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Plastic containers for intravenous injections

Récipients en plastique pour injections intraveineuses

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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 fourth edition cancels and replaces the third edition (ISO 15747:2018), which has been technically revised.

The main changes are as follows.

— The term “cannula” has been replaced by the better suited term “needle” throughout the document. Per common understanding, cannulas are flexible, while needles, such as 23G needles called for in A.10, as well as other so-called “transfer needles/devices” used to add medication through an injection point, whether they are sharp or blunt, need to be rigid to pierce said injection port and are typically made of stainless steel or moulded thermoplastic.

— Addition of subclauses 4.1.1, 4.2.1 and 4.3.1 to highlight the normative nature of the introductory subclauses A.1, A.2, B.1 and C.1, as they contain important information to properly conduct the tests. Those introductory clauses were not directly referenced in any requirement since they don’t describe test methods related to said requirements. Addition of those three subclauses led to the renumbering of all other subclauses of Clause 4.

— Usage of terms “procedure” and “method” clarified: “method” now used as way to perform a test, while “procedure” denotes a process to reach a certain state (e.g. thinking process or working process).

— Addition of a new Annex E (Rationale and guidance), to provide explanations about the history of the development of the standard and to summarize the different arguments discussed within ISO/TC 76 during the elaboration of the document.

— Addition of a new Annex F (Sustainability) and a new Annex G (Attributive and variable testing).

— Addition of references to pharmacopoeias pertaining to chemical requirements, in 4.2.

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