



International Standard

ISO 8536-13

Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact

Matériel de perfusion à usage médical —

*Partie 13: Régulateurs de débit gradués non réutilisables avec
contact à fluide*

**Second edition
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Foreword

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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 8536-13:2016), which has been technically revised.

The main changes are as follows:

- in [Clause 3](#), the new term “activation” has been added;
- [Figure 1](#) in [Clause 4](#) has been amended to include markings on the open and close positions;
- former Clause 8 “Biological requirements” has been deleted due to the specified product being non-sterile;
- [Annex A](#) has been amended by a general introduction (see [A.1](#)) on the pre-conditioning of the sample;
- Annex [A.5](#) has been amended to align the flow rate test method with other flow rate test methods in the ISO 8536 series;
- the Bibliography has been updated.

A list of all parts in the ISO 8536 series can be found on the ISO website.

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