
**Infusion equipment for medical use —
Part 14:
Clamps and flow regulators for
transfusion and infusion equipment
without fluid contact**

Matériel de perfusion à usage médical —

*Partie 14: Clamps et limiteurs de débit pour appareils de transfusion
et de perfusion sans contact à fluide*

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

- *Part 1: Infusion glass bottles*
- *Part 2: Closures for infusion bottles*
- *Part 3: Aluminium caps for infusion bottles*
- *Part 4: Infusion sets for single use, gravity feed*
- *Part 5: Burette infusion sets for single use, gravity feed*
- *Part 6: Freeze drying closures for infusion bottles*
- *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*
- *Part 8: Infusion sets for single use with pressure infusion apparatus*
- *Part 9: Fluid lines for single use with pressure infusion equipment*
- *Part 10: Accessories for fluid lines for single use with pressure infusion equipment*
- *Part 11: Infusion filters for single use with pressure infusion equipment*
- *Part 12: Check valves*
- *Part 13: Graduated flow regulators for single use with fluid contact*
- *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

Infusion equipment for medical use —

Part 14:

Clamps and flow regulators for transfusion and infusion equipment without fluid contact

1 Scope

This part of ISO 8536 specifies requirements for non-sterile clamps and flow regulators used as a subcomponent to control the flow of intravenous solutions and/or blood components through sterilized infusion and blood transfusion sets and blood bag assemblies without fluid contact.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

clamp

subcomponent applied externally to an infusion/transfusion equipment without fluid contact with an “on/off” function used to terminate or initiate the flow of fluid through the line

3.2

flow regulator

subcomponent with or without graduation applied externally to an infusion/transfusion equipment without fluid contact to control the flow of fluid through the line

3.3

flow rate

volume per time

4 Design

Clamps and flow regulators shall be designed for their application in controlling fluid transfer in infusion/transfusion equipment. These devices shall be designed for safe use, avoiding accidental operation, and shall not puncture or damage the flexible tubing during their operation.

Typical design for clamps and flow regulators is shown in [Figures 1 to 3](#).