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ICS

English Version

## Aesthetic surgery services

Services en chirurgie esthétique

Dienstleistungen in der ästhetischen Chirurgie

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

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## Foreword

This document (prEN 16372:2011) has been prepared by Technical Committee CEN/TC 403 “Aesthetic surgery services”, the secretariat of which is held by ASI.

This document is currently submitted to the CEN Enquiry.

## Introduction

This European standard provides a set of requirements, which are essential for the service provision in aesthetic surgery. Furthermore, recommendations for other aspects of good practice are provided. However, it is recalled the attention to the fact that in certain countries specific national regulations apply and take precedence over this European Standard. 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 service offered in order to ensure patient safety.

Other factors which influence the overall quality of service include: 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 avoids the risk of complications and patient criticism about poor service;
- to promote consistently high standards for aesthetic surgery providers across Europe;
- enhance patient satisfaction and reduce criticism of poor service delivery.

Furthermore this European Standard intends to provide instruments for voluntary quality assurance and improvement of aesthetic surgery services.

## 1 Scope

This European Standard addresses the requirements for clinical aesthetic practice: This covers both surgical and non-surgical medical services to patients to change 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<sup>1)</sup> procedures are excluded from the scope of this European Standard.

Aesthetic non-medical procedures (e.g. tattoos, piercing) provided by non physicians (e.g. beauticians, masseurs, hairdressers) in non-medical facilities (such as spas, salons) 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**

operations and all other invasive medical procedures where the primary aim is the change, the restoration, normalization or improvement of the appearance, the function and well-being at the request of an individual

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1) as defined in EN ISO 1942

**2.2**  
**aesthetic medical procedure**  
surgical and/or minimally invasive procedure where the primary aim is the change, the restoration, normalization or improvement of the appearance, the function and well-being at the request of an individual, including treatments with injectables, lasers and other devices

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

NOTE This definition was adapted from ISO 9000:2005, 3.1.6.

**2.4**  
**complaint**  
expression of dissatisfaction made to an organization, related to its products, or the complaints-handling process itself, where a response or resolution is explicitly or implicitly expected

[ISO 10002:2004, 3.2]

**2.5**  
**"cooling off" period**  
time between the end of the first consultation where the procedure is proposed and the decision to proceed with the treatment

**2.6**  
**facility**  
medical establishment which depending on its type may consist of waiting room, reception, examination room, treatment room, physician office, staff room and supplementary room

**2.7**  
**health**  
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

NOTE 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**  
**non-surgical services**  
services related to minimally invasive procedures where the primary aim is the change, the restoration, normalization or improvement of the appearance, the function and well-being at the request of an individual

**2.9**  
**patient satisfaction**  
patient's perception of the degree to which the patient's requirements have been fulfilled

NOTE 1 Patient complaints are a common indicator of low patient satisfaction but their absence does not necessarily imply high patient satisfaction.

NOTE 2 Even when patient requirements have been agreed with the patient and fulfilled, this does not necessarily ensure high patient satisfaction.

NOTE 3 This definition was adapted from ISO 9000:2005, 3.1.4.

**2.10**  
**practitioner**  
medical doctor

### 3 Competencies

#### 3.1 General

A registration for all practitioners performing aesthetic medical procedures is highly recommended for the future. Aesthetic medical procedures can be subdivided into surgical and minimally invasive procedures.

Formal training recognized and approved by a national competent authority (see Directive 2005/36/EC) responsible for medical training and education according to UEMS syllabi is the only controllable guarantee that the practitioner has the competence and knowledge to perform aesthetic medical procedure.

NOTE 1 Aesthetic surgery and medical procedures are already included in certain UEMS syllabi. However, national medical bodies are encouraged to recognize aesthetic medicine with examination preferably on European level through UEMS.

The practitioner shall be a medical doctor. Assistants shall be medical doctors (medical doctors in training) or nurses who shall be working under the doctor's supervision.

Practitioners are permitted to perform aesthetic medical procedures provided that these procedures are in their UEMS syllabus and are allowed to them by national regulation.

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

NOTE 2 The UEMS is the Union Européenne des Médecins Spécialistes, European Union of Medical Specialists. The UEMS syllabi are reproduced for information in Annex B.

#### 3.2 Training

A practitioner undertaking category 2 and/or category 3 procedures (see 6.1) shall have had aesthetic surgical training as part of the syllabus.

It is advised that at least 1 year of specialisation after the basic trunk training is done before the practitioner proceeds into aesthetic surgery/medicine.

A practitioner undertaking category 1 procedures (see 6.1) including non specialist medical doctors shall have at least two years of general clinical experience and at least three years of specific training in category 1 procedures they intend to do; these training facilities shall be controlled regularly by the national competent authority.

Practitioners shall meet the national requirement of training of the country in which they practise.

The training shall include at least anatomy, physiology, pharmacology, immunology, pathology, goals of particular aesthetic medical procedures, techniques and handling complications of aesthetic medical procedures.

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

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 base;
- b) improve continuously his/her professional knowledge; and
- c) attend at least two CME accredited scientific events per year relevant to aesthetic medical procedures he/she performs.

The practitioner should preferably be a member of the national society for the UEMS recognized speciality.

The continuous professional development undertaken shall enhance the practitioner's aesthetic practice and shall comply with the national requirements for relicensing.

## **4 Management and communication with patients**

### **4.1 Office staff/Booking arrangements**

- a) The practice and all its business partners that are in a position to get patient's information shall have a confidentiality policy on protecting patient's privacy complying with legal requirements that is clear, understood and well known by all staff.
- b) Financial inducements shall not be used to entice patients to consult or to have primary or combined aesthetic medical procedures. Economic considerations shall not override patient safety.
- c) The consultation process is an opportunity to explore the concept of aesthetic medical 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 the patient's native language; if a translator is used this shall be agreed by both parties. If this is not possible, an international language to which both parties agree can be used. No misunderstanding of the translation shall be accepted.
- d) The practitioner shall give impartial objective advice during the consultation for which a fee should be charged. The individual practitioner shall not give free consultation.
- e) Cancellation policies shall be clear to the patient before any payment is made. A full refund 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.
- f) The official speciality recognized by the national competent authority shall be set out accurately and honestly on letterheads and in all communication with patients.

### **4.2 Patient consultation and assessment**

- a) The pre-treatment consultation shall be with the practitioner planning to undertake the aesthetic medical procedure.
- b) 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).
- c) At the end of the first consultation all patients shall be made aware of the risks and benefits of the proposed aesthetic medical procedure and shall be given the opportunity to digest the information and reflect on discussions before deciding to proceed.
- d) Patients shall be made aware that further consultations are advisable and are to be encouraged.
- e) Processes designed to reflect intention of outcome should be used honestly. They should not be considered 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.

- f) The pre-treatment consultation(s) shall include
- 1) assessment of the patient's general health (relevant examination);
  - 2) explore the specific aesthetic concerns;
  - 3) assessment of patient's mental health/psychological state;
  - 4) assessment of patient's expectations;
  - 5) request relevant blood tests;
  - 6) request relevant investigations;
  - 7) the condition of the patient shall be assessed 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 [81].

- 8) 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 recommended in case of general anaesthesia/IV anaesthesia/regional anaesthesia preferably two days prior to the aesthetic medical procedure. If the patient suffers from dysmorphobia no aesthetic medical procedures shall be performed.

NOTE 2 The consultation is the start of the consent process, see 4.3.

NOTE 3 For consultation documentation see 4.4.

NOTE 4 For communication with allied professional see 4.13.

### 4.3 Consent

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

The process shall include a clear explanation of

- a) The limitations of the aesthetic medical procedure and any alternative procedures that may be available (including those not offered by the practitioner).
- b) The implications of the aesthetic medical procedure, including a clear explanation of the recovery time and follow up plans.
- c) The practitioner and the anaesthesiologist, if participate in the aesthetic medical 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 medical procedure.

NOTE 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.
- 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 complication sheets.

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- f) The practitioner shall ensure that the patient is informed of the limitation, implications and potential complications of the aesthetic medical procedure before booking it.
- g) Until the pre-treatment consent process is complete (the time at which the patient fully understands the limitation, implications and potential complications of the aesthetic medical procedure) all monies, except for any previously declared non-refundable deposit, shall remain refundable.
- h) No patient shall undergo a aesthetic medical procedure without completion of the consent process.
- i) Aesthetic medical 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 2) 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 procedure. Both parents or every guardian written agreement is mandatory.
- j) Consent forms should be legible.
- k) The patient's consent shall be performed in the patient's native language; if a translator is used this shall be agreed by both parties.
- l) 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)
- m) The practitioner shall inform the patients of all foreseeable financial implications for further necessary treatments and if should they suffer any complications of aesthetic medical procedure. 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

- a) Notes shall be legible.
- b) Notes 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).
- c) Digital records, where possible, shall include the practitioner's signature.
- d) Notes shall be stored in appropriate secure facilities which are restricted to authorised persons.
- e) Storage and handling of patient notes and details shall comply with national data protection legislation.
- f) Notes shall be stored and handled for a period complying with national legislation.
- g) Notes and photographs shall be available to the patient at their request, they should be available within a reasonable time, and any charge made for copying notes should be appropriate and reasonable.
- h) Photographs shall be taken for all patients undergoing aesthetic medical procedures. Photographs should be standardized where possible. Use of patient's pictures shall be strictly restrained to the use authorized and signed by the patient in the consent form.
- i) Patient photographs shall be stored appropriately and confidentiality respected.
- j) Where clinical photographs are used as clinical material and shown to other patients the appropriate consent shall be obtained.
- k) Notes shall only be released to third parties, which are not involved in the clinical care, with the patients signed consent.

#### 4.5 Investigations

- a) Preoperative tests and investigations should be performed where appropriate. The practitioner should inform the patient of the financial implications.
- b) Patients should be aware of the 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 medical procedure category (see 6.1) and on the patient's age (see 6.2.5). The minimum “cooling off” period should be:

- a) for procedure category 1: No “cooling off” period;
- b) for procedure category 2: 1 day;
- c) for procedure category 2 and for patients under the age of 18: 1 week;
- d) for procedure category 3: 1 week.

#### 4.7 Post operative follow up and dressings

- a) All patients shall receive a discharge summary when leaving the hospital, this should include information about the aesthetic medical procedure performed, post operative medication prescribed, contact details in the case of an emergency and details for first follow up consultation. Patient should be given implant(s) card in case of implantation of any kind.
- b) 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 patient personally.
- c) Follow up appointments shall be made to ensure that the patient has access to his/her practitioner throughout the recovery period and until recovery is complete. If needed, a trained practitioner may act as a substitute if the practitioner is momentarily unavailable, but the follow up is the primary practitioner's responsibility. Patients have the obligation to make the appropriate arrangements to be able to attend their follow-up appointments.
- d) The practitioner shall declare any charges made for postoperative follow up/dressings up to the patient prior to surgery.
- e) In the case of late aesthetic/functional concerns the patient shall have the right to consult his/her practitioner. The patient remains responsible to make appropriate arrangements.

#### 4.8 Publicity and advertising

Advertising should be avoided. In the case of advertising the following applies:

- a) National advertising standards guidelines shall be followed by any individual, group or business wishing to communicate with, or advertise to, patients in any country.
- 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) Web and blog transparency shall be assured and if practitioners, or their employees, are involved in blog/web communications they shall declare their true identity.
- e) The official professional status/qualification of the practitioner shall be clearly stated.
- f) Practitioner's qualifications shall not be misrepresented and only the speciality listed in Annex B in which the practitioner is qualified shall be used. No terms shall be used that give patients or the public the impression of qualification in another speciality listed in Annex B.
- g) Referring professionals or other persons, including patients, shall not receive payment/remuneration or fee discount for making patient referrals. Patients shall expect that any referral is made in their best medical interest and does not involve any financial transaction.
- h) Further documentation: see Annex A.

#### **4.9 Travelling long distance for treatment**

Travelling long distance for treatment, also known as medical tourism, is rarely in the patient's best interest. In addition to the other sub-clauses in Clause 4 the following apply for travelling long distance for treatment:

- a) Patients shall be fully aware of the implications and risks of long distance travelling for treatment, they shall be aware that follow up, and the management of even minor complications/ dissatisfaction becomes a complicated process.
- b) Patients should not be reassured that pre- and post-operative appointments made with other, local, practitioners are equivalent to seeing the own practitioner at any time that may be necessary in the future.
- c) The importance of follow up should be emphasised. Documentation shall be made of discussions explaining the difficulties in the case of complications/ dissatisfaction with result. It is advised this is presented as a risk disclosure document and that it is signed by the patient.
- d) The patient should be aware of the risk of long distance travelling in the pre- and post-operative period.
- e) Insurance schemes that hand over the responsibility for looking after complications to third parties should not be recommended, they act as an inducement by making a dangerous process slightly more attractive but no less dangerous.
- f) Patients travelling long distances for treatment shall be informed of the professional indemnity arrangements of the practitioner and the clinic.
- g) Patients should be informed of tiers of responsibility should problems arise, they shall not be misled into believing that the company making the arrangements for their trip carries insurance.

Patients shall be informed by the service provider and/or the practitioner if he/she is travelling long distance to provide treatment. Travelling practitioners shall comply with the requirements in this European Standard.

#### **4.10 Medical indemnity and insurance**

- a) Patients shall be informed that the practitioner undertaking their aesthetic medical procedure possesses professional indemnity insurance that it is recognised as being appropriate and adequate for practice in the country involved. If the indemnity insurance is held outside the country of practice the practitioner should inform the patient of this and of any potential financial/ regulatory implications.
- b) Patients shall be informed that their practitioner/practitioners possesses adequate and appropriate indemnity for the operations being undertaken.
- c) The practitioner shall honestly declare all information regarding scope and location of aesthetic medical procedure to the insurer and thus ensuring that he/she remains insured.

- d) The practitioner should not act outside his/her area of expertise and insurance cover.

#### **4.11 Fees**

- a) Fees shall be transparent.
- b) Long term financial implications should be clear.
- c) Financial arrangement for complications should be explicit.
- d) Financial discounts shall not be used to encourage patients to consider aesthetic medical procedure or further procedures.
- e) Patients shall be informed of the terms and conditions of any payment made, particularly deposits.

#### **4.12 Arrangements for out of hours and emergency cover**

- a) Patients shall be provided with contact details for their practitioner/ clinic in the case of emergency.
- b) Out of hours care would normally be expected to be provided by the practitioner involved in the procedure, unless other arrangements have been clearly defined with healthcare staff/ facilities and explained to the patient.
- c) If a practitioner is not available for any reason they shall provide patients with appropriate and adequate cover, of a similar level of professional expertise. A thorough handover of patients is expected.
- d) Practitioners shall ensure that the facility within which they operate possesses appropriate service level agreements with critical care facilities if these are not available in the operating hospital.
- e) Practitioners/clinics performing aesthetic medical procedures under category 2 or category 3 (see 6.1) shall ensure that there is appropriate anaesthetic cover in the case of emergencies.

#### **4.13 Allied health professionals**

- a) Practitioners/clinics or, if applicable, the anaesthesiologist shall ensure that there is appropriate qualified anaesthetic cover.
- b) If the practitioner deems that the environment, in which the aesthetic medical procedure shall be performed, the devices or personnel is not fit for purpose the practitioner shall cancel the procedure.

NOTE See WHO Safe Surgery Checklist [83].

- c) If during his/her preoperative consultation, the anaesthesiologist thinks the planned program is not safe, his/her advice is final.

#### **4.14 Complaints**

- a) All practices/ companies offering aesthetic services shall have a clear complaints procedure and process.
- b) Patients should be aware of the practice/ companies complaints procedure.

#### **4.15 Confidentiality**

Patients shall expect that their confidentiality be respected at all times.

#### **4.16 Multiple aesthetic medical procedures**

The anaesthesiologist shall inform the practitioner and the patient if multiple aesthetic medical procedures may be against the patient's medical/health interest.

In case of multiple aesthetic medical procedures, the opinion during an operation of either the anaesthesiologist or the practitioner to finish only the ongoing procedure shall be final. The patient has to be fully informed if he/she is deemed to be at risk.

If during his/her preoperative consultation, the anaesthesiologist thinks the planned program is not safe, his/her advice is final and the full operation shall not take place.

#### **4.17 Safe timing of procedures**

- a) The practitioner shall inform the patient if the timing of their aesthetic medical procedure could introduce additional risks/complications (e.g. abdominoplasty at the time of caesarian sections).
- b) The practitioner shall inform the patient of additional risks associated with the aesthetic medical procedure if patient behaviour may modify these, e.g. smoking cessation and weight loss.
- c) The practitioner shall inform the patient if stopping of any medication would modify risk of the aesthetic medical procedure.
- d) The practitioner shall carefully consider the age of patient when considering whether aesthetic medical procedure is appropriate.

#### **4.18 Registration**

All practitioners and clinics shall be registered with the appropriate regulatory bodies in the country of practice, and these details shall be available to the public.

### **5 Facilities**

#### **5.1 General requirements**

##### **5.1.1 Facility**

- a) The entire facility (including corridors) shall be adequately maintained and cleaned.
- b) Smoking shall be prohibited in all patient care, public and hazardous areas.
- c) There shall be adequate lavatory and changing rooms or areas for patients and personnel. The lavatory facilities shall be sufficient to accommodate patients and staff needs and shall be regularly cleaned and maintained. The changing room or area for the patient shall ensure the privacy of the patient either within all room types or in the immediate proximity.
- d) Medical supplies and devices shall be stored in a safe manner to both maintain their cleanliness, sterility, functionality and to prevent injury to patients and personnel.
- e) Storage space shall be cleaned, maintained and free of litter and clutter.
- f) The facility shall be provided with general lighting.

### 5.1.2 Treatment rooms

- a) All treatment room shall be ventilated and temperature controlled. Room air conditioner, if present, should be individually regulated, regularly cleaned and stopped upon patient request.
- b) Floor tiles shall be sealed, if individual floor tiles are used.
- c) The ceiling shall be dust-tight.
- d) All windows to the outside shall be protected against the entrance of insects, e.g. by insect window screens, and shall be view protected.
- e) Each room shall be of a size adequate to allow for the presence of all devices and personnel necessary for the performance of the aesthetic medical procedures, and shall comply with the applicable legal requirements.
- f) Each room shall have wiring that meets the original manufacturer's specifications. There shall be no overloaded wall plugs or extensions, no altered grounding plugs and no wires that are broken, worn or unshielded.
- g) There shall be an adequate table or treatment chair with all necessary auxiliary devices.

### 5.1.3 Administrative and waiting area

- a) There shall be a waiting room adequately sized, clean, maintained and free of clutter and litter and appropriately lighted.
- b) There shall be an area for administrative activities providing adequate work space and appropriately lighted. The area for administrative activities shall be ventilated, temperature controlled for personnel comfort, cleaned and maintained.
- c) There shall be adequately sized storage space for supplies. The storage space shall be organized for easy access and inventory of supplies.

### 5.1.4 Safety and security

- a) Unauthorized individuals shall be deterred from entering by means of e.g. locks, alarms, or facility personnel.
- b) All openings to external space shall be protected against the entrance of lay individuals.
- c) A medical technician or equivalent shall annually inspect all devices (including electrical outlets, breaker/fuse boxes, and emergency light and power supplies). The technician shall report in writing that the devices are safe and operating according to the manufacturer's specifications.
- d) All medical hazardous waste shall be stored in suitable containers, and separated from general waste/refuse for special collection and handling.
- e) All medical hazardous wastes shall be disposed of in sealed, labelled containers in compliance with legal requirements.
- f) There shall be a Facility Safety Manual in accordance with regulations. The Facility Safety Manual shall provide employees with information relating to all hazardous chemicals used and methods to minimize exposure to personnel.
- g) Hazardous chemicals shall be labelled as such.

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- h) If a laser device is used, all applicable laser safety standards shall be addressed and implemented, including eye-protection, black-out blinds for laser rooms, analysis for skin types, test patches, etc. The room, in which the laser is used, shall be a closed room with no reflective surface and shall have a system for air evacuation. The window shall be opaque or obscured. Warnings and signage for laser in use shall exist to warn those whose health may be affected. When using ablative lasers, the laser shall be equipped with a fume extraction mobile device. Treatments with the use of lasers (class II and higher), light- (IPL and LED) and other energy based devices shall only be applied by qualified medical practitioners.

NOTE 1 Further guidance for the safe use of laser beams on humans is provided in IEC/TR 60825-8.

NOTE 2 See EU-Directive 2006/25/EC.

- i) If an X-Ray device is used, all appropriate safety measures shall be taken to protect patients and staff from injury. Staff shall wear dosimeter badges and records shall be maintained. Warnings and signage for indicating "X-ray in use" shall be in place to warn those whose health may be affected.

NOTE 3 See Council Directives 96/29/EURATOM and 97/43/EURATOM.

- j) Any explosive or combustible materials and supplies shall be stored and handled in a safe manner with ventilation according to regulations.
- k) Compressed gas cylinders shall be stored and handled in a safe manner according to national regulations.
- l) There shall be a written policy for specifying and mandating the use of appropriate personal protective equipment for each specific task in the facility.
- m) An adequate number and type(s) of fire extinguishers shall be available. Fire extinguishers shall be regularly inspected and shall conform to local fire codes throughout the facility.
- n) Fire exit signs shall be signposted and illuminated in compliance with legal requirements.
- o) In case of power failure there shall be sufficient emergency lights for exit routes and patient care areas.
- p) Passage and hallways shall be adequate to allow evacuation of a patient by emergency personnel (including stretchers etc.).
- q) If a stairway is present, it shall be sufficiently wide enough to allow evacuation of a patient by emergency personnel (including their device). If an elevator is present, it shall be large enough to allow evacuation of a patient by emergency personnel (including their device). In case of fire elevators shall not be used.
- r) There shall be a written protocol for Security emergencies for fire and fire drills, for calling appropriate personnel for unplanned or emergency return of patient to the room and for immediate or timely return to the room for patient emergencies.
- s) There shall be a written protocol for cardiopulmonary resuscitation, for a situation in which the practitioner becomes incapacitated, for a response to power failure emergencies, for transferring patients in an emergency, for a plan for emergency evacuation of facility.
- t) Medical records shall be kept secure and confidential.
- u) A separate Surgical Log shall be maintained, either in hard copy or computerized format.

### 5.1.5 Hygiene standards for treatment rooms

- a) Aseptic technique with sterile, protective gowns, aprons, masks, eye protection and gloves shall be used as appropriate.

- b) There shall be a schedule for cleaning and disinfection for all rooms and all devices that is adequate to prevent cross-contamination.
- c) All blood and body fluids shall be cleaned using appropriate germicides indicated as virucidal, bactericidal, tuberculocidal and fungicidal.
- d) The walls and counter tops shall be covered with smooth, and easy to clean material which is free from tears, breaks or cracks. The floor shall be easily washable. Carpet and curtain shall not be used. Washable blinds are permitted.
- e) Used disposable sharp items shall be placed in secure puncture-resistant containers which are located as close to the use area as is practical.
- f) If a sterilizer produces monitoring records, they are reviewed by appropriate personnel and stored according to national regulations.
- g) Each sterilized pack shall be marked with the date of sterilization and when applicable, with the expiration date, so as to determine which supplies are to be re-sterilized and to identify supplies that were sterilized first and are therefore to be used first. When more than one steriliser is available, each pack shall additionally be labelled so as to identify in which steriliser it was sterilized.
- h) Dirty surgical devices and instruments shall be strictly separated from those which have been cleaned.
- i) Re-usable medical devices (e.g. surgical instruments) shall be processed in accordance with validated procedures and appropriate records shall be kept.
- j) Each sterilized batch need to be released separately.
- k) Before usage of medical device they need to be cleaned in an appropriate machine.
- l) For non sterilized endoscopic instruments a validated process for cleaning and disinfection shall be followed.
- m) Spore test are only necessary for gas sterilisers.

#### **5.1.6 Anaesthesia Device**

The following requirements apply only for facilities in which aesthetic medical procedures under category 2 and/or category 3 (see 6.1) are performed:

- a) An anaesthesia machine shall be present in a type II or a type III treatment room. Sufficient space should be available for this device (machine) and its personnel. Monitoring devices shall be available.
- b) There shall be an adequate and reliable source of suction.
- c) Self inflating bags, if used, shall be capable of delivering positive pressure ventilation with at least 90 % oxygen concentration.
- d) Medical gas installation shall be provided.
- e) Sufficient electrical outlets shall be available, labelled and grounded to suite the location (e.g. wet locations, cystoscopy-arthroscopy) and connected to emergency power supplies.
- f) Adequate illumination for patients, machines and monitoring device shall include battery powered illuminating systems or processes.
- g) Emergency Cart shall be available with defibrillator, necessary drugs and other device needed for cardio-pulmonary resuscitation.

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- h) Anaesthesia Personnel shall review and be familiar with the facility's written emergency protocol for cardio-pulmonary emergencies and other internal and external disasters.
- i) There shall be reliable means of two-way communication to necessary personnel in other facility locations.
- j) Appropriate testing of the anaesthesia devices as per manufacturer specifications shall be regularly performed and records of that testing shall be maintained within the facility.
- k) Appropriately sized paediatric medical device shall be available if services are provided to infants/children.

### 5.1.7 Emergency medications

- a) Adequate infusions for substitution of volume shall be available in the facility, also the facilities for handling blood and blood substitutes.
- b) If blood is used, there shall be a protocol for it to be typed, cross-matched and verified.
- c) Emergency medications shall be readily available and all staff members shall be trained to use them.
- d) There shall be a dated, sequential narcotic inventory and control record which includes the use of narcotics on individual patients. Such records may be kept in the form of a bound journal, computer record, or other immediately retrievable format consistent with legal requirements.
- e) All narcotics and controlled substances shall be adequately secured and locked, not portable, and under supervised access.
- f) Medications shall be routinely reviewed and outdated drugs need to be removed and replaced.
- g) All medications necessary for emergency cases shall be adequate available and stored in a specific area.
- h) The following medications shall be stored and available in the facility at all times:
  - Epinephrine,
  - Lidocaine,
  - Vasopressors other than Epinephrine (e.g. Ephedrine),
  - Seizure arresting medication (a benzodiazepine, e.g. Midazolam),
  - Bronchospasm arresting medication (inhaled beta agonist, e.g. Albuterol),
  - Intravenous corticosteroids (e.g. Dexamethasone),
  - IV Antihistamines (e.g. Diphenhydramine),
  - Short-acting beta-blocker (e.g. Esmolol or Labetalol), and
  - Atropine.

### 5.1.8 Personnel

- a) The Medical Director shall be a Medical Doctor who is actively involved in the management and daily routine of the facility.
- b) All employees shall be appropriately trained according to national legislation for their job and activities, including devices and procedures utilized in the treatment of emergencies. Their skills have to be updated periodically, preferably annually.
- c) There shall be a manual, which sets out all staff working practices, responsibilities and job descriptions.

### 5.1.9 Documentation of medical records

- a) There shall be adequate facilities and working spaces for documenting patients' history. All patients' history shall be retained in adequate rooms and only accessible for authorised personal.
- b) Medical records shall be legible, documented and completed accurately and in a timely manner. Medical records shall be kept by the number of years (referred to the national compliance) as required by regulations.

## 5.2 Special requirements for treatment rooms

### 5.2.1 Type I treatment room

A Type I treatment room is for office based procedures (see 6.1). Requirements specific for a Type I treatment room are the following:

- a) There shall be adequate space and all necessary equipment to ensure safe and aseptic treatment of the patient. Personal protective measures shall be available and room to put them on is provided;
- b) Mechanical air-venting is in general not necessary and window airing is deemed to be enough, but with insect window screens.
- c) The following equipment shall be minimally available:
  - Sufficient lighting for examination and treatment;
  - Sphygmomanometer;
  - Stethoscope;
  - Couch suitable for shock positioning and cardiopulmonary resuscitation.

### 5.2.2 Type II treatment room

A Type II treatment room is for intermediate/minor minimally invasive procedures (see 6.1). Requirements specific for a Type II treatment room are the following:

- a) There shall be at least a fully qualified nurse or doctor's assistant present when aesthetic medical procedures are being done. The anaesthesiologist shall be present in the facility in case of general anaesthesia or IV anaesthesia.
- b) Appropriate transportation possibilities shall be provided, e.g. wheelchair, trolley or lift facilities.
- c) The Type II treatment room shall be physically and distinctly separate and segregated from the general office area (e.g. waiting room, exam room, administrative area, physician office, staff lounges).

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- d) The Type II treatment room shall have an emergency power source, (e.g. a generator or battery powered inverter), with sufficient capacity to operate adequate monitoring, anaesthesia, surgical device, cautery and lighting a minimum of two hours. This emergency power source shall be able to begin generating ample power to operate all the essential electrical device being used in the Type II room within 3 seconds in case of a power failure. The emergency power device shall be checked regularly (e.g. monthly) to insure function.
- e) Appropriate scrub facilities shall be provided.
- f) The treatment room has to be at least 12 m<sup>2</sup>.
- g) For aesthetic medical procedures performed under sedation or general anaesthesia, there shall be a transfer agreement with a local accredited or licensed acute care hospital which is approved by the facility's medical staff or the practitioner has privileges to admit patients to such a hospital after having performed the aesthetic medical procedure in the facility.
- h) The patient shall be monitored during and after the aesthetic medical procedure.
- i) Medical gas (O<sub>2</sub> and suction) shall be provided.
- j) There shall be appropriate storage of pharmaceuticals, disposable items, material for injections, sterile medical products.
- k) The floor shall be antistatic and sealed, if individual floor tiles are used.
- l) Walls shall be washable and resistant against disinfectants.
- m) Mechanical air-venting is necessary in general.
- n) The windows shall be closed, and shall be opened only in case of emergency.
- o) The following equipment shall be minimally available in addition to those listed under 5.2.1 c):
  - Device for performing electrocoagulation;
  - Equipment allowing to view X-ray images, e.g. image viewer, PC;
  - Facilities for infusion and shock treatment.

### 5.2.3 Type III treatment room – Operating theatre

A Type III treatment room is suitable for all aesthetic medical procedures, including major surgical procedures (see 6.1). Requirements specific for a Type III treatment room are the following:

- a) There shall be at least a fully qualified nurse or doctor's assistant and anaesthesiologist present when aesthetic medical procedures are being done.
- b) Appropriate transportation possibilities shall be provided, e.g. wheelchair, trolley or lift facilities.
- c) The Type III treatment room shall be physically and distinctly separate and segregated from the general office area (e.g. waiting room, exam room, administrative area, physician office, staff lounges).
- d) The Type III treatment room shall have an emergency power source, (e.g. a generator or battery powered inverter), with sufficient capacity to operate adequate monitoring, anaesthesia, surgical device, cautery and lighting a minimum of two hours. This emergency power source shall be able to begin generating ample power to operate all the essential electrical device being used in the Type III room within 3 seconds in case of a power failure. The emergency power device shall be checked regularly (e.g. monthly) to insure function.

- e) Appropriate scrub facilities shall be provided.
- f) For surgical procedures performed under sedation or general anaesthesia, there shall be a transfer agreement with a local accredited or licensed acute care hospital which is approved by the facility's medical staff or the practitioner has privileges to admit patients to such a hospital after having surgery in the facility.
- g) The patient shall be monitored during and after the aesthetic medical procedure.
- h) Facilities shall have a minimum of 1,22 meters of clear space on 3 sides of the Operating Room table – because on one side is the anaesthesia – to accommodate emergency personnel and device in case of emergency.
- i) The floor shall be antistatic and sealed, if individual floor tiles are used.
- j) Walls shall be washable and resistant against disinfectants. The junction between walls and floor has to be round to avoid collection of dirt.
- k) Cleaning and disinfection of the room (e.g. flooring and walls), including device and furniture, shall be ensured.
- l) Temperature shall be comfortable for the operative team but shall not put patient at risk of hypothermia. The Temperature should be regulated around 20 °C.
- m) Ventilation and air conditioning, e.g. low-turbulence displacement flow in the area of the operating table, shall be ensured.
- n) Low-particle air and controlled direction of air flow with overpressure in the Type III treatment room shall be ensured.
- o) Windows shall be closed, and shall be opened only in case of emergency.
- p) Medical gas installation and exhaust evacuation shall be provided.
- q) The following equipment shall be minimally available in addition those listed under 5.2.1 c) and 5.2.2 o):
  - Adequate medication to treat malignant hyperthermia;
  - operating light;
  - operating table including accessories with appropriate positioning for the respective surgery;
  - device for monitoring vital signs and resuscitation;
  - device for performing electro coagulation;
  - instrument table and side table and storage space;
- r) There shall be functional side rooms affiliated to the type III treatment room with floor material covering the floor from wall to wall, i.e.
  - to be used for handing over the patient,
  - changing rooms for the staff,
  - room for material supply and disposal,
  - storage rooms for medical products,

- rooms for preparation of medical products (if not outsourced),
  - rooms for post-operative monitoring,
  - post recovery unit,
  - rooms for hand cleaning and disinfection,
  - dressing room for patients including sanitary facilities, and
  - offices;
- s) A physician or nurse who is qualified in advanced cardio-pulmonary resuscitation shall be immediately available until all patients have met the criteria for discharge from the surgical facility.

## 6 Procedures

### 6.1 Aesthetic medical procedure categories

The following procedure categories apply:

- Category 1: **Office based procedures** reasonably undertaken with/without anaesthesia (including botulinum toxins, fillers, non-ablative laser treatments)
- Category 2: **Intermediate/minor minimally invasive procedures** reasonably undertaken under local anaesthetic in clinic/ minor ops environment (including blepharoplasty, brachioplasty, liposuction face)
- Category 3: **Major surgical procedures** undertaken under local/general anaesthesia in hospital/ clinic facility (including most aesthetic facial/ eyelid/ nasal surgery, most aesthetic breast and body contouring)

### 6.2 Identifying factors

The following factors influence the outcome of an aesthetic medical procedure.

#### 6.2.1 Practitioner

The practitioner is the most important identifying factor. A thorough knowledge of the specific aesthetic medical procedures a practitioner wishes to perform shall be obtained through recognized training bodies (see Clause 3 and Annex B).

#### 6.2.2 Facility

To promote patient safety, minimum standards shall be fulfilled to ensure that the practitioner will be able to deal with all unforeseen circumstances and potential complications of any treatment they may undertake. The standards shall include regulations about general safety measures, hygiene, anaesthesia, device and medication, infrastructure and personal competencies as presented in Clause 5.

Type I for minimally invasive procedures,

Type II for small and moderate procedures,

Type III Operating theatre.

### 6.2.3 Anaesthesia level

- I Topical or no anaesthesia,
- II Local anaesthesia,
- III Local, loco-regional anaesthesia with or without sedation,
- IV General anaesthesia or loco-regional anaesthesia (plexus, nerve root or epidural) with or without sedation.

### 6.2.4 Risk level of procedure

Risk levels are defined as follows:

- A Minimal risk (i.e. mild transient signs/symptoms);
- B impairment (i.e. moderate transient signs/symptoms);
- C disability (permanent damage without functional restrictions);
- D handicap (permanent damage with functional restrictions).

### 6.2.5 Physical and mental/psychological status and age of the patient

All patients shall be assessed as described in Clause 4 (see 4.2.9 f)1):

- 1 normal healthy patient,
- 2 patient with mild systemic disease,
- 3 patient with severe systemic disease.

NOTE This classification is based on the ASA physical status classification system. The ASA categories for a patient with severe systemic disease that is a constant threat to life, for a moribund patient who is not expected to survive with or without the operation and for a declared brain-dead patient whose organs are being removed for donor purposes are not used for this European Standard.

Two age-levels are defined:

- A 18 years of age or above.
- B Below 18 years of age.

### 6.2.6 Duration of the procedure

Multiple aesthetic medical procedures during one operation place a greater risk on the patient. Justification for performing multiple aesthetic medical procedures shall be documented. The risks of multiple aesthetic medical procedures shall be explained to the patient.

### 6.3 Procedure identification

A list of procedures is identified from the UEMS syllabi of the relevant specialties (see Annex B) and is combined with the categories included in 6.1 and 6.2, resulting in the relations outlined in Figure 1.

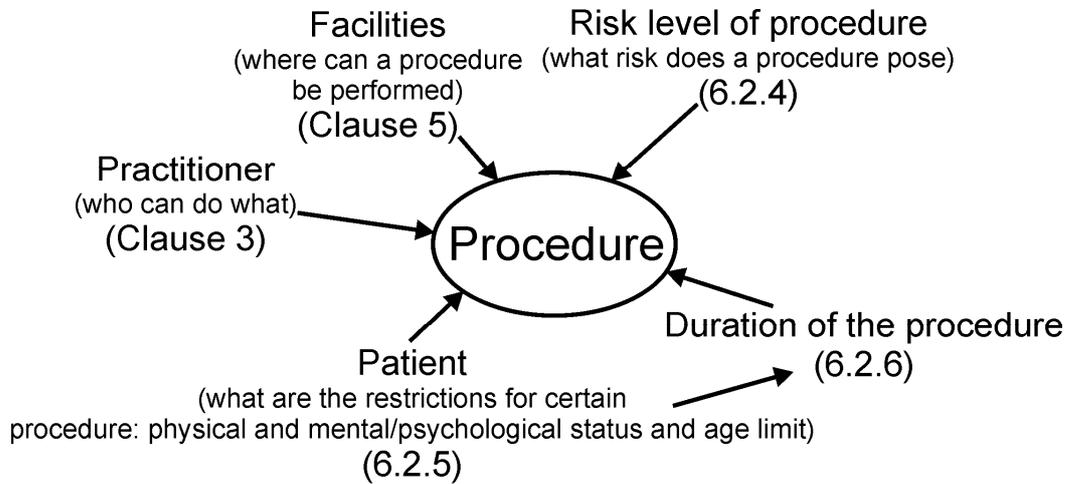


Figure 1 — Relations

The UEMS syllabi do not all specify the procedures which they may include and, for these specialties, those procedures falling within an anatomical region specific of specialist's competence have been selected.

Aesthetic medical procedures, which are not included in Table 1 or Table 2 shall be allocated by the practitioner to an 'equivalent' procedure that is included in Table 1 or Table 2. Aesthetic medical procedures that cannot be allocated shall be listed separately. These procedures and procedures that do not yet exist at this time shall be classified as follows:

- Every new or unmentioned aesthetic medical procedure shall be judged compared to already existing or mentioned procedures, using clinical common sense.
- The age shall be restricted to adults and the ASA classification for new aesthetic medical procedures shall be restricted to healthy individuals (physical status 1 according to 6.2.5).

### 6.4 Procedure list

Based on the factors identified in 6.2

- minimally invasive aesthetic medical procedures are classified in Table 1,
- surgical aesthetic medical procedures are classified in Table 2.

Table 1 — Classification of minimally invasive aesthetic medical procedures

Procedures	Type of facility (Clause 5)	Risk level (6.2.4)	Physical and mental/psychological status of patient (6.2.5)	Patient age (6.2.5)
<b>Chemical peels</b>				
Superficial	I	A	1-3	A
Medium	I	C	1-2	A
<b>Fillers</b>				
Filler resorbable	I	C	1-3	A
Permanent fillers	I	D	1-3	A
<b>Botulinum toxin injection</b>	I	B	1-3	A
<b>Electromagnetic radiations</b>				
Lasers for skin pigmentation	I	C	1-3	A
Lasers for hair removal	I	C	1-3	A
Non-Ablative Fractional Photothermolysis	I	B	1-3	A
Ablative Fractional Photothermolysis	I	B	1-3	A
Intense pulse light (IPL) treatments	I	C	1-3	A
Photodynamic therapy	I	B	1-3	A
Radiofrequency for skin tightening	II	C	1-3	A
Infrared and other devices e.g. for skin tightening procedures	I	B	1-3	A
<b>Injection Lipolysis</b>	I	C	1-2	A
<b>Microdermabrasion</b>	I	A	1-3	A
<b>Sclerotherapy</b>	I	C	1-2	A

Table 2 — Classification of surgical aesthetic medical procedures (continued)

Procedures	Type of facility (Clause 5)	Risk level (6.2.4)	Physical and mental/psychological status of patient (6.2.5)	Patient age* (6.2.5)
<b>General</b>				
Dermabrasion mechanical	II	C	1-3	A
Free fat grafting facial	III	D	1-2	A
Free fat grafting other body	III	C	1-2	A
Body liposuction	III	D	1-2	A, B
Deep chemical peels (Phenol or other)	II/III	D	1	A
Laser Skin Resurfacing (partial resurfacing)	II	C	1-3	A
Laser Skin Resurfacing (full resurfacing)	III	C	1-3	A
<b>Head and neck</b>				
Blepharoplasty	II	D	1-3	A
Brow lift minor	II	C	1-3	A
Brow lift extensive	III	D	1-2	A
Rhinoplasty	III	D	1-2	A

Table 2 — Classification of surgical aesthetic medical procedures (continued)

Procedures	Type of facility (Clause 5)	Risk level (6.2.4)	Physical and mental/psychological status of patient (6.2.5)	Patient age* (6.2.5)
Correction of Rhinophyma	II	C	1-2	A
Rhytidectomy (all facelift procedures including midface and neck)	III	D	1-2	A
Liposuction face	II	D	1-2	A, B
Alloplastic facial implants	III	D	1-2	A
Hair micro grafts (Follicular Unit Transplantation and Follicular Unit Extraction)	II	C	1-3	A
Hair flaps and scalp reduction	III	D	1-2	A
Thread lifts	II	D	1-3	A
Correction of prominent ears (otoplasty)	III	C	1-3	A, B
Genioplasty	III	D	1-2	A
<b>Chest and Breast</b>				
Augmentation mammoplasty	III	D	1-2	A
Correction of breast ptosis/mastopexy	III	D	1-2	A
Breast reduction (mammoplasty)	III	D	1-2	A, B
Nipple areola correction	II	C	1-3	A, B
Gynecomastia	III	C	1-2	A, B
Breast asymmetry correction	III	D	1-2	A
<b>Upper limbs</b>				
Liposuction	III	C	1-3	A
Brachioplasty	II	D	1-2	A
<b>Trunk, abdomen and Genitalia</b>				
Abdominoplasty	III	D	1-2	A
Body lift	III	D	1-2	A
Penis augmentation	III	D	1-2	A
Nymphoplasty (correction of external female genitals)	II	C	1-3	A, B
<b>Lower limbs</b>				
Liposuction	III	D	1-2	A
Thigh lift	III	D	1-2	A
Buttock lift	III	D	1-2	A
Implants	III	D	1-2	A
* For patients under the age of 18 years (B) see 4.3 i).				

## 7 Quality assurance and improvement

### 7.1 General

The quality work shall be based on the requirements included in clause 3, clause 4, clause 5 and clause 6. The work with quality and quality assurance shall involve the top management of the facility, the practitioner(s) and the patients.

The quality assurance and improvement work shall consist of:

- a) risk analysis;
- b) patient feedback (e.g. patient complaint handling);
- c) consultation with patients;
- d) patient surveys (e.g. client evaluation of service); and
- e) internal quality audit.

The quality assurance and audit should take place frequently and continuously.

NOTE 1 General guidance for quality management systems for health services is provided in CEN/TS 15224.

NOTE 2 To enhance patient safety use of the WHO Surgical Safety Checklist [83] is recommended.

### 7.2 Risk analysis

The practitioner shall not undertake any aesthetic medical procedure requested by a patient where the practitioner believes there is an unacceptable risk to the patient as a consequence.

Adverse events which involving a medical device or medicinal product used in an aesthetic medical procedure, e.g. disrupted implants, and that meet the relevant criteria shall be reported to the vigilance contact point in the national competent authorities. Provisions shall be in place if such adverse events occurs in terms of product recall, contact to the manufacture of the product, etc.

The risk analysis shall be used in the framework of complication management and emergency management.

NOTE General guidance for risk analysis is provided in ISO 31000, including

- Principles: Risk management creates and protects value, is an integral part of all organizational processes, is part of decision making, explicitly addresses uncertainty, is systematic, structured and timely, is based on the best available information, is tailored, takes human and cultural factors into account, is transparent and inclusive, is dynamic, iterative and responsive to change and facilitates continual improvement of the organization.
- Framework based on a Plan-Do-Check-Act process.
- Identification, analysis, evaluation and treatment of risks.

### 7.3 Patient feedback

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:
  - hospital/facility;
  - medical staff; and
  - outcome/result.

NOTE General guidance for complaints handling is provided in ISO 10001, ISO 10002 and ISO 10003.

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.

#### **7.4 Consultation with patients**

The consultation with the patient shall be carried out according to Clause 4 and consultation intervals shall be adapted according to the aesthetic medical procedure that was carried out.

#### **7.5 Patient surveys**

The patient survey should aim to be carried out upon discharge and long-term follow up (1 year and after 5 years).

#### **7.6 Internal quality audit**

The internal quality audit shall be carried out by the appointed quality management representative of the facility (other than practitioner) as appropriate to European and national legislation and standards.

NOTE General guidance for internal audits is provided in ISO 19011.

## **Annex A** (normative) **Code of Ethics for marketing and advertising**

Practitioners shall act in accord with the principles of the Code of Ethics in all marketing endeavours with patients, peers and the general public. Further, practitioners are individually responsible and accountable for their actions and words, as well as the use of their names by any individual or entity. Practitioners shall be subject to disciplinary action for violation of any of the specific aspects reviewed herein.

Practitioners may advertise through public communications media such as professional announcements, telephone and medical directories, computer bulletin boards, Internet web pages and broadcast and electronic media. The information shall be factual and verifiable, and should adhere to national advertising standards and where available to National Medical Association Guidelines for advertising and the Law of the Land on medical advertising.

All promotional opportunities shall adhere to the same standards of legality, decency, honesty and truthfulness.

- Marketing materials shall be drafted and designed to safeguard patients from unrealistic expectations as a result of aesthetic medical procedures;
- any advertisements in journals, newspapers, magazines or other print media should use photographs depicting real life results. If models are used to depict the results of any procedure or treatment, this shall be stated clearly;
- the information published shall not make unjustifiable claims or offer cures/guarantees;
- services shall not be advertised by visiting or telephoning prospective patients, either in person or through a deputy;
- advertisements shall not offer discounts linked to a deadline date for booking appointments for aesthetic medical procedure or other date-linked incentives;
- financial incentives (vouchers, discounts) are strongly discouraged;
- a practitioner shall not be the financial intermediary;
- a practitioner shall not participate in sweepstakes (lottery) of aesthetic medical procedures;
- makeover shows, or "reality TV" opportunities are strongly discouraged, as they promote unrealistic expectations of what aesthetic medical procedure can achieve, although educational documentaries may be acceptable;
- practitioners shall not compensate or give anything of value directly or indirectly to a representative of the press, radio, television or other communication medium in anticipation of or in return for recommending the services for professional publicity;
- a practitioner may pay the reasonable cost of marketing services, but shall approve all communications before dissemination, and shall retain a copy or record in their entirety for one year;
- professional Association logos shall only be used truthfully and where specifically allowed by the organization in question;
- practitioners shall be honest about their own experience with any treatment and openly declare known audit figure complications and their own complication rate;

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- practitioners shall be honest about the science of any aesthetic medical procedure they offer and how its efficacy has been evaluated scientifically or observationally;
- practitioners shall refer to patients as patients and not clients;
- referring professionals shall not receive payment/remuneration for making for patient referrals. Patients shall expect that any referral is made in their best interest and does not involve any financial transaction. Any financial relationship between the referring party and/or the practitioner and/or the facility shall be declared to the patient.

Practitioners shall be held personally responsible for any violation of the Code of Ethics incurred by public relations, advertising or similar firm which he or she retains, or any entity that advertises on the practitioner's behalf.

## **Annex B** **(informative)** **UEMS**

Only specialists with a specific interest in aesthetic medical procedures are addressed.

Defined UEMS monospeciality sections relevant for this European Standard are:

- Dermatology
- General Surgery
- Gynaecology
- Ophtalmology
- Oro-Maxillo-Facial surgery and stomatology
- Otorhinolaryngology
- Plastic, reconstructive and aesthetic surgery
- Urology

Other practitioners provided that aesthetic medical procedures are in the national syllabus:

- Medical Doctors, if they meet the requirements specified in this European Standard, certified by the national competent authority.

NOTE 1 Information on UEMS syllabi is provided on the website of UEMS [www.uems.net](http://www.uems.net).

NOTE 2 It is intended to include aesthetic medical doctors once the structure for training and accreditation is in place and recognized by UEMS.

## Bibliography

- [1] CEN/TR 15133, *Nomenclature – Collective terms and codes for groups of medical devices*
- [2] CEN/TR 15592, *Health services – Quality management systems – Guide for the use of EN ISO 9004:2000 in health services for performance improvement*
- [3] CEN/TS 15224, *Health services – Quality management systems – Guide for the use of EN ISO 9001:2000*
- [4] CEN/TS 15277, *Non-active surgical implants – Injectable implants*
- [5] EN 207, *Personal eye-protection equipment – Filters and eye-protectors against laser radiation (laser eye-protectors)*
- [6] EN 285, *Sterilization – Steam sterilizers – Large sterilizers*
- [7] EN 455-1, *Medical gloves for single use – Part 1: Requirements and testing for freedom from holes*
- [8] EN 455-2, *Medical gloves for single use – Part 2: Requirements and testing for physical properties*
- [9] EN 455-3, *Medical gloves for single use – Part 3: Requirements and testing for biological evaluation*
- [10] EN 455-4, *Medical gloves for single use – Part 4: Requirements and testing for shelf life determination*
- [11] EN 794-3, *Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators*
- [12] EN 980, *Symbols for use in the labelling of medical devices*
- [13] EN 1040, *Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)*
- [14] EN 1041, *Information supplied by the manufacturer of medical devices*
- [15] EN 1422, *Sterilizers for medical purposes – Ethylene oxide sterilizers – Requirements and test methods*
- [16] EN 1500, *Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2)*
- [17] EN 1644-1, *Test methods for nonwoven compresses for medical use – Part 1: Nonwovens used in the manufacture of compresses*
- [18] EN 1644-2, *Test methods for nonwoven compresses for medical use – Part 2: Finished compresses*
- [19] EN 12470 (all parts), *Clinical thermometers*
- [20] EN 13060, *Small steam sterilizers*
- [21] EN 13795, *Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels*
- [22] EN 14180, *Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing*

- [23] EN 15986, *Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates*
- [24] EN 60601-2-4, *Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4:2002)*
- [25] EN 60601-2-25, *Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993 + A1:1999)*
- [26] EN 60601-2-26, *Medical electrical equipment – Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002)*
- [27] EN 60601-2-27, *Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005)*
- [28] EN 60601-2-30, *Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999)*
- [29] EN 60601-2-34, *Medical electrical equipment – Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000)*
- [30] EN 60601-2-41, *Medical electrical equipment – Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009)*
- [31] EN 60601-2-46, *Medical electrical equipment – Part 2-46: Particular requirements for the safety of operating tables (IEC 60601-2-46:1998)*
- [32] EN 60601-2-47, *Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (IEC 60601-2-47:2001)*
- [33] EN 60601-2-52, *Medical electrical equipment – Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009)*
- [34] EN 80601-2-12, *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/IEC/FDIS 80601-2-12:2010)*
- [35] EN 80601-2-55, *Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO/DIS 80601-2-55:2009)*
- [36] EN ISO 1942, *Dentistry – Vocabulary (ISO 1942:2009, Corrected version 2010-03-01)*
- [37] EN ISO 6009, *Hypodermic needles for single use – Colour coding for identification (ISO 6009:1992)*
- [38] EN ISO 7396 (all parts), *Medical gas pipeline systems*
- [39] EN ISO 8362-6, *Injection containers and accessories – Part 6: Caps made of aluminium-plastics combinations for injection vials (ISO 8362-6:2010)*
- [40] EN ISO 8362-7, *Injection containers and accessories – Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part (ISO 8362-7:2006)*
- [41] EN ISO 9000, *Quality management systems – Fundamentals and vocabulary (ISO 9000:2005)*
- [42] EN ISO 9170-2, *Terminal units for medical gas pipeline systems – Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)*
- [43] EN ISO 10079 (all parts), *Medical suction equipment*

- [44] EN ISO 10781, *Electronic Health Record-System Functional Model, Release 1.1 (ISO 10781:2009)*
- [45] EN ISO 11073 (all parts), *Health informatics – Point-of-care medical device communication*
- [46] EN ISO 11135-1, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)*
- [47] EN ISO 11810-1, *Lasers and laser-related equipment – Test method and classification for the laser resistance of surgical drapes and/or patient protective covers – Part 1: Primary ignition and penetration (ISO 11810-1:2005)*
- [48] EN ISO 11810-2, *Lasers and laser-related equipment – Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers – Part 2: Secondary ignition (ISO 11810-2:2007)*
- [49] EN ISO 12967 (all parts), *Health informatics – Service architecture*
- [50] EN ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2003)*
- [51] EN ISO 13606 (all parts), *Health informatics – Electronic health record communication*
- [52] EN ISO 14607, *Non-active surgical implants – Mammary implants – Particular requirements (ISO 14607:2007)*
- [53] EN ISO 14630, *Non-active surgical implants – General requirements (ISO 14630:2008)*
- [54] EN ISO 14644-1, *Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness (ISO 14644-1:1999)*
- [55] EN ISO 14971, *Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*
- [56] EN ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO/DIS 15223-1:2009)*
- [57] EN ISO 15225, *Medical devices – Quality management – Medical device nomenclature data structure (ISO 15225:2010)*
- [58] EN ISO 16054, *Implants for surgery – Minimum data sets for surgical implants (ISO 16054:2000)*
- [59] EN ISO 16061, *Instrumentation for use in association with non-active surgical implants – General requirements (ISO 16061:2008, Corrected version 2009-03-15)*
- [60] EN ISO 17665-1, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*
- [61] EN ISO 18812, *Health informatics – Clinical analyser interfaces to laboratory information systems – Use of profiles (ISO 18812:2003)*
- [62] EN ISO 21090, *Health Informatics – Harmonized data types for information interchange (ISO 21090:2011)*
- [63] EN ISO 25424, *Sterilization of medical devices – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2009)*
- [64] EN ISO 27789, *Health informatics – Audit trails for electronic health records (ISO/DIS 27789:2010)*

- [65] EN ISO 27799, *Health informatics – Information security management in health using ISO/IEC 27002 (ISO 27799:2008)*
- [66] EN ISO 80601-2-61, *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO/FDIS 80601-2-61:2010)*
- [67] ISO 10001, *Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations*
- [68] ISO 10002, *Quality management – Customer satisfaction – Guidelines for complaints handling in organizations*
- [69] ISO 10003, *Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations*
- [70] ISO/TR 12773 (all parts), *Business requirements for health summary records*
- [71] ISO 17090 (all parts), *Health informatics – Public key infrastructure*
- [72] ISO 18308, *Health informatics – Requirements for an electronic health record architecture*
- [73] ISO 19011, *Guidelines for auditing management systems*
- [74] ISO/TS 21547, *Health informatics – Security requirements for archiving of electronic health records – Principles*
- [75] ISO/TR 21548, *Health informatics – Security requirements for archiving of electronic health records – Guidelines*
- [76] ISO/TS 22600 (all parts), *Health informatics – Privilege management and access control*
- [77] ISO 26000, *Guidance on social responsibility*
- [78] ISO 31000, *Risk management – Principles and guidelines*
- [79] ISO 80601-2-13, *Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*
- [80] IEC/TR 60825-8, *Safety of laser products – Part 8: Guidelines for the safe use of laser beams on humans*
- [81] ASA (American Society of Anaesthesiologists) physical status classification system, [www.asahq.org/For-Members/Clinical-Information/ASA-Physical-Status-Classification-System.aspx](http://www.asahq.org/For-Members/Clinical-Information/ASA-Physical-Status-Classification-System.aspx)
- [82] Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19.-22. June 1946; (Official Records of the World Health Organization, no. 2, p. 100)
- [83] WHO Surgical Safety Checklist, 2009 edition  
<http://www.who.int/patientsafety/safesurgery/en/>
- [84] WHO Guidelines for Safe Surgery 2009,  
[http://whqlibdoc.who.int/publications/2009/9789241598552\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf)
- [85] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation
- [86] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

- [87] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications
- [88] Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)
- [89] Fractional photothermolysis: a new concept for cutaneous remodeling using microscopic patterns of thermal injury. Manstein D et al. *Lasers Surg Med.* 2004;34(5):426-38.
- [90] Short-term side effects of fractional photothermolysis. Fisher GH et al. *Dermatol Surg.* 2005 Sep;31(9 Pt 2):1245-9; discussion 1249.
- [91] Skin Responses tot Fractional Photothermolysis. Laubach H. et al. *Lasers Surg Med.* 2006 Feb; 38(2):142-9.
- [92] Novel use of erbium:YAG (2,940-nm) laser for fractional ablative photothermolysis in the treatment of photodamaged facial skin: a pilot study. Lapidoth M, Yagima Odo ME, Odo LM. *Dermatol Surg.* 2008 Aug;34(8):1048-53.
- [93] Fractional laser skin therapy Marc Oliver Bodendorf et al. *JDDG*; 2009; 7: 301–308.
- [94] Update dermatologic laser therapy. Sonja Grunewald et al. *JDDG*;2010; 8: 2-13.
- [95] Fraxel. 3 Versatile Fraxel Laser Treatments With Remarkable Results and Minimal Downtime. Available at: <http://www.fraxel.com/Fraxel-Lasers-Compare-Technology> Accessed January 15, 2011.
- [96] Reilly MJ, Cohen M, Hokugo A, Keller G. Molecular effects of fractional carbon dioxide laser resurfacing on photodamaged human skin. *Arch Facial Plast Surg.* 2010;12(5):321-325.
- [97] Manuskiatti W, Fitzpatrick RE, Goldman MR Long-term effectiveness and side effects of carbon dioxide laser resurfacing for resurfacing of photoaged facial skin. *J Am Acad Dermatol.* 1999;40:401-411.
- [98] Fractional Laser Skin Resurfacing treatment complications: a review. Metelitsa A, Alster T, *Dermatol Surg* 2010;36:299–306
- [99] Effect of pretreatment on the incidence of hyperpigmentation following cutaneous CO2 laser resurfacing. West TB, Alster TS. *Dermatol Surg.* 1999 Jan; 25(1):15-7.