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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 26825:2022 sisaldab Euroopa standardi EN ISO 26825:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 26825:2022 consists of the English text of the European standard EN ISO 26825:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 09.02.2022.	Date of Availability of the European standard is 09.02.2022.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10, 11.040.25

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 26825

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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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 26825:2022 E

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.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 26825:2020 has been approved by CEN as EN ISO 26825:2022 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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 General

4.1 Adhesive requirements

The label shall be self-adhesive and shall withstand the following test:

a) Apply the label to a 10 ml polyethylene syringe for at least 12 h at (23 ± 2) °C.

NOTE Polyethylene was chosen as the material of the test syringe because it has poor adhesion properties and represents the "worst case".

b) Immerse the syringe and label in a 50 % solution (volume fraction) of isopropanol in water for 5 min.

c) After immersion, remove the syringe from the liquid, hold vertically and allow it to air dry for 5 min.

d) The label shall not move, curl or lift at the edge when touched by hand.

4.2 Labels provided as a tape

If the labels are provided as a tape, the location where the tape shall be cut between labels shall be perforated or clearly marked. If there is backing material, the label shall be easily separable from it and from adjacent labels.