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Estetisk kirurgi – Tjänster

Aesthetic surgery services

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Europastandarden EN 16372:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 16372:2014.

The European Standard EN 16372:2014 has the status of a Swedish Standard. This document contains the official version of EN 16372:2014.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Estetisk kirurgi, SIS/TK 553.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 16372

December 2014

ICS 03.080.99; 11.020

English Version

Aesthetic surgery services

Services en chirurgie esthétique

Dienstleistungen in der ästhetischen Chirurgie

This European Standard was approved by CEN on 28 October 2014.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 16372:2014) has been prepared by Technical Committee CEN/TC 403 “Project Committee - Aesthetic surgery and aesthetic non-surgical medical services”, the secretariat of which is held by ASI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2015 and conflicting national standards shall be withdrawn at the latest by June 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard provides a set of requirements, which are deemed to be essential for the provision of aesthetic surgery services. However, attention is drawn to the fact that in certain countries specific national regulations apply and take precedence over this European Standard. Users of this European Standard are advised to inform themselves of the applicability or non-applicability for this European Standard by their national responsible authorities.

Furthermore, recommendations for other aspects of good practice are provided. The Bibliography provides a list of European and International Standards and other documents of general interest for aesthetic surgery services. This list is not intended to be exhaustive.

Emphasis is placed on defining requirements for the quality of the aesthetic surgery services offered in order to ensure patient safety.

Other factors which influence the overall quality of service include: qualifications and professional competencies, staff behaviour, facility design and choice of products and suppliers.

This European Standard is designed to bring the following advantages to those that adopt it:

— improvement in aesthetic surgery services which can enhance patient safety and reduce the risk of complications;

— to promote consistently high standards for aesthetic surgery service providers across Europe;

— enhance patient satisfaction.

Requirements for a quality management system based on EN ISO 9001:2008 for health care services are provided in EN 15224.

1 Scope

This European Standard addresses the requirements for clinical aesthetic practice: This covers surgical services to patients who want to change their physical appearance.

This European Standard provides recommendations for procedures for clinical treatment, including the ethical framework and general principles according to which clinical services are provided by all aesthetic practitioners. These recommendations apply before, during and after the procedure.

Dentistry[1)] procedures, reconstructive surgery procedures and aesthetic non-surgical medical procedures are excluded from the scope of this European Standard.

Aesthetic non-medical procedures (e.g. tattoos, piercing) which can be legally performed by non-physicians (e.g. beauty therapists, hairdressers) are excluded from the scope of this European Standard.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
aesthetic surgery services
services related to operative procedures where the primary aim is the change, the restoration or improvement of the appearance, the function and well-being at the request of an individual

Note 1 to entry: A list of aesthetic surgical procedures is included in Table 1.

2.2
adverse event
situation or event that has caused harm to a patient

Note 1 to entry: “Adverse event” is defined in ISO/TS 19218-1:2011, 2.1 as event associated with a medical device that led to death or serious injury of a patient, user or other person, or that might lead to death or serious injury of a patient, user or other person if the event recurs. This definition is consistent with guidance in GHTF/SG2/N54/R8:2006 and definition includes malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

Note 2 to entry: “Adverse event” is defined in Directive 2001/20/EC, Article 2 (m) as any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

[SOURCE: EN 15224:2012, 3.5.2, modified – Note 1 to entry and Note 2 to entry have been added.]

2.3
claim
expression of dissatisfaction with services or results where a personal compensation is explicitly or implicitly expected with a medical or financial compensation

Note 1 to entry: Medical or financial compensations are e.g. corrective operation, reimbursement or compensation under the terms of an insurance policy.

1) As defined in EN ISO 1942.

2.4
competence
demonstrated and qualified ability to apply knowledge and skills according with the law and regulations of the country where is practiced

2.5
complaint
expression of dissatisfaction made to an organization, related to its services and/or results, or the complaints-handling process itself, where a response or resolution is explicitly or implicitly expected

2.6
"cooling off" period
time between the end of the consultation where the procedure is proposed, its risks are explained and the detailed fee estimation is given, and the decision to proceed with this procedure

2.7
facility
establishment, medical or clinical

2.8
health
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

Note 1 to entry: This definition is from the preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

2.9
patient satisfaction
patient's perception of the degree to which the patient's requirements have been fulfilled

Note 1 to entry: Patient complaints are a common indicator of low patient satisfaction but their absence does not necessarily imply high patient satisfaction.

Note 2 to entry: Even when patient requirements have been agreed with the patient and fulfilled, this does not necessarily ensure high patient satisfaction.

Note 3 to entry: This definition was adapted from EN ISO 9000:2005, 3.1.4.

2.10
practitioner
medical doctor authorized by national competent authority to practice autonomously

2.11
reporting
notification of an adverse event, defective health care product or negligent service delivery to the relevant competent authorities

2.12
surgeon
medical doctor who has successfully completed a nationally recognized surgical speciality training programme and a final professional surgical examination and holds a certificate of completion of speciality surgical training and holds a license from the national competent authority