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STANDARD

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**Cardiac defibrillators — Connector  
assembly for implantable defibrillators —  
Dimensional and test requirements**

*Défibrillateurs cardiaques — Ensemble connecteur pour défibrillateurs  
implantables — Prescriptions dimensionnelles et d'essai*



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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.

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.

International Standard ISO 11318 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee SC 2, *Cardiovascular implants*, in collaboration with IEC Sub-Committee 62D, *Electromedical equipment*.

Annexes A and B form an integral part of this International Standard. Annexes C, D and E are for information only.

## Introduction

The purpose of this International Standard is to specify a standard connector assembly, DF-1, to provide interchangeability between implantable defibrillator leads and defibrillator pulse generators from different manufacturers. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

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# Cardiac defibrillators — Connector assembly for implantable defibrillators — Dimensional and test requirements

## 1 Scope

This International Standard specifies a unipolar connector assembly, DF-1, intended for use in connecting implantable defibrillator leads to implantable defibrillator generators which do not produce more than 1 kV/50 A peak output. Essential dimensions and performance requirements are specified along with test methods.

This International Standard does not specify other connector features such as fastening means and material. Nor does it address all aspects of functional compatibility or reliability of different implantable defibrillator leads and implantable defibrillator generators assembled into an implantable defibrillator system.

NOTE 1 Defibrillator connector systems not conforming to this International Standard may be safe and reliable, and may have clinical advantages.

## 2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7436:1983, *Slotted set screws with cup point*.

## 3 Definitions

For the purposes of this International Standard, the following definitions apply.

**3.1 connector assembly:** Assembly, consisting of a lead connector and a connector cavity, for the elec-

trical and mechanical connection to a defibrillator generator.

**3.2 lead connector:** That part of the connector assembly which is inserted into the connector cavity.

**3.3 connector cavity:** That part of the connector assembly which is part of the defibrillator generator.

**3.4 sealing mechanism:** Circumferential barrier intended to maintain the electrical insulation between electrically isolated parts of the connector assembly.

**3.5 seal zone:** Surface in the connector cavity and on the lead connector on which one or more seals are intended to bear.

**3.6 sealing mechanism zone:** Portion of the lead connector (and optionally the connector cavity) in which the sealing mechanism is permitted.

**3.7 connector cavity GO gauge:** Tool for assessing the ability of a connector cavity to accept a lead connector of maximum size.

**3.8 lead connector GO gauge:** Tool for assessing the ability of a lead connector to be inserted into a connector cavity of minimum size.

**3.9 lead connector pin:** Conductive element of the lead connector intended to contact the connector cavity conductive element.

**3.10 defibrillator system:** Assembly consisting of defibrillator generator and a defibrillator lead(s).

**3.11 defibrillator lead:** Means of electrically connecting a defibrillator generator to the patient.

**3.12 defibrillator generator:** Portion of the defibrillator system which includes the power supply and electronic circuits.