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Concentrates for haemodialysis and related therapies

Concentrés pour hémodialyse et thérapies apparentées



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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.

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 13958 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 13958:2002), which has been technically revised.

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Introduction

The requirements and goals established by this International Standard will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This International Standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and government representatives, to develop a standard for performance levels that could be reasonably achieved at the time of publication. The term “consensus” as applied to the development of voluntary medical device standards does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests must be merged.

Throughout this International Standard, recommendations are made to use ISO-quality water. Therefore, it is recommended to review ISO 13959 along with this International Standard.

This International Standard does not cover the dialysis fluid that is used to clinically dialyse patients. Dialysis fluid is covered in ISO 11663. The making of dialysis fluid involves the proportioning of concentrate and water at the bedside or in a central dialysis fluid delivery system. Although the label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

In addition, this International Standard does not cover haemodialysis equipment, which is addressed in the new edition of IEC 60601-2-16.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard; and
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.