Suunised mitteaktiivset meditsiinitehnikat käsitlevate standardite EN 29001 ja 46001 ning EN 29002 ja EN 46002 rakendamiseks.

Guidance on the application of EN 29001 and 46001 and of EN 29002 and EN 46002 for non-active medical devices

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 724:1999 sisaldab Euroopa standardi EN 724:1994 ingliskeelset teksti.	This Estonian standard EVS-EN 724:1999 consists of the English text of the European standard EN 724:1994.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks .	Date of Availability of the European standard is .
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Võtmesõnad: design, maintenance, manufacturing, medical equipment, quality, quality assurance, quality control, specifications,

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English version

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices

Guide d'application des EN 29001 et EN 46001 et des EN 29002 et EN 46002 pour les dispositifs médicaux non actifs

Anleitung zur Anwendung von EN 29001 und EN 46001 und von EN 29002 und EN 46002 für nicht-aktive Medizinprodukte

This European Standard was approved by CEN on 1994-10-27.

CEN 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 CEN 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 CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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

CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the Commission of the European Communities and the European Free Trade Association and supports essential requirements of the relevant EC Directives.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by April 1995 at the latest.

Annexes designated informative are given only for information. In this standard, annexes A, B and C are informative.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This European Standard has been written to give guidance to organizations providing a non-active medical device who wish to ensure that they will comply with EN 29001/EN 29002 and the particular requirements given in EN 46001/EN 46002. It is also intended to provide guidance for certifying and regulatory bodies.The guidance in this standard for the fulfilment of requirements should always be in relation to the products being manufactured and interpreted accordingly.

This standard needs to be read in conjunction with the EN 29000 series of standards with which compliance is sought. This standard is not intended as a replacement for EN 29004 which has its own very distinct relationship with the EN 29000 series of standards.

The combination of EN 29001/EN 46001 and EN 29002/EN 46002 embraces the principles of Good Manufacturing Practices (GMP) which have been in operation in the manufacture of non-active medical devices for a number of years.

This document seeks to assist in the transition from GMP to quality systems by presenting familiar concepts under the relevant paragraphs of EN 29001/EN 46001 and EN 29002/EN 46002.

The references which have been made to EN 29004 are not necessarily exhaustive but seek to identify sections of EN 29004 with particular relevance to the guidance in this document. Consideration of this document alone is not an alternative to understanding EN 29004 and it is therefore recommended that EN 29004 is first read and understood in its entirety. For ease in the use of this standard, references to clauses in EN 29004 have been cited within the framework of EN 29001 and EN 29002.

Annex A to this European Standard provides additional guidance on those elements of quality systems to which particular emphasis should be placed for medical devices which are supplied either sterile or to a defined standard of microbial or particulate cleanliness. The guidance in annex A is intended to be considered in addition to that provided in the body of the standard.

1. Scope

This European Standard provides guidance on the establishment and maintenance of the quality systems specified in EN 29001/EN 46001 or EN 29002/EN 46002 for the manufacture of non-active medical devices. It does not add to, or otherwise change, the requirements of those standards and is not intended to be used for the assessment of a manufacturer's quality system.

This European Standard provides examples of how to meet the requirements, recognising that other methods which achieve the same ends are equally acceptable ; gives general advice on how to meet the requirements; and draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with quality systems for non-active medical devices.

Annex A to this European Standard provides guidance on the elements of quality systems which are relevant to the manufacture of medical devices which are to be supplied either sterile or at a defined level of microbiological or particulate cleanliness.

The adoption of systems other than those described in this European Standard is not to be regarded as a non-compliance with EN 29001 and EN 29002 and/or the specific requirements in EN 46001 and EN 46002.

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.

EN 29001 : 1987 Quality systems - Model for quality assurance in design/development, production, installation and servicing

EN 29002 : 1987 Quality systems - Model for quality assurance in production and installation

EN 29004 : 1987 Quality management and quality system elements - Guidelines

EN 46001 : 1993 Quality systems - Medical devices - Particular requirements for the application of EN 29001

EN 46002 : 1993 Quality systems- Medical devices - Particular requirements for the application of EN 29002

3. Definitions

For the purpose of this standard the definitions given in EN 46001 and EN 46002 apply, together with the following :

3.1 contract

Any agreement between the supplier and the purchaser concerning the supply of product

NOTE : A contract may be in writing, verbal, or a combination of both.

3.2 design

Process of developing a product from concept to manufacture.

3.3 purchaser

Recipient of product and/or service delivered by the supplier.