इंटरनेट मानक

Disclosure to Promote the Right To Information

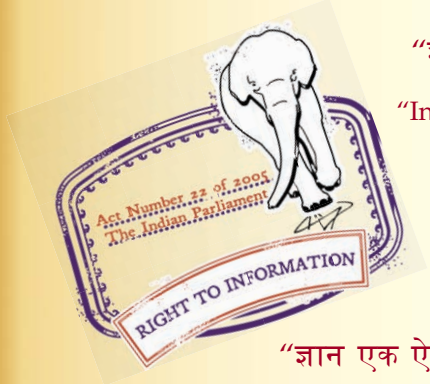
Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

"जानने का अधिकार, जीने का अधिकार"
Mazdoor Kisan Shakti Sangathan
"The Right to Information, The Right to Live"

"पुराने को छोड नये के तरफ"
Jawaharlal Nehru
"Step Out From the Old to the New"

IS 16004 (2013): Hypodermic Needles for Single Use - Colour Coding for Identification [MHD 10: Medical Laboratory Instruments]

"ज्ञान से एक नये भारत का निर्माण"
Satyanarayan Gangaram Pitroda
"Invent a New India Using Knowledge"



"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

BLANK PAGE

PROTECTED BY COPYRIGHT

IS 16004 : 2013
ISO 6009 : 1992

भारतीय मानक

एक बार उपयोग की अधस्वचीय सुइयाँ — पहचान के लिए रंग कोडिंग

Indian Standard

HYPODERMIC NEEDLES FOR SINGLE USE — COLOUR CODING FOR IDENTIFICATION

ICS 01.070; 11.040.25

© BIS 2013

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

February 2013 **Price Group 5**

Medical Laboratory Instruments Sectional Committee, MHD10

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 6009 : 1992 'Hypodermic needles for single use — Colour coding for identification' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Medical Laboratory Instruments Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard specifies colours code to enable rapid visual identification of the outside diameter of single-use hypodermic needles. The presence of colour coding on a needle or package does not absolve the user of the responsibility to check the marked size of the needle.

The colours used to code needles may be applied in either opaque or transparent form, and the colour code is equally applicable to normal-walled, thin-walled and extra-thin-walled needles. This does not imply that hypodermic needles of all the listed nominal outside diameters are currently manufactured.

This standard establishes a colour code but does not specify that needles are to be colour-coded or to what portion of the needle and/or packaging the colour is to be applied. Such requirements may be given in the relevant product standards such as ISO 7864 : 1993/IS 10654 : 1991 'Sterile hypodermic needles for single use'.

The measurement of the colour zone of an opaque colour, especially of an item of the size and shape of the hub of a needle, is a complex procedure requiring apparatus and expertise that is to be found in relatively few laboratories and test houses. It may therefore be inconvenient, difficult or impossible for a manufacturer or purchaser routinely to assess compliance of a product with colour zone values. Such difficulties are compounded in the case of translucent colours, which are being used increasingly by needle manufacturers to allow air bubbles inside the hub to be seen and eliminated before injection.

As a consequence, the colours in this standard are specified by name, accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance. This subjectivity may be minimized by viewing the hubs under controlled lighting conditions [for example, "daylight" (D_{65}) illumination at 1 000 lx to 1 500 lx] and by the use of assessors of medically-demonstrated correct colour vision. Visual comparison of the colour of a product with a reference colour sample is simple and quick, and is therefore a useful routine method of product assessment. Accordingly, reference colour samples have been made available.

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.

Technical corrigendum 1 published in 2008 to the above International Standard has been given at the end of this publication.

In this adopted standard, reference appear 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:

(*Continued on third cover*)

Indian Standard

HYPODERMIC NEEDLES FOR SINGLE USE — COLOUR CODING FOR IDENTIFICATION

1 Scope

This International Standard establishes a colour code for the identification of single-use hypodermic needles of nominal outside diameters in the range 0,3 mm to 3,4 mm. It applies to normal-walled, thin-walled and extra-thin-walled needles and to opaque and translucent colours.

2 Colour code

The colour shall indicate the nominal outside diameter of the tube of the needle, and shall be as given in table 1.

NOTES

1 Attention is drawn to the sets of reference hubs available as reference colour samples (see annex A).

2 The colour zones of opaque colours, and the nearest colour samples in a number of colour atlases are given for information in annexes B and C respectively.

Table 1 — Colour code

Nominal outside diameter of needle mm	Colour
0,3	yellow
0,33	red
0,36	blue-green
0,4	medium grey
0,45	brown
0,5	orange
0,55	medium purple
0,6	deep blue
0,7	black
0,8	deep green
0,9	yellow
1,1	cream
1,2	pink
1,4	red-violet
1,6	white
1,8	blue-grey
2,1	pale green
2,4	purple
2,7	pale blue
3	green-yellow
3,4	olive brown

Annex A
(informative)

Reference colour samples

The reference colour samples referred to in this International Standard are available by contacting:

Melab

Medizintechnik und Labor GmbH

Heimsheimer Weg 17

D-7259 Friolzheim

Germany

Tel: + 70 44 4 18 84

Fax: + 70 44 4 24 20

This information is given for the convenience of the users of this International Standard and does not constitute an endorsement by ISO of the reference colour samples.

Annex B
(informative)

Colour zones for opaque colours

B.1 Conditions of colour measurement

The chromaticity (x, y) and luminance index Y ($\beta = 10^{-2}Y$) are determined with a spectrophotometer by the equidistant wavelengths method ($\Delta\lambda = 10$ nm) under the following conditions:

a) **Lighting and examination condition:** (O/d), in accordance with CIE Publication No. 15.2, specular brilliant excluded;

b) **Reference colorimetric observer**: 2°, in accordance with CIE Publication No. 15.2;

c) **Illuminant**: C source in accordance with CIE Publication No. 15.2;

d) **Reference white**: perfect reflecting diffuser, approximated by a barium sulfate plate.

B.2 Colour zones

The colour zones for opaque colours are given in table B.1.

Table B.1 — Colour zones for opaque colours

Nominal outside diameter of needle mm	Colour	Colour zone		
0,3	yellow	$x = 0{,}448$	$x = 0{,}507$	
		$y = 0{,}468$	$y = 0{,}492$	
				$\beta > 0{,}40$
		$x = 0{,}488$	$x = 0{,}468$	
		$y = 0{,}511$	$y = 0{,}456$	
0,33	red	$x = 0{,}540$	$x = 0{,}560$	
		$y = 0{,}326$	$y = 0{,}280$	
				$0{,}10 < \beta < 0{,}20$
		$x = 0{,}500$	$x = 0{,}610$	
		$y = 0{,}289$	$y = 0{,}330$	
0,36	blue-green	$x = 0{,}203$	$x = 0{,}267$	
		$y = 0{,}300$	$y = 0{,}347$	
				$0{,}30 < \beta < 0{,}50$
		$x = 0{,}246$	$x = 0{,}234$	
		$y = 0{,}306$	$y = 0{,}370$	
0,4	medium grey	$x = 0{,}302$	$x = 0{,}323$	
		$y = 0{,}314$	$y = 0{,}315$	
				$0{,}20 < \beta < 0{,}65$
		$x = 0{,}313$	$x = 0{,}303$	
		$y = 0{,}324$	$y = 0{,}302$	

Nominal outside diameter of needle mm	Colour	Colour zone
0,45	brown	$x = 0{,}360$ $x = 0{,}452$ $y = 0{,}332$ $y = 0{,}338$ $0{,}04 < \beta < 0{,}15$ $x = 0{,}440$ $x = 0{,}367$ $y = 0{,}356$ $y = 0{,}325$
0,5	orange	$x = 0{,}482$ $x = 0{,}561$ $y = 0{,}394$ $y = 0{,}394$ $0{,}22 < \beta < 0{,}40$ $x = 0{,}542$ $x = 0{,}498$ $y = 0{,}421$ $y = 0{,}375$
0,55	medium purple	$x = 0{,}258$ $x = 0{,}294$ $y = 0{,}193$ $y = 0{,}243$ $0{,}07 < \beta < 0{,}20$ $x = 0{,}274$ $x = 0{,}285$ $y = 0{,}237$ $y = 0{,}201$
0,6	deep blue	$x = 0{,}151$ $x = 0{,}203$ $y = 0{,}178$ $y = 0{,}182$ $0{,}05 < \beta < 0{,}10$ $x = 0{,}197$ $x = 0{,}164$ $y = 0{,}218$ $y = 0{,}132$
0,7	black	$x = 0{,}296$ $x = 0{,}350$ $y = 0{,}313$ $y = 0{,}319$ $\beta < 0{,}05$ $x = 0{,}315$ $x = 0{,}290$ $y = 0{,}338$ $y = 0{,}273$
0,8	deep green	$x = 0{,}013$ $x = 0{,}310$ $y = 0{,}745$ $y = 0{,}441$ $0{,}09 < \beta < 0{,}20$ $x = 0{,}310$ $x = 0{,}254$ $y = 0{,}685$ $y = 0{,}397$
0,9	yellow	$x = 0{,}448$ $x = 0{,}507$ $y = 0{,}468$ $y = 0{,}492$ $\beta > 0{,}40$ $x = 0{,}488$ $x = 0{,}468$ $y = 0{,}511$ $y = 0{,}456$

Nominal outside diameter of needle mm	Colour	Colour zone
1,1	cream	$x = 0{,}331$ $x = 0{,}377$ $y = 0{,}341$ $y = 0{,}364$ $0{,}65 < \beta < 0{,}80$ $x = 0{,}356$ $x = 0{,}341$ $y = 0{,}372$ $y = 0{,}337$
1,2	pink	$x = 0{,}328$ $x = 0{,}407$ $y = 0{,}308$ $y = 0{,}338$ $0{,}40 < \beta < 0{,}60$ $x = 0{,}332$ $x = 0{,}373$ $y = 0{,}321$ $y = 0{,}282$
1,4	red-violet	$x = 0{,}300$ $x = 0{,}320$ $y = 0{,}287$ $y = 0{,}270$ $0{,}40 < \beta < 0{,}65$ $x = 0{,}288$ $x = 0{,}316$ $y = 0{,}254$ $y = 0{,}293$
1,6	white	$x = 0{,}297$ $x = 0{,}330$ $y = 0{,}308$ $y = 0{,}318$ $\beta > 0{,}80$ $x = 0{,}310$ $x = 0{,}303$ $y = 0{,}326$ $y = 0{,}295$
1,8	blue-grey	$x = 0{,}250$ $x = 0{,}295$ $y = 0{,}267$ $y = 0{,}314$ $0{,}10 < \beta < 0{,}20$ $x = 0{,}262$ $x = 0{,}290$ $y = 0{,}309$ $y = 0{,}299$
2,1	pale green	$x = 0{,}302$ $x = 0{,}320$ $y = 0{,}367$ $y = 0{,}339$ $0{,}45 < \beta < 0{,}65$ $x = 0{,}337$ $x = 0{,}307$ $y = 0{,}376$ $y = 0{,}336$
2,4	purple	$x = 0{,}329$ $x = 0{,}411$ $y = 0{,}233$ $y = 0{,}241$ $0{,}10 < \beta < 0{,}20$ $x = 0{,}338$ $x = 0{,}376$ $y = 0{,}194$ $y = 0{,}267$

Nominal outside diameter of needle mm	Colour	Colour zone
2,7	pale blue	$x = 0{,}197$ $x = 0{,}291$ $y = 0{,}197$ $y = 0{,}306$ $0{,}20 < \beta < 0{,}65$ $x = 0{,}200$ $x = 0{,}289$ $y = 0{,}260$ $y = 0{,}294$
3	green-yellow	$x = 0{,}350$ $x = 0{,}380$ $y = 0{,}525$ $y = 0{,}450$ $0{,}30 < \beta < 0{,}50$ $x = 0{,}336$ $x = 0{,}420$ $y = 0{,}450$ $y = 0{,}525$
3,4	olive brown	$x = 0{,}402$ $x = 0{,}392$ $y = 0{,}443$ $y = 0{,}372$ $0{,}10 < \beta < 0{,}25$ $x = 0{,}362$ $x = 0{,}454$ $y = 0{,}386$ $y = 0{,}415$

Annex C
(informative)

Colour samples for opaque colours

The nearest colour samples to the colours given in this International Standard are given in table C.1.

Table C.1 — Colour samples for opaque colours

Nominal outside diameter of needle mm	Colour samples			
	Munsell atlas	Fed. Std. 595a	RAL 840 HR	NF X 08-002
0,3	3,75 Y 8/14	23 655	1 021	1 330
0,33	—	—	—	—
0,36	7,5 BG 5/8	—	—	—
0,4	N7	26 231	7 035	3 630
0,45	10 R 4/4	10 075	8 017	2 020
0,5	3,75 YR 6/12	12 473	2 003	1 130
0,55	2,5 P 4/8	27 144	4 005	2 710
0,6	2,5 PB 3/8	15 090	5 010	1 540
0,7	N 2,0	27 038	9 005	2 603
0,8	2,5 G 4/8	14 090	6 001	2 455
0,9	3,75 Y 8/14	23 655	1 021	1 330
1,1	10 YR 9/2	27 769	1 015	2 225
1,2	2,5 R 7/6	11 630	3 015	2 870
1,6	N 9,5	27 875	9 010	2 665
1,8	5,0 B 4/2	35 189	7 031	3 520
2,1	10 GY 8/2	24 504	6 019	3 470
2,4	—	—	—	—
2,7	2,5 PB 7/8	35 190	5 012	2 590
3	—	—	—	—
3,4	—	—	—	—

Annex D
(informative)

Bibliography

[1] ISO 7864:1988, *Sterile hypodermic needles for single use.*

[2] ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

[3] CIE Publication No. 15.2:1986, *Colorimetry.*[1)]

[4] Munsell Book of Color.[2)]

[5] USA Federal Standard 595a, *Colors-Vol.1.*[3)]

[6] German Standard RAL 840, *HR Farbregister* (Colour register).[4)]

[7] French Standard NFX 08-002, *Collection réduite des couleurs — Désignation et catalogue des couleurs CCR — Étalons secondaires (Limited collection of colours — Designation and catalogue of CCR colours — Secondary Standards).*[5)]

1) Available from the Honorary Librarian (National Illumination Committee of Great Britain), c/o The Library, Thorn Lighting Ltd., 146 Lincoln Road, Enfield, Middlesex EN1 1SB, UK.

2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore, MD 21218, USA.

3) Available from Superintendent of Documents, US Government Printing Office, Washington DC 20402, USA.

4) Available from RAL Deutsches Institut für Gütesicherung und Kennzeichnung eV, Bornheimer Strasse 180, 5300 Bonn 1, Germany.

5) Available from AFNOR, Tour Europe, Cedex 7, 92080 Paris La Défense, France.

TECHNICAL CORRIGENDUM 1

Technical Corrigendum 1 to ISO 6009:1992 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

Page 2

Replace Annex A with the following.

Annex A
(informative)

Reference colour samples

The reference colour samples referred to in this International Standard are available by contacting:

Melab
Medizintechnik und Labor GmbH
Mollenbachstrasse 19
71229 Leonberg
Germany
info@melab.de

This information is given for the convenience of the users of this International Standard and does not constitute an endorsement by ISO of the reference colour samples.

(*Continued from second cover*)

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 7864 : 1993 Sterile hypodermic needles for single use	IS 10654 : 1991 Sterile hypodermic needles for single use	Identical

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, 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 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 10 (0062).

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.org.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 : SCO 335-336, Sector 34-A, CHANDIGARH 160022 — 260 3843, 260 9285

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. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE. DEHRADUN. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAJKOT. THIRUVANATHAPURAM. VISAKHAPATNAM.

Published by BIS, New Delhi