International

ISO 1135-5

Transfusion equipment for medical use —

Part 5: Transfusion sets for single use with pressure infusion apparatus

Matériel de transfusion à usage médical —

Partie 5: Transfuseurs non réutilisables avec des appareils de perfusion sous pression

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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 cancels and replaces the first edition (ISO 1135-5:2015), which has been technically revised.

The main changes are as follows:

— the definitions of the different ‘volume’ terms have been amended;

— 6.11 “Injection site” has been amended regarding the use of needle-free injection ports and Luer-activated devices;

— 6.13 “Protective caps” has been amended to clarify how to prevent contamination;

— 6.14 has been completely revised and renamed to clarify the described volume;

— Clause 8 has been revised to meet state-of-the-art methodology:

  — biological risk assessment shall follow ISO 10993-1;

  — sterility subclause remains;

  — subclause on hemocompatibility assessment has been revised;

— Clause 9 “Labelling” has been updated especially regarding the referenced ISO 15223-1;

— Clause 10 “Packaging” has been amended by adding a reference to ISO 11607-1;

— Annex A “Physical test” has been amended by a general introduction on the pre-conditioning. In addition, the description of the test for leakage has been extended;

— Annex C “Biological tests” has been deleted;

— the Normative references have been updated.

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