SLOVENSKI STANDARD
SIST EN 16844:2017

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Storitve estetske medicine - Nekirurški medicinski posegi

Aesthetic medicine services - Non-surgical medical treatments

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

Services en médecine esthétique - Traitements médicaux, non chirurgicaux

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Aesthetic medicine services - Non-surgical medical treatments

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European foreword

This document (EN 16844:2017) 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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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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.

Note 2 to entry: "Adverse event" is defined in 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.

2.3
competence
demonstrated and qualified ability to apply established scientific knowledge and skills according with the law and regulations of the country where is practiced

2.4
complaint
expression of dissatisfaction made to an organization or a practitioner, related to its services and/or results, or the complaints-handling process itself, where a response or resolution is explicitly or implicitly expected

2.5
"cooling off" period
time between the end of the consultation where the treatment is proposed, its risks are explained and the detailed fee estimation is given, and the decision to proceed with this treatment

2.6
facility
medical establishment where aesthetic medical treatments and procedures are performed

2.7
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.

2.8
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 9000:2015, 3.9.2.

2.9
practitioner
medical doctor authorized by national competent authority to practice medicine autonomously

2.10
reporting
notification of an adverse event, defective health care product or negligent service delivery to the relevant competent authorities

3 Competencies

3.1 General

3.1.1 During care activity, the practitioner shall control the competencies and capacities of person(s) doing work under his/her control. In addition, the medical establishment or the practitioner when he/she is the employer shall:

— determine the necessary competence of person(s) doing work under its control,

— ensure these persons are competent on the basis of training, skills and experience,

— where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken,

— retain documented information as evidence of competence,

— check the professional credentials and certified training of any professional applying to provide services under its responsibility.

3.1.2 If the aesthetic medicine services are delivered in a facility placed under supervision of a managing director, tasks described in 3.1.1 are under responsibility of both practitioner and managing director.

3.1.3 A registration for all practitioners performing aesthetic medical treatments is highly recommended within two years after publication of this European Standard. This register shall be national, certified, updated regularly and freely accessible to public in particular via the internet.

3.1.4 Directive 2005/36/EC demands formal basic medical training or specialist medical training to be recognized by a national competent authority.

3.1.5 The practitioner shall be a medical doctor authorized by national competent authority to practice medicine autonomously. Medical doctors authorized by the national competent authority are entitled to perform aesthetic medical treatments provided they are trained to these treatments. Assistants shall be medical doctors, who are in a recognized post-graduate training scheme, or authorized healthcare professionals who shall be working under the practitioner's direct supervision (direct supervision means to be physically present in the facility and able to respond and act according to the level of risk of the procedure).

3.1.6 Authorized healthcare professionals who are allowed to work under the practitioner's direct supervision shall have a professional training of at least 3 years.

3.1.7 Treatments with the use of lasers (class 2 and higher), light- (IPL and LED) and other energy based devices shall only be applied by qualified medical practitioners or by authorized healthcare professionals under practitioner's direct supervision.

3.1.8 Delegation of aesthetic medical treatments to practitioners who do not meet the national required competency shall not be allowed.

3.2 Training

3.2.1 A practitioner undertaking aesthetic medical treatments shall be trained in the respective treatment and this training shall be in compliance with the national competent authority's rule with a minimum of 3 years.

3.2.2 This training shall include outcomes which require a firm understanding of the basic science principles and evidence past which underpin treatments. This includes but is not exclusive to anatomy, physiology, pharmacology, immunology, pathology and mechanistic understanding in the respective treatment. Adequate knowledge is required to minimize inappropriate treatment or missed diagnosis. Knowledge of appropriate medical treatment options is required to optimize care. Recognition, diagnosis and the ability to manage complications relating to the relevant treatment is required.

3.2.3 Training should also include issues relating to ethics, psychology, consent and indemnity.

3.2.4 Training shall have a theoretical part and a practical part. The practical part of the training shall include a period of mentorship.

3.3 Continuous professional development (CPD) and continuous medical education (CME)

3.3.1 The practitioner shall:

a) maintain a valid registration by the national competent authorities of the country of practice and shall be involved in aesthetic practice on a regular basis; and

b) attend at least two CME accredited scientific events per year relevant to the sphere of aesthetic practice he/she performs or accreditation by the recognized national profession society.

3.3.2 Practitioners should preferably be member of a scientific society of their profession.

3.3.3 The continuous professional development undertaken shall enhance the practitioner's aesthetic practice and shall comply with the national educational requirements, relicensing and/or maintenance of practice agreement.

4 Management and communication with patients

4.1 Office staff/Booking arrangements

4.1.1 Hospitals, private establishments and private practices as well as all their medical or otherwise involved partners that are in a position to obtain patient's information shall have a confidentiality policy on protecting patient's privacy that is clear, understood and well known by all staff.

4.1.2 Financial inducements shall not be used towards patient, practitioners, staff, or other professionals to entice patients to consult or to have primary or combined aesthetic medical treatments. Economic considerations shall not override patient safety.

4.1.3 The consultation process is an opportunity to explore the concept of aesthetic medical treatment during which the patients shall have the implications, limitations and complications of treatment explained in language they understand, and with written information, including information presented on internet websites, for them to read later – it shall not involve any enticement to proceed. The consultation shall be done in a language both parties can understand and agree on.

4.1.4 The practitioner shall give impartial objective advice during the consultation for which a fee should be charged.

4.1.5 Cancellation policies shall be clear to the patient before any payment is made. A full refund of treatment fees shall be given if any pre-payment is made when the cancellation is within the "cooling off" period. Further arrangements are at the practitioner/clinics discretion but shall be clearly explained and set out in writing to patients.

4.1.6 The identification of any practitioner who performs the treatment and his/her speciality(ies) officially recognized by the national competent authority shall appear accurately and without ambiguity on letterheads and in all communications with the patient.

4.2 Patient consultation and assessment

4.2.1 The initial consultation shall be with the practitioner planning to undertake the aesthetic medical treatment.

4.2.2 Any other professional involved in the consultation process shall declare their name, expertise and qualifications and explain their role in the consultation, i.e. junior doctor in training, medical secretary or nurse. Practitioners should explain their role in screening or general health assessments. Nurses and non-medical professionals shall not be used as a shortcut for the practitioner who remains responsible for carefully assessing the patients and thoroughly undertaking the consent process (see 4.3). Practitioners should make themselves aware of regulators' guidance on remote prescribing. Practitioners should stay informed of guidelines and recommendations issued by competent authorities on telemedicine. It is good practice to wear an identification badge.

4.2.3 The practitioner shall be knowledgeable on the legislation and scientific literature on the treatments that he/she performs, the devices that he/she uses and the related safety issues.

4.2.4 The practitioner shall inform the patient on outcome indicators of the treatment that he/she performs, the devices he/she uses and be able to relate these outcome indicators with alternative treatments and devices.

4.2.5 The practitioner shall provide information that is understandable, timely, verifiable, accurate, complete, truthful and not misleading.

4.2.6 The practitioner shall provide information on the aim of the aesthetic medical treatment, benefits and harms, potential adverse consequences, including their frequency, alternative options and costs.

4.2.7 The practitioner shall provide transparency on the device or product used and possible alternatives. The rationale should include quality assurance and evidence. The practitioner shall provide background literature on the device or product and its use upon request.

4.2.8 At the end of the first consultation all patients shall be made aware of the risks and benefits of the proposed aesthetic medical treatment and shall be given the opportunity to digest the information and reflect on discussions before deciding to proceed.

4.2.9 Patients shall be made aware that further consultations are advisable and shall be encouraged for more risky/serious treatments. Patients should be informed that all consultations necessary to his/her consent are available to him/her but also duly informed of financial arrangement regarding this additional consultations.

4.2.10 Processes designed to reflect intention of outcome shall be used honestly. They shall not be used as a marketing tool. The limitations of the process shall be explained to the patient. Practitioners are advised that when example photographs are used to demonstrate outcomes, they should be accompanied by a disclaimer explaining the result cannot be guaranteed. Photographs shall not be modified to manipulate the outcome of the treatment.

4.2.11 The initial consultation(s) shall include

a) verification of the patient's condition to check medical feasibility of the planned treatment;

b) explore the specific aesthetic concerns;

c) assessment of patient's mental health/psychological state, including past psychological/mental health history where possible;

d) assessment of patient's expectations;

e) request relevant blood tests, if necessary;

f) request other relevant investigations;

g) request to communicate with relevant medical colleagues;

If in doubt, the practitioner should consult with or refer medical specialists.

h) if the patient is diagnosed with dysmorphobia no aesthetic medical treatments shall be performed;

i) pre-treatment tests and investigations shall be performed where appropriate. The practitioner shall inform the patient of the financial implications.

NOTE 1 The consultation is the start of the consent process, see 4.3.

NOTE 2 For consultation documentation, see 4.4.

4.2.12 If the practitioner deems that the environment in which the aesthetic medical treatment shall be performed, the devices or personnel are not fit for purpose the practitioner shall cancel the treatment.

4.3 Consent

4.3.1 Consent is an ongoing process extending from the time of first contact until the day of the aesthetic medical treatment; the majority of this process should be completed prior to booking.

4.3.2 The process shall include the following:

a) A clear explanation of the limitations of the aesthetic medical treatment and alternative treatments that may be available (including those not offered by the practitioner).

b) A clear explanation of the implications of the aesthetic medical treatment, including a clear explanation of the recovery time, duration of recommended absence from work and follow up plans.

c) The practitioner shall ensure that the patient clearly understands the risks involved with the planned treatment. The frequently occurring and the rare, but serious, complications should be fully explained and understood. A personal low rate of complication shall not be used to entice patient to undertake aesthetic medical treatment.

If data are available, personal risks should be stated in natural numbers and in relation to a number of treated patients, for example 1 out of 200 patients suffer from this side effect rather than 0,5 % of all patients.

d) The discussion shall include an explanation, in clear and understandable terms, of the practitioner's expectations of outcome and the relation between the outcome of the treatment with those of alternative treatments.

e) Written information shall be given as additional material and shall not take the place of an informed discussion. Practitioners should keep a record of both the discussions and of the information given to the patient. Both parties shall sign the informed consent form.

f) The practitioner shall ensure that the patient is informed of the limitation, implications and potential complications of the aesthetic medical treatment before booking it.

g) Until the initial consent process is complete (the time at which the patient fully understands the limitation, implications and potential complications of the aesthetic medical treatment) all monies, except for any previously declared non-refundable deposit, shall remain refundable.

h) No patient shall undergo an aesthetic medical treatment without completion of the consent process.

i) Aesthetic medical treatments for patients under the age of 18 years should be exceptional and linked to a documented medical assessment of the risks and benefits (health, social consequences). In those cases where it is clinically or psychologically necessary, the consent form shall be available in a legal form of words appropriate to the patient and/or their parents or guardians prior to the aesthetic medical treatment. Parental or guardian written agreement is mandatory.

j) The consent forms should be legible, understandable and signed by both parties.

k) The patient's consent shall be performed in a language both parties can understand and agree on.

4.4 Documentation

4.4.1 Medical records and notes shall be legible and understandable.

4.4.2 Medical records shall include patient identification (at least patient's full name, date of birth) and practitioner's signature as well as details of the serial numbers, batch, lot numbers for any devices or healthcare products that are used on a patient (e.g. dermal fillers and other injectables).

4.4.3 Digital records, where possible, shall include the practitioner's signature.

4.4.4 Medical records and notes shall be stored in appropriate secure facilities which are restricted to authorized persons.

4.4.5 Data protection in storage and handling of patient medical records and notes and details shall be ensured.

4.4.6 Medical records and notes shall be stored and handled for a period as legally required. If there is no legally required period it shall be at least 10 years.

4.4.7 Medical records, notes and photographs shall be available to the patients at their request, they should be available within a reasonable time, and any charge made for copying notes should be appropriate and reasonable.

4.4.8 Photographs should be taken for all patients undergoing aesthetic medical treatments. Photographs should be standardized where possible. Use of patient's pictures shall be strictly limited to the use authorized and signed by the patient in the consent form.

4.4.9 Patient's photographs shall be stored appropriately and confidentiality respected.

4.4.10 Where clinical photographs are used as clinical material and shown to other patients the appropriate consent shall be obtained.

4.4.11 Medical records shall only be released to third parties with the patients or legal representatives signed consent. Medical records shall only be released to third parties in case of patient's death.

4.5 Post-treatment follow up and patient satisfaction

4.5.1 Patients should receive a discharge summary when leaving the office or the facility, if applicable. This should include information about any aesthetic medical treatment performed, if applicable information about injected medicine/medical device used, post-treatment medication prescribed, clinical warning signs to watch for, contact details in the case of an emergency and details for first follow up consultation.

4.5.2 The practitioner shall inform the patients whom they will see at follow up and whom they can contact if there is a problem after treatment. It is best practice for the practitioner to see the patients personally. Some aesthetic medical treatments do not need dressings; the practitioner shall inform the patient accordingly.

4.5.3 Follow up shall be ensured, if necessary.

4.5.4 The practitioner shall keep a documented record of treatments, used devices and products and follow-up treatments.

4.5.5 In the case of late aesthetic/functional concerns the patient shall have the right to consult his/her practitioner. The patient shall be informed, that he/she remains responsible to make appropriate arrangements.

4.5.6 The patient survey should aim to be carried out upon discharge and long-term follow up.

4.5.7 Post-treatment information related to the treatment should be made available to the patient.

4.6 Advertising

Advertising should be avoided.

In countries, where advertising is allowed, the following applies:

a) National advertising rules and prohibition shall be followed by any individual, group or business wishing to communicate with, or advertise to, patients in the country concerned.

b) Advertising and marketing in any form shall be legal, decent, honest, truthful and socially responsible.

NOTE General guidance on social responsibility is provided in ISO 26000.

c) Advertorial transparency shall be assured and patients shall be aware from the text when an article is an advertorial.

d) Free consultation shall not be used as a marketing tool.

e) No models shall be used either in advertising or marketing and a declaration of conflict of interest shall be prominent.

f) Web, blog and any social media transparency shall be assured and if practitioners, or their employees, are involved in blog/web communications they shall declare their true identity.

g) The official professional status/qualification of the practitioner shall be clearly stated.