Indian Standard

IMPLANTS FOR SURGERY — ACTIVE IMPLANTABLE MEDICAL DEVICES

PART 1 GENERAL REQUIREMENTS FOR SAFETY, MARKING AND FOR INFORMATION TO BE PROVIDED BY THE MANUFACTURER

1 Scope

ThispartofISO14708specifiesrequirementsthataregenerallyapplicabletoactiveimplantablemedical devices.

NOTE For particular typesof activeimplantablemedical devices, thesegeneral requirementsaresupplementedor modifiedbytherequirementsof particular standardswhichformadditional partsof ISO14708. Special careisrequiredin applyingthispartofISO14708toactiveimplantablemedicaldeviceswherenoparticularstandardexists.

Theteststhat arespecifiedinthispart of ISO14708aretypetestsintendedtobecarriedout onsamplesof a devicetoshowcompliance,andarenotintendedtobeusedfortheroutinetestingofmanufacturedproducts.

ThispartofISO14708isapplicablenotonlytoactiveimplantablemedical devicesthatareelectricallypowered,but alsotothosepoweredbyotherenergysources(forexamplegaspressureorsprings).

ThispartofISO14708isalsoapplicabletosomenon-implantablepartsandaccessoriesofthedevices(see3.3).

2 Normativereferences

Thefollowingnormativedocumentscontainprovisionswhich,throughreferenceinthistext,constituteprovisionsof thispartofISO14708.Fordatedreferences,subsequentamendmentsto,orrevisionsof,anyofthesepublications donotapply. However, partiestoagreementsbasedonthispart of ISO14708areencouragedtoinvestigatethe possibilityof applyingthemost recent editionsof thenormativedocumentsindicatedbelow. For undated references, thelatest editionof thenormativedocument referredtoapplies. Membersof ISOandIECmaintain registersofcurrentlyvalidInternational Standards.

ISO8601:1988, *Dataelementsandinterchangeformats—Informationinterchange—Representationofdatesand times*

ISO11607:1997, *Packagingforterminallysterilizedmedicaldevices.*

ISO14155:1996, *Clinicalinvestigationofmedicaldevices*

ISO15223 : 2000,*Medicaldevices—Symbolstobeusedwithmedicaldevicelabels,labellingandinformationtobe supplied*

IEC 60068-2-14:1986, *Environmentaltesting — Part 2: Tests, Test N: Change of temperature*

IEC 60068-2-32:1990, *Environmentaltesting — Part 2: Tests, Test Ed: Free fall (Procedure 1)*

IEC60068-2-47:1999, *Environmentaltesting—Part 2-47:Test methods—Mountingof components,equipment and other articlesfor vibration,impact and similar dynamictests*

IEC60068-2-64:1993, *Environmentaltesting—Part2: Test methods—Test Fh: Vibration,broad-bandrandom (digitalcontrol)andguidance.*

IEC60601-1 : 1988,*Medicalelectricalequipment—Part1:Generalrequirementsforsafety.Amendment1:1991 andAmendment2:1995.*

IEC60601-1-1:1992, *Medical electricalequipment—Part1: General requirementsforsafety—1. Collateral standard:Safetyrequirementsformedicalelectricalsystems.*

IEC60601-1-2 : 1993, *Medical electricalequipment—Part 1: General requirementsforsafety—2. Collateral standard:Electromagneticcompatibility–Requirementsandtests.*

IEC60601-1-4 :1996, *Medicalelectricalequipment—Part1:Generalrequirementsforsafety—4.Collateral standard:Programmableelectricalmedicalsystems.*

IEC60601-2-27:1994, *Medical electrical equipment—Part2: Particular requirementsfor the safety of electrocardiographicmonitoringequipment*

IEC61000-4-2:1995, *Electromagneticcompatibility(EMC)—Part 4: Testingandmeasurement techniques—Section2:Electrostaticdischargeimmunitytest.BasicEMCPublication.*