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Cardiovascular implants and extracorporeal systems — Plasmafilters

Implants cardiovasculaires et systèmes extracorporels — Filtres pour plasma

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Foreword

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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 13960 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 13960:2003), which has been technically revised.

Introduction

This International Standard contains requirements and acceptance criteria (including test methods) for safety related parameters for plasmafilters. Only those requirements that are specific to plasmafilters have been included. Non-specific requirements are covered by references to other International Standards, listed in Clause 2. This International Standard does not cover matters related to toxicity. Such issues are covered in relevant parts of ISO 10993.