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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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# 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.

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# Implants for surgery — Active implantable medical devices —

# Part 5: Circulatory support devices

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## 1 Scope

This document specifies requirements for safety and performance of active implantable circulatory support devices, including type tests, animal studies and clinical evaluation requirements.

NOTE The device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify main requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

The tests that are specified in this document are type tests and are to be carried out on a sample of a device to assess device behavioural responses and are not intended to be used for the routine testing of manufactured products.

Included in the scope of this document are:

— ventricular assist devices (VAD), left or right heart support;

— total artificial hearts (TAH);

— biventricular assist devices (biVAD);

— percutaneous assist devices;

— paediatric assist devices.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

IEC 60068-1:2013, *Environmental testing — Part 1: General and guidance*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: rough handling shocks, primarily for equipment-type specimens*

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IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: vibration, broadband random and guidance*

IEC 60601-1:2018, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 62304:2006, *Medical device software — Software life cycle processes*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and ISO 14971 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

**3.1**
**accessory device**
separate part of a circulatory support system that is not essential to the primary function of the circulatory support system

Note 1 to entry: Examples are programming units, monitoring units and alternative *power source* (3.18) units.

**3.2**
**artificial valve**
**prosthetic valve**
component of the circulatory support system that directs the unidirectional flow of the blood into and out of the pump

**3.3**
**atrial cuff**
connector between the right or left atrial ring after resection of the natural ventricle and the inlet of the right or left blood pump in *total artificial heart* (3.31) replacement

**3.4**
**biVAD**
**biventricular assist device**
configuration in which two VADs are used to support both ventricles respectively

**3.5**
**cavitation**
sudden formation and collapse of low-pressure bubbles in the blood by means of mechanical forces

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