

BS EN ISO 6009:2016



BSI Standards Publication

Hypodermic needles for single use — Colour coding for identification

National foreword

This British Standard is the UK implementation of EN ISO 6009:2016. It supersedes BS EN ISO 6009:1994 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Hypodermic needles for single use - Colour coding for identification (ISO 6009:2016)

Aiguilles hypodermiques non réutilisables - Code de couleurs pour l'identification (ISO 6009:2016)

Medizinische Einmalkanülen - Farbcodierung zur Identifizierung (ISO 6009:2016)

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European foreword

This document (EN ISO 6009:2016) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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The text of ISO 6009:2016 has been approved by CEN as EN ISO 6009:2016 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#).

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This fourth edition cancels and replaces the third edition (ISO 6009:1992), which has been technically revised. It also incorporates a Technical Corrigendum ISO 6009:1992/Cor.1:2008.

The main changes to the previous edition of ISO 6009 introduced by this revision are the following:

- a) broadening of the range of needles to designated needle size down to 0,18 mm;
- b) review of the use of instrumentally determined colour zones (chromaticity and luminance index) as used in previous editions to specify opaque colours and has decided that instrumental measurement is not practicable;
- c) revision of [Annex A](#);
- d) deletion of Annex 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.

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 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)

Designated metric size mm	Gauge	Colour
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 ¹
			5012	2925 C ¹
			5024	7454 C ¹
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: corpnj@pantone.com

Web: www.pantone.com

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- [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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