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एकल उपयोग के लिए हाइपोडर्मिक  
सुइयाँ — पहचान के लिए रंग कोडिंग  
( पहला पुनरीक्षण )

**Hypodermic Needles for Single  
Use — Colour Coding for  
Identification**  
( *First Revision* )

ICS 01.070; 11.040.25

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## NATIONAL FOREWORD

This Indian Standard (First Revision) which is identical to ISO 6009 : 2016 ‘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 Hospital Equipment and Surgical Disposable Products Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 2013 and was identical to ISO 6009 : 1992 ‘Hypodermic needles for single use — Colour coding for identification’. This revision has been brought out to align it with the latest version of ISO 6009 : 2016. After publication of this standard, IS 16004 : 2013/ISO 6009 : 1992 stands withdrawn.

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’; and
- 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.

# Contents

Page

<b>Introduction</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Terms and definitions</b> .....	<b>1</b>
<b>3 Colour code</b> .....	<b>1</b>
<b>Annex A (informative) Reference colour samples</b> .....	<b>3</b>
<b>Bibliography</b> .....	<b>6</b>

## Introduction

The intention of this International Standard is to specify colours to enable rapid visual identification of the outer 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. This revision defines, in addition, colours for more fine needles to follow the trend in the market.

The colours used to code needles may be applied in either opaque or transparent form, and the colour code is equally applicable to regular walled, thin-walled, extra-thin and ultra-thin walled needles. The nominal outer diameters of needles listed in this International Standard for which colours are given are those specified in ISO 9626.

This International 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.

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 International Standard are only referenced by a colour reference system (RAL) or by Pantone Matching System accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

*Indian Standard*

# HYPODERMIC NEEDLES FOR SINGLE USE — COLOUR CODING FOR IDENTIFICATION

( *First Revision* )

## 1 Scope

This International Standard establishes a colour code for the identification of single-use hypodermic needles of designated metric size in the range of 0,18 mm (34 Gauge) to 3,4 mm (10 Gauge) . It applies to regular-walled, thin-walled, extra-thin-walled and ultra-thin walled needles, and to opaque and translucent colours.

This International Standard is not applicable to pen-needles.

## 2 Terms and definitions

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

### 2.1

#### **designated metric size**

outer diameter designation of the tubing as defined in [Table 1](#)

Note 1 to entry: It is expressed in millimetres.

### 2.2

#### **gauge**

legacy size designation

Note 1 to entry: A particular gauge size corresponds to a designated metric size defining limits for outer diameters.

## 3 Colour code

The colour shall indicate the nominal outer diameter of the tube of the needle and shall be as given in [Table 1](#).

[Annex A](#) contains certain guidance to commonly applied colour reference systems for opaque materials.

**Table 1 — Colour code**

Designated metric size mm	Gauge	Colour
0,18	34	Orange
0,2	33	Black
0,23	32	Deep green
0,25	31	White
0,3	30	Yellow
0,33	29	Red
0,36	28	Blue-green
0,4	27	Medium grey
0,45	26	Brown
0,5	25	Orange
0,55	24	Medium purple

**Table 1** (continued)

<b>Designated metric size mm</b>	<b>Gauge</b>	<b>Colour</b>
0,6	23	Deep blue
0,7	22	Black
0,8	21	Deep green
0,9	20	Yellow
1,1	19	Cream
1,2	18	Pink
1,4	17	Red-violet
1,6	16	White
1,8	15	Blue-grey
2,1	14	Pale green
2,4	13	Purple
2,7	12	Pale blue
3	11	Green-yellow
3,4	10	Olive brown

## Annex A (informative)

### Reference colour samples

**Table A.1 — Reference colour samples**

Designated metric size mm	Gauge	Colour	RAL reference	Pantone reference
0,18	34	Orange	2007	1575
			2003	157
			2008	164
0,2	33	Black	9004	Black 3
			9005	Black 4
			9017	Black 6
0,23	32	Deep green	6010	348
			6001	349
			6002	350
0,25	31	White	9003	11-0601
			9010	11-0602
			9016	11-0103
0,3	30	Yellow	1018	102
			1021	107
			1023	109
0,33	29	Red	3017	1797
			3018	711
			3031	187
0,36	28	Blue-green	5009	3025
			5001	302
			5020	309
0,4	27	Medium grey	7047	427
			7035	428
			7044	429
0,45	26	Brown	8016	7517
			8017	7518
			8015	7519
0,5	25	Orange	2007	1575
			2003	157
			2008	164
0,55	24	Medium purple	4001	666
			4005	667
			Not available	668

**Table A.1** (continued)

Designated metric size mm	Gauge	Colour	RAL reference	Pantone reference
0,6	23	Deep blue	5005	294
			5010	541
			5002	540
0,7	22	Black	9004	Black 3
			9005	Black 4
			9017	Black 6
0,8	21	Deep green	6010	348
			6001	349
			6002	350
0,9	20	Yellow	1018	102
			1021	107
			1023	109
1,1	19	Cream	1014	4545
			1015	4535
			1001	4527
1,2	18	Pink	Not available	196
			3015	197
			3014	701
1,4	17	Red-violet	Not available	2395
			4006	2405
			4008	2415
1,6	16	White	9003	11-0601
			9010	11-0602
			9016	11-0103
1,8	15	Blue-grey	7000	7544
			7031	7545
			7011	7546
2,1	14	Pale green	Not available	331
			6019	344
			6021	345
2,4	13	Purple	4001	666
			4005	667
			Not available	668



**Table A.1** (continued)

Designated metric size mm	Gauge	Colour	RAL reference	Pantone reference
2,7	12	Pale blue	5015	285 C <sup>1</sup>
			5012	2925 C <sup>1</sup>
			5024	7454 C <sup>1</sup>
3	11	Green-yellow	Not available	367
			6018	368
			Not available	369
3,4	10	Olive brown	6007	554
			6008	553
			6015	5605

**RAL Colour palette:**

RAL CLASSIC Colour palette K5, Edition 2012 used for definition in ISO 6009

Two other colour palettes available from RAL were not taken into consideration:

RAL EFFECT Colour palette E2, Edition 2007

RAL DESIGN Colour palette D2, Edition 2013

**Manufacturer:**

RAL gemeinnützige GmbH

Siegburger Straße 39

53757 Sankt Augustin

Germany

Telephone (within Germany): 0 22 41 – 2 55 16 – 30

Telephone (international): +49 (0) 22 41 – 2 55 16 – 60

Fax: + 49 (0) 22 41 – 2 55 16 - 16

E-Mail: RAL-Colours@RAL-gmbH.de

**Pantone colour palette:**

PANTONE COLOR BRIDGE uncoated

PANTONE COLOR BRIDGE coated

**Manufacturer:**

Pantone LLC

590 Commerce Boulevard

Carlstadt, New Jersey

07072-3098 USA

Tel: 201-935-5500

Fax: 201-896-0242

E-Mail: [corpny@pantone.com](mailto:corpny@pantone.com)

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## Bibliography

- [1] ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*
- [2] ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*
- [3] ISO/TR 19244, *Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters*



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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 website-[www.bis.gov.in](http://www.bis.gov.in) or [www.standardsbis.in](http://www.standardsbis.in).

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### Amendments Issued Since Publication

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