ICS 11.040.10, 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA Máj 2022

STN	**Anestetické a dýchacie prístroje Používateľské značky na injekčné striekačky obsahujúce lieky používané počas anestézie Farby, konštrukcia a technické požiadavky (ISO 26825: 2020)**	**STN EN ISO 26825** 85 2117

Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance (ISO 26825:2020)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/22

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 26825

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ICS 11.040.10; 11.040.25

English Version

Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance (ISO 26825:2020)

Matériel d'anesthésie et de réanimation respiratoire - Étiquettes apposées par l'utilisateur sur les seringues contenant des médicaments utilisés pendant l'anesthésie - Couleurs, aspect et propriétés (ISO 26825:2020)

Anästhesie und Beatmungsgeräte - Aufkleber für Spritzen mit Arzneimitteln zur Anwendung bei der Anästhesie, die vom Anwender angebracht werden - Farben, Design und Leistung (ISO 26825:2020)

This European Standard was approved by CEN on 7 February 2022.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Contents

Page

European foreword

The text of ISO 26825:2020 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 26825:2022 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by August 2022, and conflicting national standards shall be withdrawn at the latest by August 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 26825:2020 has been approved by CEN as EN ISO 26825:2022 without any modification.

INTERNATIONAL STANDARD

ISO 26825

Second edition
2020-10

Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance

Matériel d'anesthésie et de réanimation respiratoire — Étiquettes apposées par l'utilisateur sur les seringues contenant des médicaments utilisés pendant l'anesthésie — Couleurs, aspect et propriétés

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This second edition cancels and replaces the first edition (ISO 26825:2008), which has been technically revised. The main changes compared to the previous edition are as follows:

— change of the former requirement on the drug name into a recommendation in 5.4.1;

— revision of the labels for benzodiazepines, suxamethonium, muscle relaxant reversal drugs and adrenaline;

— addition of a requirement on the size of diagonal stripes on the label in 5.4.4;

— revision of the indication of the concentration of the drug on the label;

— addition of recommendations on labelling of ready mixed drugs;

— deletion of the colour fluorescent red;

— revision of Table 1 on background colour coding, Table 2 on representation of colours and Table A.1 on examples of alternative colour designations, and merging of the relevant information into one table (Table 1).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

INTERNATIONAL STANDARD ISO 26825:2020(E)

Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance

CAUTION — The use of colours is intended only as an aid in the identification of drug groups and does not absolve the user from the duty of reading the label and correctly identifying the drug prior to use.

1 Scope

This document gives requirements for labels attached to syringes so that the contents can be identified just before use during anaesthesia. It covers the colour, size, design and general properties of the label and the typographical characteristics of the wording for the drug name.

NOTE National or regional regulations might require additional labelling, which can include bar coding. No requirements for this additional labelling are given.

2 Normative references

There are no normative references in this document.