INTERNATIONAL STANDARD

ISO 28620

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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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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 28620 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

Medical devices — Non-electrically driven portable infusion devices

1 Scope

This International Standard specifies essential requirements and related test methods for non-electrically driven portable infusion devices[1)]. It applies to devices designed for continuous (fixed or adjustable) flow and/or for bolus application.

These devices can be used in health care and non-health care settings. They can be applied or administered by health care professionals or by the intended patient.

These devices can be pre-filled by the manufacturer or filled before use by a health care professional or the intended patient.

This International Standard does not apply to

— electrically driven or electrically controlled infusion pumps that are covered by IEC 60601-2-24;

— implantable devices;

— enteral feeding pumps;

— transdermal delivery devices;

— devices where the energy for infusion is not provided by the device or through active intervention by the patient (e.g. devices only powered by gravity).

2 Normative references

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

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

1) Thereafter called “device”.