Irish Standard
I.S. EN 16372:2014

Aesthetic surgery services

I.S. EN 16372:2014

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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.

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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of an identical text or by endorsement, at the latest by June 2015 and conflicting national standards shall be withdrawn at the latest by June 2015.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.

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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.