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Implants for surgery — Active implantable medical devices —

Part 5: Circulatory support devices

Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 5: Dispositifs d'assistance circulatoire

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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).

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For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-5:2010), which has been technically revised. The main change compared to the previous edition is as follows:

— alignment to the revised ISO 14708-1:2014.

A list of all parts in the ISO 14708 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document specifies requirements for safety and performance of active implantable circulatory support devices. It amends and supplements ISO 14708-1:2014, hereinafter referred to as ISO 14708-1. The requirements of this document take priority over those of ISO 14708-1.

Heart failure is a major public health problem. It is estimated that worldwide more than 5 million people die per year due to heart failure. In addition, it accounts for a large portion of health care expenditure and rehospitalisation (see Reference [35]). Circulatory support devices are needed for promoting myocardial recovery following acute heart failure as well as long-term support until eventual transplantation or permanent therapy. Circulatory support devices may be fully implanted, partially implanted, or delivered by percutaneous approach. The growth of heart failure is expected to increase with the aging population (see Reference [30]).

The requirements of this document supplement or modify those of ISO 14708-1.

In this document, terms printed in italics are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in italics unless the concept thus qualified is also defined.

Information is also provided in Annex A that explains the relationship between ISO/TR 14283, ISO 14708-1 and this document.

Notes on this document are provided in Annex B for information.

Annex C provides guidance on pre-clinical in vitro and in silico evaluation. Annex D provides information device hazards, associated failure modes, and evaluation methods. All annexes are informative.