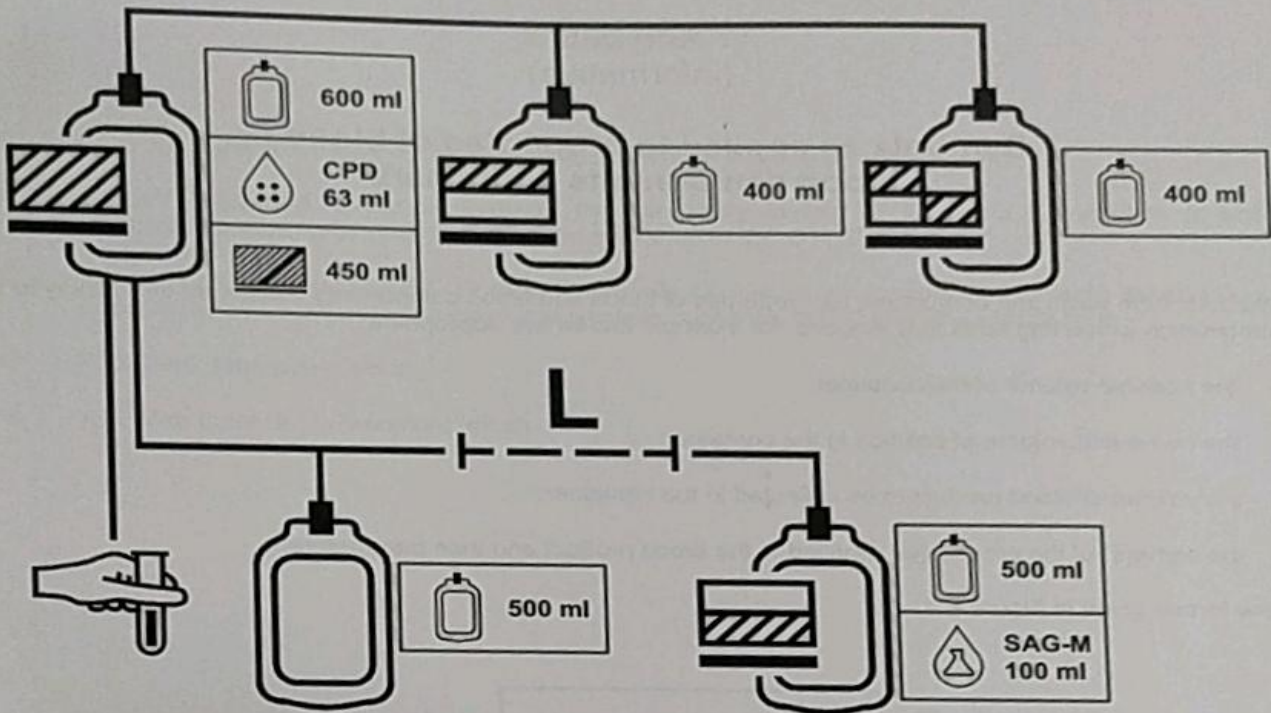


Figure A.5 — Example 2 of a proposed schematic representation of the blood collection top and bottom bag with integrated donor line including side sampling, integrated filter for red cells and platelets storage bag as presented in ISO 3826-3:2006, Figure 1

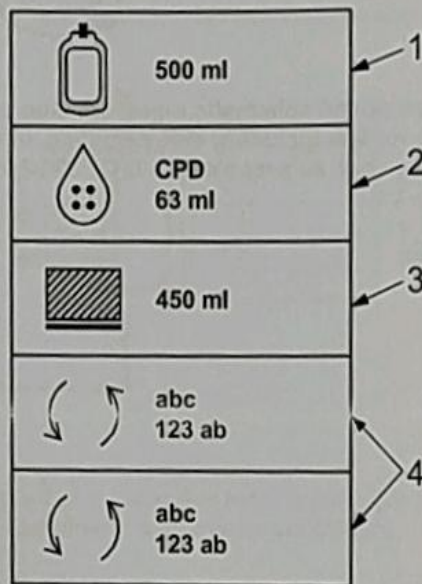
Annex B (informative)

Symbols as applied to properties of blood or blood components containers

Symbols, both basic and compound, for properties of blood and blood components containers are displayed in combination with a bag label that includes, for example and where appropriate:

- the nominal volume of the container;
- the name and volume of solution in the container;
- the volume of blood product to be collected in the container;
- the name(s) of the process(es) applied to the blood product and their parameters;

in the format given in Figure B.1.



Key

- 1 total capacity of the container
- 2 name and volume of solution in the container
- 3 volume of whole blood product to be collected in the container
- 4 name(s) of the process(es) applied to the blood product and their parameters

Figure B.1 — Format to be used when including symbols on a tag label system

Bibliography

- [1] ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*
- [2] IEC 60417-DB-12M, *Graphical symbols for use on equipment — 12-month subscription to online database comprising all graphical symbols published in IEC 60417*
- [3] IEC 60417 ISO 7000-DB-12M, *Graphical symbols for use on equipment — 12-month subscription to online database comprising all graphical symbols published in IEC 60417 and ISO 7000*
- [4] ISO Store, <http://www.iso.org>
- [5] IEC Web Store, <http://webstore.iec.ch>

IS/ISO 3826-2 : 2008

NATIONAL ANNEX A
(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

(Continued from second cover)

In this adopted standard, reference appears to the following International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is listed below along with its degree of equivalence for the edition indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2012 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied : Part 1 General requirements (<i>first revision</i>)	Identical with ISO 15223-1 : 2012

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: MHD 12 (0327).

Amendments Issued Since Publication

Amendment No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002

Telephones: 2323 0131, 2323 3375, 2323 9402

Website: www.bis.gov.in

Regional Offices:

Telephones

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110002

{ 2323 7617
{ 2323 3841

Eastern : 1/14, C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi
KOLKATA 700054

{ 2337 8499, 2337 8561
{ 2337 8626, 2337 9120

Northern : Plot No. 4-A, Sector 27-B, Madhya Marg, CHANDIGARH 160019

{ 26 50206
{ 265 0290

Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600113

{ 2254 1216, 2254 1442
{ 2254 2519, 2254 2315

Western : Manakalaya, E9 MIDC, Marol, Andheri (East)
MUMBAI 400093

{ 2832 9295, 2832 7858
{ 2832 7891, 2832 7892

Branches: AHMEDABAD. BENGALURU. BHOPAL. BHUBANESWAR. COIMBATORE.
DEHRADUN. DURGAPUR. FARIDABAD. GHAZIABAD. GUWAHATI.
HYDERABAD. JAIPUR. JAMMU. JAMSHEDPUR. KOCHI. LUCKNOW. NAGPUR.
PARWANOO. PATNA. PUNE. RAIPUR. RAJKOT. VISAKHAPATNAM.

Published by BIS, New Delhi