National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 50103:1995

ICS 11.040.01
03.120.01

National Standards
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GUIDANCE ON THE APPLICATION OF EN 29001 AND EN 46001 AND OF EN 29002 AND EN 46002 FOR THE ACTIVE (INCLUDING ACTIVE IMPLANTABLE) MEDICAL DEVICE INDUSTRY

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Údarás um Chaighdeáin Náisiúnta na hÉireann

DECLARATION

OF

SPECIFICATION

ENTITLED

GUIDANCE ON THE APPLICATION OF EN 29001 AND EN 46001 AND OF EN 29002 AND EN 46002 FOR THE ACTIVE (INCLUDING ACTIVE IMPLANTABLE) MEDICAL DEVICE INDUSTRY

AS

THE IRISH STANDARD SPECIFICATION FOR

GUIDANCE ON THE APPLICATION OF EN 29001 AND EN 46001 AND OF EN 29002 AND EN 46002 FOR THE ACTIVE (INCLUDING ACTIVE IMPLANTABLE) MEDICAL DEVICE INDUSTRY

Forfás in exercise of the power conferred by section 20 (3) of the Industrial Research and Standards Act, 1961 (No. 20 of 1961) and the Industrial Development Act, 1993 (No. 19 of 1993), and with the consent of the Minister for Enterprise and Employment, hereby declares as follows:

1. This instrument may be cited as the Standard Specification (Mechanical properties of fasteners - Part 7 : Torsional test and minimum torques for bolts and screws with nominal diameters 1mm to 10mm (ISO 898-7 : 1992)) Declaration, 1995.

2. (1) The Specification set forth in the Schedule to this declaration is hereby declared to be the standard specification for Mechanical properties of fasteners - Part 7 : Torsional test and minimum torques for bolts and screws with nominal diameters 1mm to 10mm (ISO 898-7 : 1992). The Schedule comprises the text of EN 50103 : 1995.

(2) The said standard specification may be cited as Irish Standard/EN 50103:1995 or as I.S./EN 50103:1995.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50103

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Descriptors: Medical electrical equipment, active medical device, quality system, quality assurance, manufacturing

English version

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry

Guide pour l'application des EN 29001 et EN 46001 et des EN 29002 et EN 46002 à l'industrie des dispositifs médicaux actifs (comprenant les dispositifs actifs implantables)

Anleitung für die Anwendung von EN 29001 und EN 46001 und von EN 29002 und EN 46002 für die aktive (einschließlich implantierbare aktive) Medizinprodukte herstellende Industrie

This European Standard was approved by CENELEC on 1994-07-05. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

Ref. No. EN 50103:1995 E

Foreword

This European Standard was prepared by the Working Groups "Quality systems for active implantable medical devices" and "GMP for active medical devices" of Technical Committee CENELEC TC 62, Electrical equipment in medical practice, with advice from the joint CEN/CENELEC "Coordinating Working Group on Quality Supplements".

The draft was submitted to the IEC-CENELEC parallel vote as prEN 61272 in October 1993. Although approved at IEC level, the IEC was not in a position to issue the document as an International Standard because the documents EN 46001 and EN 46002 referred to have not been approved on an international basis.
The draft was approved by CENELEC as EN 50103 on 1994-07-05.

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) 1995-12-15
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1995-12-15

INTRODUCTION

This European Standard gives guidelines for SUPPLIERS of ACTIVE MEDICAL DEVICES (including ACTIVE IMPLANTABLE MEDICAL DEVICES) who wish to ensure that they comply with EN 46001 (Quality systems - Medical devices - Particular requirements for the application of EN 29001 for medical devices) or EN 46002 (Quality systems - Medical devices - Particular requirements for the application of EN 29002 for medical devices). Additionally this European Standard is intended to contribute to a common understanding between SUPPLIERS and third parties.

This European Standard is meaningful only if read in conjunction with EN 29000/ISO 9000 and EN 46000 series standards. The guidelines are not intended as a replacement or supplement to ISO 9004, which has its own very distinct relationship with the EN 29000/ISO 9000 series of standards.

NOTE 1 - The guidance given in this document has been arranged so that the numbers of the subclauses are the same as those of the requirements of EN 29001 and EN 46001, to which the guidance always refers. The respective subclause numbers of EN 29002 and EN 46002 are provided in parentheses.

NOTE 2 - Not all requirements of EN 29001 and EN 46001 and of EN 29002 and EN 46002 are addressed in this European Standard. It is, therefore, generally advisable to read these guidelines in parallel with ISO 9004.

NOTE 3 - This document provides guidelines both for manufacturers of ACTIVE MEDICAL DEVICES and ACTIVE IMPLANTABLE MEDICAL DEVICES. Most of the wording of this document is drafted to cover both PRODUCT groups: the class ACTIVE MEDICAL DEVICE includes ACTIVE IMPLANTABLE MEDICAL DEVICES by definition. In a few places the guidance applies specifically only to ACTICE IMPLANTABLE MEDICAL DEVICES or to non-implantable ACTIVE MEDICAL DEVICES: such exceptions are clearly indicated in the text.