SLOVENSKI STANDARD
kSIST prEN 16844:2016

01-april-2015

Storitve estetske medicine - Nekirurški medicinski postopki

Aesthetic medicine services - Non-surgical medical procedures

Dienstleistungen in der ästhetischen Medizin - Nichtchirurgische, medizinische Eingriffe

Services en médecine esthétique - Interventions non chirurgicales médicales

Ta slovenski standard je istoveten z: **FprEN 16844**

ICS:

11.020.10	Zdravstvene storitve na splošno	Health care services in general

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

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FINAL DRAFT
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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

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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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European foreword

This document (FprEN 16844:2016) 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 document is currently submitted to the Formal Vote.

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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.

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1 Scope

This European Standard addresses the requirements for aesthetic medicine services to patients (non-surgical medical treatments).

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. The following aesthetic medical treatments are explicitly included in the scope of this European Standard:

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

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

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

— other aesthetic medical treatments such as deep chemical peels, full ablative lasers, hair transplantation (strip follicular unit transplant and follicular unit extraction) and thread lifts.

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 change, the 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
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 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

1) As defined in EN ISO 1942.