



SLOVENSKI STANDARD
SIST EN ISO 3826-1:2019/A1:2023

01-junij-2023

Plastični zložljivi vsebniki za človeško kri in krvne komponente - 1. del: Običajni vsebniki - Dopolnilo A1 (ISO 3826-1:2019/Amd 1:2023)

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers - Amendment 1 (ISO 3826-1:2019/Amd1:2023)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel - Änderung 1 (ISO 3826-1:2019/Amd 1:2023)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles - Amendement 1 (ISO 3826-1:2019/Amd 1:2023)

Ta slovenski standard je istoveten z: EN ISO 3826-1:2019/A1:2023

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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SIST EN ISO 3826-1:2019/A1:2023 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 3826-1:2019/A1

April 2023

ICS 11.040.20

English Version

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers - Amendment 1 (ISO 3826-1:2019/Amd1:2023)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles - Amendement 1 (ISO 3826-1:2019/Amd 1:2023)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel - Änderung 1 (ISO 3826-1:2019/Amd 1:2023)

This amendment A1 modifies the European Standard EN ISO 3826-1:2019; it was approved by CEN on 30 January 2023.

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

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European foreword

This document (EN ISO 3826-1:2019/A1:2023) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" 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 October 2023, and conflicting national standards shall be withdrawn at the latest by October 2023.

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 3826-1:2019/Amd 1:2023 has been approved by CEN as EN ISO 3826-1:2019/A1:2023 without any modification.

INTERNATIONAL
STANDARD

ISO
3826-1

Third edition
2019-09

AMENDMENT 1
2023-03

**Plastics collapsible containers
for human blood and blood
components —**

**Part 1:
Conventional containers**

AMENDMENT 1

*Poches en plastique souple pour le sang et les composants du sang —
Partie 1: Poches conventionnelles*

SIST AMENDEMENT 1 2019/A1:2023

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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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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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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).

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