INTERNATIONAL STANDARD

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AMENDMENT 1

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

AMENDEMENT 1

PROOF/ÉPREUVE

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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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Part 1:
Conventional containers

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6.2.5

Replace the text with the following:

6.2.5.1 General

The instructions for use shall indicate if the plastics container is intended for freezing and/or irradiation applications.

The user shall be aware of particular requirements from any other regulatory authority (e.g. EDQM Guide to the preparation, use and quality assurance of blood components).

6.2.5.2 Freezing

This requirement refers primarily to plasma-freezing bags.

The plastics container, filled to half of its nominal capacity with water as specified in ISO 3696, shall withstand a slow freezing to and storage at −80 °C for 24 h, subsequent immersion in water at (37 ± 2) °C for 60 min, and returning to a temperature of (23 ± 2) °C. The plastics container shall meet the requirements of 5.6.3, 5.9, 6.2.7, and 6.2.8.

Plastics containers intended to be shock-frozen (blast frozen) shall be validated for this application.

If a refrigerant solution is used, the plastics container may be enclosed in a protective bag to avoid direct contact between the refrigerant solution and the plastics container.

6.2.5.3 Ionizing irradiation

This requirement refers primarily to containers intended to store irradiated blood components.

The plastics container, filled to nominal capacity with water (for containers with a nominal capacity of greater 350 ml the maximum filling volume shall not exceed 350 ml), shall withstand a maximum irradiation dose of 50 $m^2 \cdot s^{-2}$ (Gy) using validated irradiation equipment.

The plastics container following irradiation shall meet the requirements of 5.6.3, 5.9, 6.2.4, 6.2.7 and 6.2.8.

The integrity of plastics containers intended to be irradiated shall be validated for this specific application.