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National Standards
Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Fax: (01) 807 3838

ACTIVE IMPLANTABLE MEDICAL DEVICES - PART 2-1: PARTICULAR REQUIREMENTS FOR ACTIVE IMPLANTABLE MEDICAL DEVICES INTENDED TO TREAT BRADYARRHYTHMIA (CARDIAC PACEMAKERS)

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Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

Dispositifs médicaux implantables actifs - Partie 2-1: Règles particulières pour les dispositifs médicaux implantables actifs destinés à traiter la bradyarythmie (stimulateurs cardiaques)

Aktive implantierbare medizinische Geräte - Teil 2-1: Besondere Festlegungen für aktive implantierbare medizinische Geräte zur Behandlung von Bradyarrhythmie (Herzschrittmacher)

This European Standard was approved by CEN and CENELEC on 1 September 2003.

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CEN Management Centre:
rue de Stassart, 36 B-1050 Brussels

CENELEC Central Secretariat:
rue de Stassart, 35 B-1050 Brussels

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Foreword

This European Standard has been prepared by the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (CEN/CLC JWG AIMD). Members of the Joint Working Group were nominated by one of the member bodies of either CEN or CENELEC.

The text of the draft was submitted to the formal vote and was approved by CEN and CENELEC as EN 45502-2-1 on 2003-09-01.

This European Standard, together with EN 45502-2-2, supersedes EN 50061:1988 + A1:1995 + A1:1995/corrigendum Oct. 1995.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2004-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2005-09-01

This European Standard has been prepared under mandates given to CEN and CENELEC by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of Directive 90/385/EEC.

EN 45502-2-1:2004 is identical to EN 45502-2-1:2003 issued by CENELEC on 2003-12-19.

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