EESTI STANDARD EVS-EN 50103:2001

Juhised EN 29001, EN 46001, EN 29002 ja EN 46002 standardite rakendamiseks aktiivsete meditsiiniseadmete (sealhulgas aktiivsete implantaatide) tööstuses

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 50103:2001 sisaldab Euroopa standardi EN 50103:1995 ingliskeelset teksti.	This Estonian standard EVS-EN 50103:2001 consists of the English text of the European standard EN 50103:1995.
Standard on kinnitatud Eesti Standardikeskuse 16.04.2001 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 16.04.2001 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 03.120.10, 11.040.01

EUROPEAN STANDARD

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EN 50103

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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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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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.

CONTENTS

1 Scope

The guidelines contained in this European Standard are applicable to a QUALITY SYSTEM as specified by EN 29001 and EN 46001 or EN 29002 and EN 46002. This European Standard does not add to, or otherwise change the requirements of those standards, and is not intended to be used directly in the assessment of a SUPPLIER'S QUALITY SYSTEM.

The guidelines provide concepts and objectives which should be considered by a SUPPLIER of ACTIVE MEDICAL DEVICES while developing and maintaining his QUALITY SYSTEM.

This European Standard:

- provides examples of how to meet the requirements, while recognizing that other methods which achieve the same ends are equally acceptable;
- gives general advice on how to meet the requirements;
- draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with QUALITY SYSTEMS used in the ACTIVE MEDICAL DEVICE industry.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

International registration :	Title:	European registration :
ISO 8402:1994	Quality management and quality assurance Vocabulary	---

ISO 9001:1987	Quality systems - model for quality assurance in design/development, production, installation and servicing	EN 29001:1987
ISO 9002:1988	Quality systems - model for quality assurance in production and installation	EN 29002:1988
----------	Quality systems - medical devices - particular requirements for the application of EN 29001	EN 46001:1993
----------	Quality systems - medical devices - particular requirements for the application of EN 29002	EN 46002:1993

3 Terminology and definitions

3.1 Terminology

3.1.1 *should*
This auxiliary verb indicates that a certain course of action is preferred but not necessarily required.

3.1.2 *may*
This auxiliary verb indicates a course of action often followed by established SUPPLIERS of similar ACTIVE MEDICAL DEVICES.

3.1.3 *specific*
This adjective, when used with parameters or conditions, refers to a particular value or standardized arrangement, usually to those required in a European Standard or a legal requirement.

3.1.4 *specified*
This adjective, when used with parameters or conditions, refers to a value or arrangement to be chosen for the purpose under consideration and indicated usually in accompanying documents.

3.2 Definitions

NOTE - In this European Standard, terms printed in capital letters are used as defined in EN 46001 and ISO 8402 or as given in subclauses 3.2.1 to 3.2.4. Annex A provides an index of the terms used.
Where a defined term is used as a qualifier in another term it is not printed in capital letters, unless the concept thus qualified is also defined.