



BSI Standards Publication

Medical devices — Non-electrically driven portable infusion devices

National foreword

This British Standard is the UK implementation of ISO 28620:2020. It supersedes BS ISO 28620:2010, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Medical devices — Non-electrically driven portable infusion devices

*Dispositifs médicaux — Diffuseurs portables de médicaments, non
mus électriquement*





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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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*.

This second edition cancels and replaces the first edition (ISO 28620:2010), which has been technically revised. The main changes compared with the previous edition are as follows:

- the Scope has been amended to explicitly cover neuraxial and intravascular or hypodermic applications;
- the requirements on components and their fittings have been aligned with the appropriate parts of the ISO 80369 series, i.e. ISO 80369-1, ISO 80369-6 and ISO 80369-7;
- the requirements on filter and tubing have been updated;
- a test method for the efficiency of the fluid filter has been added;
- [Table 1](#), which gives information to be provided by the manufacturer, has been updated.

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