SLOVENSKI STANDARD
oSIST prEN ISO 3826-2:2026

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Plastični zložljivi vsebniki za človeško kri in krvne komponente - 3. del: Grafični simboli, ki se uporabljajo na označbah in navodilih (ISO/DIS 3826-2:2026)

Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets (ISO/DIS 3826-2:2026)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 2: Graphische Symbole zur Verwendung auf Etiketten und Beipackzetteln (ISO/DIS 3826-2:2026)

Poches en plastique souple pour le sang et les composants du sang - Partie 2: Symboles graphiques à utiliser sur les étiquettes et les notices d'utilisation (ISO/DIS 3826-2:2026)

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ICS:

01.080.20	Grafični simboli za posebno opremo	Graphical symbols for use on specific equipment
11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

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DRAFT International Standard

ISO/DIS 3826-2

Plastics collapsible containers for human blood and blood components —

Part 2: Graphical symbols for use on labels and instruction leaflets

Poches en plastique souple pour le sang et les composants du sang —

Partie 2: Symboles graphiques à utiliser sur les étiquettes et les notices d'utilisation

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Foreword

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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 document 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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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 3826-2:2008), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Key 1 in Figure B.1 has been corrected;

— update of normative references;

— complete editorial revision.

A list of all parts in the ISO 3826 series can be found on the ISO website.

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.

Introduction

This document has been prepared to:

— reduce the need for multiple translations of words into national languages;

— simplify and rationalize the labelling of blood treatment and transfusion devices which are medical devices used in critical situations, thereby reducing risk of misidentification, promoting safety for the patient and reducing the amount of training required by healthcare personnel;

— promote the movement of blood treatment and transfusion devices across national boundaries;

— support the general safety and performance requirements of relevant EU Directives.

The meaning of many of these graphical symbols should be self-evident. The meaning of others will become clear with use or when viewed in the context of the device itself. If appropriate, the meaning of symbols should be explained in accompanying literature when provided. Annex A provides examples of how the symbols specified in this document can be used. These are illustrative only and do not represent the only ways in which requirements of this document can be met.