

Richtlijnen voor de toepassing van
EN 29001 en EN 46001 en van EN 29002
en EN 46002 voor de industrie van
actieve medische produkten
(met inbegrip van actieve implantaten)

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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Dit document bevat de officiële Engelse versie van de Europese norm EN 50103, juni 1995.

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VOORBEELD
Preview

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Prijsklasse 60

Nederlands voorwoord

Voor de in deze norm vermelde andere normen bestaan in Nederland de volgende equivalenten:

<u>Vermelde norm:</u>	<u>Nederlandse norm:</u>	<u>Titel:</u>
EN 46001:1993	NEN-EN 46001:1994	Kwaliteitssystemen. Medische apparatuur. Bijzondere eisen voor de toepassing van EN 29001
EN 46002:1993	NEN-EN 46002:1994	Kwaliteitssystemen. Medische apparatuur. Bijzondere eisen voor de toepassing van EN 29002
ISO 8402:1994	NEN-ISO 8402:1994	Kwaliteitszorg en kwaliteitsborging. Termen en definities
ISO 9001:1987 ¹⁾	-	-
ISO 9002:1988 ²⁾	-	-

- 1) Inmiddels vervangen door een nieuwe druk, in Nederland overgenomen als NEN-EN-ISO 9001:1994
- 2) Inmiddels vervangen door een nieuwe druk, in Nederland overgenomen als NEN-EN-ISO 9002:1994

ICS 03.120.10; 11.040.00

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

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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

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 ACTIVE IMPLANTABLE MEDICAL DEVICES or to non-implantable ACTIVE MEDICAL DEVICES: such exceptions are clearly indicated in the text.

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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.

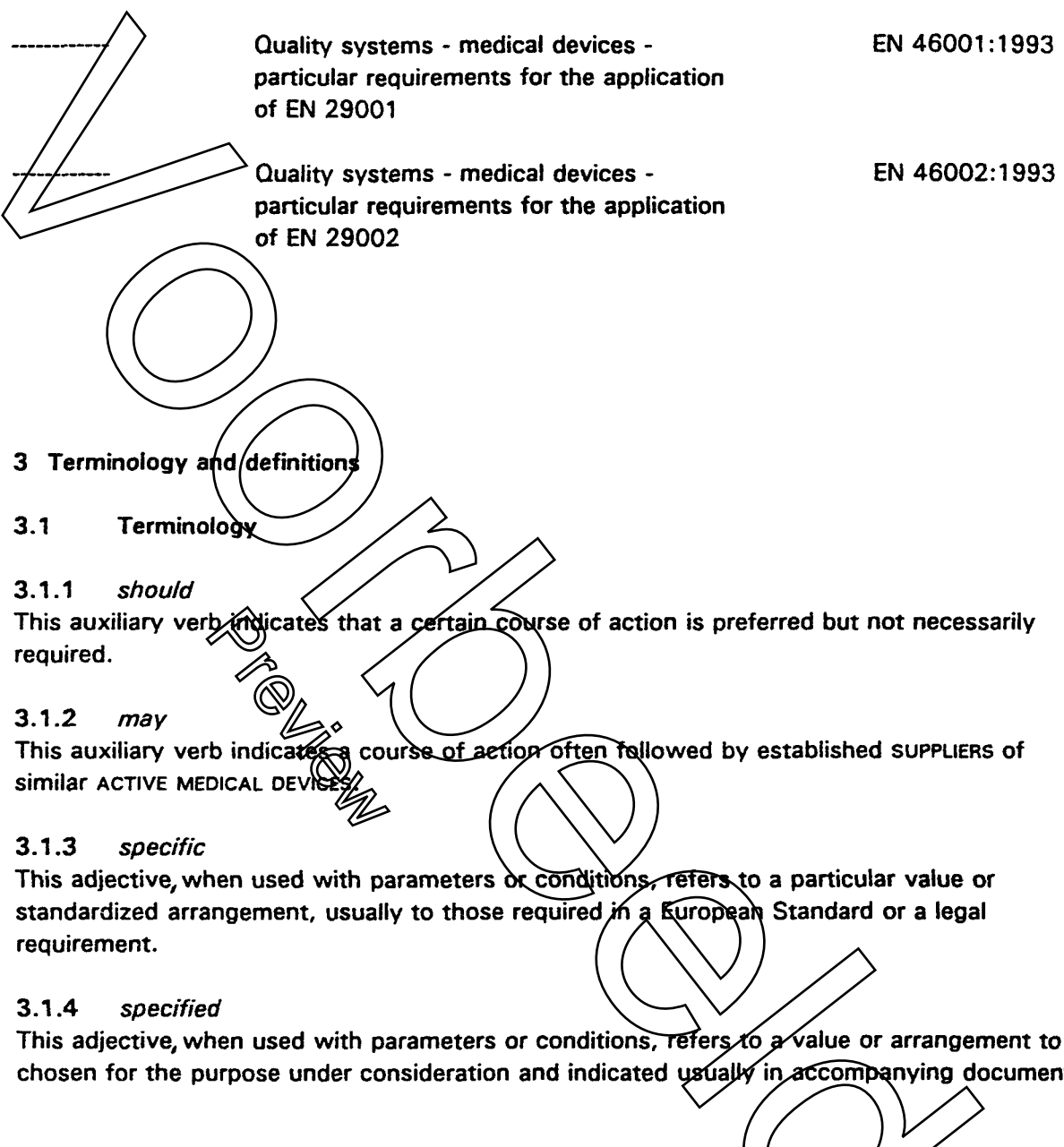
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registration :

Title:

ISO 8402:1994

Quality management and quality assurance
Vocabulary

European
registration :

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.

For the purposes of this European Standard, the definitions given in EN 46001 apply together with the following definitions.

ISO 8402 and

3.2.1 *specified requirements*

Either

- requirements prescribed by the PURCHASER and agreed by the SUPPLIER in a contract for PRODUCT;
- requirements prescribed by the SUPPLIER which are perceived as satisfying a market need;
- regulatory requirements

3.2.2 *device history record*

A compilation of records containing the complete production history of a finished device

3.2.3 *device master record*

A compilation of records containing the design, SPECIFICATION, complete manufacturing PROCEDURES, QUALITY ASSURANCE requirements and labels and LABELLING of a finished device

3.2.4 *custom-made devices*

Any MEDICAL DEVICE specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his authority, specific design characteristics and is intended to be used only for an individual named patient

4 Guidance on quality system requirements

4.1 Management responsibility

4.1.1 QUALITY POLICY

[Also applies to 4.1.1 of EN 29002 and EN 46002; see note 1 in Introduction]

When defining and documenting the SUPPLIER'S QUALITY POLICY, commitment and Objectives, the management should express the policy in language that the staff can understand. The policy should be specific to the PRODUCT supplied and to the staff employed.

Management should be seen to demonstrate commitment to their QUALITY POLICY both actively and on a continuing basis.

4.1.2 Organization

4.1.2.1 Responsibility and authority

[Also applies to 4.1.2.1 of EN 29002 and EN 46002]

The SUPPLIER'S staff should be aware how the scope, responsibility and authority of their roles contribute to the achievement of corporate quality objectives. Staff should have a clear understanding of their freedom to take action to ensure quality objectives are met.

Additionally, for the manufacture of MEDICAL DEVICES, EN 46001 and EN 46002 require that management documents the organizational structure, to show the levels of responsibility, authority and staff inter-relationships. These inter-relationships are commonly shown on organization charts.

Staff having the authority to change the QUALITY SYSTEM or the processes controlled by the QUALITY SYSTEM should be identified and their job requirements defined.

Duties to be shared between the job specifications include

- the control and maintenance of the QUALITY SYSTEM, aimed at the prevention of quality deficiencies against the SPECIFIED REQUIREMENTS;
- the control of a CORRECTIVE ACTION system that prevents the recurrence of the quality deficiencies, by ensuring that changes to the QUALITY SYSTEM intended to prevent manufacture of non-conforming PRODUCT are effective;
- organising formal and systematic MANAGEMENT REVIEW of the QUALITY SYSTEM, to ensure that it remains appropriate to the quality objectives;
- the expert assessment of any PROCEDURES for microbiological control, and the validation protocols for all processes where microbiological control is of significance;
- managerial control of any sterilization processes, and ensuring these operate within VALIDATED parameters.

4.1.2.2 VERIFICATION resources and personnel [Also applies to 4.1.2.2 of EN 29002 and EN 46002]

VERIFICATION resources include the provision of adequate time for the test and VERIFICATION PROCEDURES to be carried out.

Management may consider obtaining specialist professional control through a sub-contract to another organization, while employing their own staff to implement agreed PROCEDURES in a routine manner.

4.1.2.3 Management representative [Also applies to 4.1.2.3 of EN 29002 and EN 46002]

A SUPPLIER of ACTIVE MEDICAL DEVICES should appoint a management representative within his organization whose function is to maintain and coordinate the implementation of the QUALITY SYSTEM. If the management representative has other functions to perform, these should not cause a conflict of interests.

To ensure that the management representative's duties remain clearly defined, they alone should be authorized to delegate their defined authority.

The management representative should have the responsibility and authority for ensuring that EN 29001 in combination with EN 46001 or EN 29002 in combination with EN 46002 are

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