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Second edition
2021-02

Infusion equipment for medical use — Part 12: Check valves for single use

*Matériel de perfusion à usage médical —
Partie 12: Clapets antiretour à usage unique*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

This second edition cancels and replaces the first edition (ISO 8536-12:2007), which has been technically revised. It also incorporates the Amendment ISO 8536-12:2007/Amd.1:2012.

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

- the title of this document has been amended by "for single use";
- [Clause 3](#) has been completely reviewed;
- [Clause 4](#), 'Designation' refers now to 'Labelling';
- the requirement on tensile strength has been deleted;
- the connecting requirements have been aligned to the ISO 80369 series;
- [Clause 11](#) has been added;
- [Annex A](#) has been completely updated and aligned with the physical requirements given in [Clause 6](#);
- the normative references have been updated;
- a bibliography has been added;
- complete editorial review.

A list of all parts in the ISO 8536 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.