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Aesthetic medicine services - Non-surgical medical treatments

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN 16844:2017+A1:2018 sisaldab Euroopa standardi EN 16844:2017+A1:2018 ingliskeelset teksti.	This Estonian standard EVS-EN 16844:2017+A1:2018 consists of the English text of the European standard EN 16844:2017+A1:2018.
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 20.06.2018.	Date of Availability of the European standard is 20.06.2018.
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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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English Version

Aesthetic medicine services - Non-surgical medical treatments

Services en médecine esthétique - Traitements médicaux, non chirurgicaux

Dienstleistungen in der ästhetischen Medizin - Nicht-chirurgische, medizinische Behandlungen

This European Standard was approved by CEN on 27 February 2017 and includes Amendment 1 approved by CEN on 20 December 2017.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 16844:2017+A1:2018) has been prepared by Technical Committee CEN/TC 403 “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of an identical text or by endorsement, at the latest by December 2018, and conflicting national standards shall be withdrawn at the latest by December 2018.

This document includes Amendment 1 approved by CEN on 12 December 2017.

This document supersedes EN 16844:2017.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

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 medicine services (non-surgical medical treatments).

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 medicine services. This list is not intended to be exhaustive.

Emphasis is placed on defining requirements for the quality of the aesthetic medicine 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 medicine services which can enhance patient safety and reduce the risk of complications;

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

— enhance patient satisfaction.

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

Requirements concerning the occupational health and safety of service providers and their staff at work are provided in relevant EU-Directives and national occupational health and safety legislation.

1 Scope

This European Standard addresses the requirements for certain aesthetic non-surgical medical treatments:

— treatments with resorbable injectables, botulinum toxin and micro needling;

— treatments with non-ablative fractional resurfacing and superficial peels, lasers and comparable energy based devices;

— treatments with fractional ablative lasers and comparable energy based devices and medium depth peels; and

— other treatments such as deep chemical peels, full ablative lasers and thread lifts.

This European Standard provides recommendations for aesthetic non-surgical medical treatments, including the ethical framework and general principles according to which aesthetic medicine services are provided by all practitioners and stakeholders of the aesthetic medical field. These recommendations apply before, during and after the treatment.

Any aesthetic medical treatment that goes deeper than the stratum corneum or which has, or claims to have, a biological effect beyond the stratum corneum (with or without instrument or devices) is included in the scope of this European Standard.

Aesthetic surgical procedures covered by EN 16372 and dentistry[1)] procedures are excluded from the scope of this European Standard.

Aesthetic non-medical treatments (tattooing and any treatment not affecting tissue deeper than the stratum corneum) which can be legally performed by non-physicians (e.g. tattooist, beauty therapists) 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 medicine services
services related to non-surgical medical treatments where the primary aim is the aesthetic change, restoration or improvement of the appearance, the function and/or well-being at the request of an individual with medical treatments, including the prevention and treatment of all kind of aesthetic concern, aging process, as well as the promotion of health

2.2
adverse event
unfavourable, unexpected or unintended temporary or permanent medical outcome to the patient

Note 1 to entry: "Adverse event" is defined in ISO/TS 19218-1:2011, 2.1 as an 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 the 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.

1) As defined in EN ISO 1942.