SLOVENSKI STANDARD
SIST EN 16372:2015

01-februar-2015

Storitve estetske kirurgije

Aesthetic surgery services

Dienstleistungen in der ästhetischen Chirurgie

Services en chirurgie esthétique

Ta slovenski standard je istoveten z: **EN 16372:2014**

ICS:

11.020.10	Zdravstvene storitve na splošno	Health care services in general

SIST EN 16372:2015 **en**

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

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Ref. No. EN 16372:2014 E

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of an identical text or by endorsement, at the latest by June 2015 and conflicting national standards shall be withdrawn at the latest by June 2015.

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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.

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

3 Competencies

3.1 General

3.1.1 The facility 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.

3.1.2 It shall be the responsibility of the clinical director or the responsible officer or the chief executive of the facility to check the professional credentials, certified training and criminal record of any professional applying to provide services in the facility.

3.1.3 A registration for all practitioners performing aesthetic surgical procedures is highly recommended within two years after publication of this European Standard.

3.1.4 Directive 2005/36/EC demands formal training recognized by a national competent authority. Medical training and education for practitioners according to UEMS syllabi is the guarantee that these practitioners have the education to perform aesthetic surgical procedures. National competent authorities may recognize additional training and education for the performance of aesthetic surgical procedures for practitioners who are not classified in UEMS monospeciality sections in their respective countries.

NOTE Aesthetic surgical procedures are already included in certain UEMS syllabi. UEMS is the Union Européenne des Médecins Spécialistes, European Union of Medical Specialists. The information on UEMS syllabi is given in Annex B.

3.1.5 Practitioners shall be monospeciality surgeons with aesthetic surgery in the field of their competence or otherwise competent, qualified medical doctors authorized by national competent authority to practise aesthetic surgery. The competent, qualified, experienced medical doctor shall have had appropriate basic surgical training of two years followed by at least four years training in aesthetic surgery supervised by a national authorized trainer in aesthetic surgery.

3.1.6 Anaesthesiologists shall be qualified specialists authorized by national competent authority to practice autonomously. Assistants shall be medical doctors, who are in a recognized post-graduate training scheme, or nurses or qualified operating room assistants who shall be working under the practitioner's supervision. 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 under their supervision.

3.1.7 Delegation of aesthetic surgical procedures to practitioners who do not meet the national required competency shall not be allowed.

3.2 Training

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

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

3.2.3 Training shall have a theoretical part and a practical part.

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.

3.3.2 The UEMS registered practitioner should preferably be a member of the national society for the UEMS recognized speciality. Other practitioners should preferably be a member of a recognized national profession society.

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 business partners that are in a position to get 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 to entice patients to consult or to have primary or combined aesthetic surgical procedures. Economic considerations shall not override patient safety.

4.1.3 The consultation process is an opportunity to explore the concept of aesthetic surgical procedure during which the patients shall have the implications, limitations and complications of procedure 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. No misunderstanding of the translation shall be accepted.

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 procedure 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 act 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 surgical procedure.

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 cosmetic advisors are neither trained nor insured to assess/discuss surgical risk, technique or outcome – they should 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). 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 procedures 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 procedure that he/she performs, the devices he/she uses and be able to relate these outcome indicators with alternative procedures 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, benefits and harms and potential adverse consequences of the aesthetic surgical procedure, the potential positive and negative results and options, including costs.

4.2.7 Where a device or implant is used the practitioner shall provide transparency on the choice of the particular device or implant and possible alternatives. The rationale should include quality assurance and evidence. The practitioner shall provide background literature on the device or implant 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 surgical procedure 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 are to be encouraged. 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.

4.2.11 The initial consultation(s) shall include:

a) assessment of the patient's general health (relevant examination);

b) explore the specific aesthetic concerns;

c) assessment of patient's mental health/psychological state;

d) assessment of patient's expectations;

e) request relevant blood tests;

f) request other relevant investigations;

g) the condition of the patient shall be assessed preferably according to ASA classification;

NOTE 1 The ASA (American Society of Anesthesiologists) physical status classification system is a system for assessing the fitness of patients before surgery, see [84].

h) request to communicate with relevant medical colleagues:

If in doubt, the practitioner should refer to a specialist in the relevant field. A consultation with an anaesthesiologist is mandatory in case of general anaesthesia/IV anaesthesia/nerve block anaesthesia preferably at least two days prior to the aesthetic surgical procedure.

NOTE 2 Nerve blocks are e.g. epidural, spinal or brachial plexus.

i) If the patient suffers from dysmorphobia no aesthetic surgical procedures shall be performed.

NOTE 3 The consultation is the start of the consent process, see 4.3.

NOTE 4 For consultation documentation, see 4.4.

NOTE 5 For communication with allied professional, see 4.13.

4.3 Consent

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

4.3.2 The process shall include the following:

4.3.2.1 A clear explanation of the limitations of the aesthetic surgical procedure and alternative procedures that may be available (including those not offered by the practitioner).

4.3.2.2 A clear explanation of the implications of the aesthetic surgical procedure, including a clear explanation of the recovery time, duration of recommended absence from work and follow up plans.

4.3.2.3 The practitioner and the anaesthesiologist, if this one participates in the aesthetic surgical procedure, shall ensure that the patient clearly understands the risks involved with the planned procedure. 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 surgical procedure.

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.

4.3.2.4 The discussion shall include an explanation, in clear and understandable terms, of the practitioner's expectations of outcome.

4.3.2.5 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 complication sheets.

4.3.2.6 The practitioner shall ensure that the patient is informed of the limitation, implications and potential complications of the aesthetic surgical procedure before booking it.

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

4.3.2.8 No patient shall undergo an aesthetic surgical procedure without completion of the consent process.

4.3.2.9 Aesthetic surgical procedures for patients under the age of 18 years should be exceptional and linked to a medical assessment of the risks and benefits (health, social consequences). In those cases where it is clinically or psychologically necessary (see Table 1) 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 surgical procedure. Both parents or every guardian written agreement is mandatory.

4.3.2.10 Consent forms should be legible and understandable.

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

4.3.2.12 The patients should be aware of the medical facilities available in the hospital/clinic to which they will be admitted (single rooms, day case facility, critical care facility).

4.3.2.13 The practitioner shall inform the patients of all potential financial implications for further necessary treatments should they suffer any complications of aesthetic surgical procedure(s). The terms and conditions of this service shall be explained prior to payment and the patient should receive a written explanation of these.

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. breast implants, 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.

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 surgical procedures. 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 Notes shall only be released to third parties, who are not involved in the clinical care, with the patients or legal representatives signed consent.

4.5 Investigations

4.5.1 Preoperative tests and investigations shall be performed where appropriate. The practitioner shall inform the patient of the financial implications.

4.5.2 Patients shall be made aware of the possible need for histological examination of any tissue specimens and the costs involved.

4.6 Cooling off period

The “cooling off” period depends on the aesthetic surgical procedure category (see 6.2) and on the patient's age (see 6.3.6). The minimum “cooling off” period should be:

a) for procedure category 1: 1 week;

b) for procedure category 1 where the patient is under the age of 18: 1 week;

c) for procedure category 2: 1 week.

4.7 Post-operative follow up and dressings

4.7.1 All patients shall receive a discharge summary when leaving the hospital or day case clinic, this should include information about any aesthetic surgical procedure performed, post-operative medication prescribed, clinical warning signs to watch for, contact details in the case of an emergency and details for first follow up consultation. Patient shall be given implant(s) card in case of implantation of any kind.

4.7.2 The practitioner shall inform the patients whom they will see at follow up and whom they can contact if there is a problem postoperatively. It is best practice for the operating practitioner to see the patients personally.

4.7.3 Follow up shall be ensured.

4.7.4 The practitioner shall keep a documented record of procedures, used devices and implants and follow-up procedures.

4.7.5 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.

4.7.6 The patient survey should aim to be carried out upon discharge and long-term follow up (1 year).

4.7.7 A post-operative questionnaire should be made available to the patient. This post-operative questionnaire shall address:

a) post intervention pain;

b) time until back to work;

c) would repeat intervention/operation;

d) would refer patients;

e) patient satisfaction with:

   1) hospital/facility;

   2) medical staff; and

   3) outcome/result;

f) the occurrence of postoperative nausea and vomiting after general anaesthesia.

The results of a patient satisfaction survey can give an indication of patient needs and satisfaction. The measurement shall assess important elements for quality improvement such as overall satisfaction level; key drivers for patient satisfaction, etc. Required improvements shall be documented and acted upon.