BS EN 16372:2014

BSI Standards Publication

Aesthetic surgery services

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National foreword

This British Standard is the UK implementation of EN 16372:2014.

The UK committee agrees that this standard provides a framework to work by for those working in Aesthetic Services and also a guideline for those seeking treatment. It will act as a benchmark for Aesthetic Services in the United Kingdom and across Europe.

Please note that Annex C, which lists A-deviations for the UK, is notrelevant to the Aesthetic Surgical Services Standard. It only appliesto prEN 16844 Aesthetic medicine services - Non-surgical medicalprocedures, which was developed at the same time as this standard.Therefore, this text is not relevant to this Aesthetic Surgical ServicesStandard in the United Kingdom.

The UK participation in its preparation was entrusted to Technical Committee CH/403, Aesthetic Surgery and Aesthetic Non-Surgical Medical Services.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Aesthetic surgery services

Services en chirurgie esthétique

Dienstleistungen in der ästhetischen Chirurgie

This European Standard was approved by CEN on 28 October 2014.

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of an identical text or by endorsement, at the latest by June 2015 and conflicting national standards shall be withdrawn at the latest by June 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Introduction

This European Standard provides a set of requirements, which are deemed to be essential for the provision of aesthetic 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.

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 ensured and patients shall be aware from the text when an article is an advertorial.

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

e) No models should be used neither in advertising nor marketing and a declaration of conflict of interest shall be prominent.

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

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

h) 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.

i) 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.

j) For 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 emphasized. 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.

h) Patients shall be informed by the service provider and/or the practitioner if he/she is travelling long distance to provide treatment. Requirements in this European Standard also apply to travelling practitioners.

4.10 Medical indemnity and insurance

4.10.1 Practitioners shall have a medical indemnity insurance (negligence). This insurance should also cover damages or problems that are unexpected or unforeseeable at the time of operation.

4.10.2 Patients shall be informed that the practitioner undertaking their aesthetic surgical procedure possesses professional indemnity insurance that it is recognized 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.

4.10.3 Patients shall be informed that their practitioner/practitioners possesses adequate and appropriate indemnity for the operations being undertaken, registered in the country where the operation is performed.

4.10.4 The practitioner shall honestly declare all information regarding scope and location of aesthetic surgical procedure to the insurer and thus ensuring that he/she remains insured.

4.10.5 The practitioner shall not act outside his/her area of expertise and insurance cover.

4.11 Fees

4.11.1 Fees shall be transparent and a detailed and written quote shall be delivered prior consent.

4.11.2 Long term financial implications should be clear.

4.11.3 Financial arrangement for complications should be explicit.

4.11.4 Financial discounts shall not be used to encourage patients to consider aesthetic surgical procedure or further procedures.

4.11.5 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

4.12.1 Patients shall be provided with contact details for their practitioner/ clinic in the case of emergency.

4.12.2 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.

4.12.3 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.

4.12.4 Practitioners performing aesthetic surgical procedures shall ensure that the facility within which they operate possesses procedures for referral.

4.12.5 Practitioners/clinics performing aesthetic surgical procedures shall ensure that there is appropriate anaesthetic cover in the case of emergencies.

4.13 Allied health professionals

4.13.1 Practitioners/clinics or, if applicable, the anaesthesiologist shall ensure that there is appropriate qualified anaesthetic cover.

4.13.2 If the practitioner deems that the environment, in which the aesthetic surgical procedure shall be performed, the devices or personnel is not fit for purpose the practitioner shall cancel the procedure.

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

4.14 Complaints

4.14.1 All practices/ companies offering aesthetic surgery services shall have a clear complaints procedure and process, including timeframe for responding.

4.14.2 Patients should be made aware of the practice/ companies complaints procedure.

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

4.15 Confidentiality

Patient's confidentiality shall be respected at all times.

4.16 Multiple aesthetic surgical procedures

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

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

4.16.3 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

4.17.1 The practitioner shall inform the patient if the timing, complexity, or duration of their aesthetic surgical procedure could introduce additional risks/complications (e.g. abdominoplasty at the time of caesarian sections).

4.17.2 The practitioner shall inform the patient of additional risks associated with the aesthetic surgical procedure if patient behaviour may modify these, e.g. smoking cessation and weight loss.

4.17.3 The practitioner shall inform the patient if stopping or taking any medication would modify risk of the aesthetic surgical procedure.

4.17.4 The practitioner shall carefully consider the age of patient when considering whether aesthetic surgical procedure is appropriate.

4.18 Registration

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

5 Facilities

5.1 Evaluation of compliance and risk management

5.1.1 Consistent with its commitment to compliance, a procedure(s) for periodically evaluating compliance with applicable legal requirements shall be established, implemented and maintained. Records of the results of the periodic evaluations shall be kept.

5.1.2 The practitioner shall not undertake any aesthetic surgical procedure requested by a patient if it is considered that the risk-benefit balance is unfavourable (primum non nocere).

5.1.3 Adverse events which involve a medical device or medicinal product used in an aesthetic surgical 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. Procedures to call back patients shall be pre-established if such adverse events occur. The database allowing recalling patients shall be regularly updated.

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

NOTE General guidance for risk management 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.

5.2 Personnel

5.2.1 The Medical Director shall be a Medical Doctor who is actively involved in the management and daily routine of the facility.

5.2.2 All employees shall be appropriately trained complying with requirements for their job and activities, including devices and procedures utilized in the treatment of emergencies. Their skills shall be updated periodically, preferably annually.

5.2.3 All medical personnel directly involved in patient care should be trained in Advanced Cardiac Life Support (ACLS) and in specific emergencies relevant to aesthetic surgical procedures.

5.2.4 There shall be a manual, which sets out all staff working practices, responsibilities and job descriptions.

5.3 Documentation of medical records

5.3.1 There shall be facilities and working spaces for documenting patients' history. All patients' history shall be retained in rooms and only accessible for authorized personal.

5.3.2 Medical records shall be legible, documented and completed accurately and in a timely manner. Medical records shall be kept by the number of years legally required and at least 10 years.

5.4 Facility

5.4.1 The entire facility (including corridors) shall be maintained and cleaned.

5.4.2 Smoking shall be prohibited in the whole healthcare facility.

5.4.3 There shall be a lavatory and changing rooms or areas for patients and personnel. The lavatory facilities shall 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.

5.4.4 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.

5.4.5 Storage space shall be cleaned, maintained and free of litter and clutter.

5.4.6 The facility shall be provided with appropriate general lighting for the purpose of area concerned.

5.4.7 Medical devices, products and equipment shall be handled and used only in accordance with the stated intended use supplied by the manufacturer. Off label use is the specific responsibility of the practitioner and the patient shall be informed of any off label use.

5.5 Administrative and waiting area

5.5.1 There shall be a waiting room clean, maintained and free of clutter and litter and lighted.

5.5.2 There shall be an area for administrative activities providing work space and lighted. The area for administrative activities shall be ventilated, temperature controlled for personnel comfort, cleaned and maintained.

5.5.3 There shall be storage space for supplies. The storage space shall be organized for easy access and inventory of supplies.

5.6 General requirements and recommendations for procedure rooms and operating theatres

5.6.1 The facility shall determine, provide and maintain the facilities needed for the safe provision of aesthetic surgery services.

5.6.2 All procedure rooms and operating theatres shall be ventilated and temperature controlled. Room air conditioner, if present, should be individually regulated, regularly cleaned and stopped upon patient request. In addition the air treatment system(s) shall be regularly controlled, cleaned and verified.

5.6.3 Floor tiles shall be sealed, if individual floor tiles are used.

5.6.4 The ceiling shall be dust-tight.

5.6.5 All openable windows to the outside shall be protected against the entrance of insects, e.g. by insect window screens, and shall be view protected.

5.6.6 Each room shall be of a size to allow for the presence of all devices and personnel necessary for the performance of the aesthetic surgical procedures.

5.6.7 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.

5.6.8 There shall be an operating table or treatment chair with all necessary auxiliary devices.

5.6.9 An automated external defibrillator (AED) shall be present and staff members trained to use it.

5.7 Safety and security

5.7.1 Unauthorized individuals shall be prevented from entering by means of e.g. locks, alarms, or facility personnel.

5.7.2 All openings to external space shall be protected against the entrance of lay individuals.

5.7.3 All medical facilities shall be wired appropriately and all medical facilities and devices shall be inspected annually by an appropriate, independent organization(s). The outcome of these inspections shall be recorded. Based on the outcome any corrective measures shall be implemented without undue delay.

5.7.4 All medical hazardous waste shall be stored in suitable containers, and separated from general waste/refuse for special collection and handling.

5.7.5 All medical hazardous wastes shall be disposed of in sealed, labelled containers.

5.7.6 There shall be a Facility Safety Manual. The Facility Safety Manual shall provide employees with information relating to all hazardous chemicals used and methods to minimize exposure to personnel.

5.7.7 Hazardous chemicals shall be labelled and stored in accordance with recognized standards.

5.7.8 If a class 3B or class 4 laser or intense pulsed light (IPL) device is used, all applicable laser safety standards shall be addressed and implemented.

NOTE 1 Further guidance for the safe use of laser beams on humans and laser equipment is provided in IEC/TR 60825-8 and EN 60601-2-57:2011.

NOTE 2 See EU Directive 2006/25/EC.

5.7.9 If an X-Ray device is used, all appropriate safety measures shall be taken to protect patients and staff from overexposure to radiation. 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 1 See Council Directives 96/29/Euratom and 97/43/Euratom.

5.7.10 Any explosive or combustible materials and supplies shall be stored and handled in a safe manner with ventilation.

5.7.11 Compressed gas cylinders shall be stored and handled in a safe manner.

5.7.12 There shall be a written policy for specifying and mandating the use of appropriate personal protective equipment for each specific task in the facility.

5.7.13 Fire extinguishers shall be available, regularly inspected and shall conform to local fire codes throughout the facility.

5.7.14 Fire exit signs shall be signposted and illuminated.

5.7.15 In case of power failure there shall be emergency lights for exit routes and patient care areas.

5.7.16 Passage and hallways shall allow evacuation of a patient by emergency personnel (including stretchers, etc.).

5.7.17 If a stairway is present, it shall be 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.

5.7.18 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.

5.7.19 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.

5.7.20 Medical records shall be kept secure and confidential.

5.7.21 A separate Surgical Log shall be maintained, either in hard copy or computerized format.

5.8 Anaesthesia Device

The following requirements apply only for facilities in which aesthetic surgical procedures are performed under general anaesthesia or loco-regional anaesthesia with sedation:

a) An anaesthesia machine shall be present in all operating theatres (see 5.12). It shall be present in a procedure room (see 5.11) only if procedures require this. Space should be available for this device (machine) and its personnel. Monitoring devices shall be available.

b) There shall be a 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 suit the location and connected to emergency power supplies.

f) Illumination for patients, machines and monitoring device shall include battery powered illuminating systems or processes.

g) Emergency equipment shall be available with defibrillator, necessary drugs and other devices needed for cardiopulmonary resuscitation.

h) Anaesthesia personnel shall review and be familiar with the facility’s written emergency protocol for emergencies, including cardio-pulmonary emergencies.

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 patients under the age of 18 years.

5.9 Hygiene standards for procedure rooms and operating theatres

5.9.1 Aseptic conditions shall be ensured by using sterile, protective gowns, aprons, masks, eye protection and gloves as appropriate.

5.9.2 There shall be a schedule for cleaning and disinfection for all rooms and all devices to prevent cross-contamination.

5.9.3 All contaminations caused by blood and body fluids shall be cleaned using appropriate germicides indicated as virucidal, bactericidal, tuberculocidal and fungicidal.

5.9.4 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.

5.9.5 Used disposable sharp items shall be placed in secure puncture-resistant containers which are located as close to the use area as is practical.

5.9.6 If a sterilizer produces monitoring records, they are reviewed by appropriate personnel and stored.

5.9.7 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 sterilizer is available, each pack shall additionally be labelled so as to identify in which sterilizer it was sterilized. Sterilized instruments should be stored in a manner that preserves the integrity of the package. They should be stored in enclosed cabinets, racking or drawers free from moisture or, and not stored on the floor, under sinks, on window sills, or adjacent to air vents.

5.9.8 Dirty surgical devices and instruments shall be strictly separated from those which have been cleaned.

5.9.9 Re-usable medical devices (e.g. surgical instruments) shall be processed in accordance with validated procedures and appropriate records shall be kept.

5.9.10 Each sterilized batch need to be released separately.

5.9.11 Before usage of re-usable medical device they shall be decontaminated, cleaned and sterilized according to relevant standards, including personal protection, for cleaning, disinfection and sterilization.

5.9.12 For instruments that cannot be sterilized by a heating process a validated process for cleaning and disinfection shall be followed.

5.10 Medications

5.10.1 Infusions for substitution of volume shall be available in the facility, also the means for handling blood and blood substitutes.

5.10.2 If blood is used, there shall be a protocol for it to be typed, cross-matched and verified.

5.10.3 Emergency medications shall be readily available, their list maintained and all medical staff members shall be trained to use them.

5.10.4 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.

5.10.5 All narcotics and controlled substances shall be secured and locked, not portable, and under supervised access.

5.10.6 Medications shall be routinely reviewed and outdated drugs need to be removed and replaced.

5.10.7 All medications necessary for emergency cases shall be available and stored in a specific area.

5.10.8 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),

— Atropine, and

— Medication for malignant hyperthermia (e.g. dantrolene and supportive therapy for instance insulin, calcium, infusion of HCO_3 and NaCl) when procedures are performed under general anaesthesia.

5.11 Procedure room (PR)

A procedure room is for minor aesthetic surgical procedures (see 6.2). Requirements specific for a procedure room shall include the following:

a) There shall be at least a fully qualified nurse or doctor's assistant present when aesthetic surgical 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 procedure 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 procedure room shall have an emergency power source, (e.g. a generator or battery powered inverter), with sufficient capacity to operate 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 procedure within 3 s in case of a power failure. The emergency power device shall be checked regularly (e.g. monthly) to ensure function.

e) Appropriate scrub facilities for hand disinfection shall be provided.

f) The procedure room shall be at least 12 m^2.

g) For aesthetic surgery 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 surgical procedure in the facility.

h) The patient shall be monitored during and after the aesthetic surgical procedure.

i) Medical gas (O_2 and suction) shall be provided.

j) Emergency Cart shall be available with defibrillator, necessary drugs and other devices needed for cardiopulmonary emergency.

k) There shall be appropriate storage of pharmaceuticals, disposable items, material for injections, sterile medical products.

l) The floor shall be antistatic and sealed.

m) Walls shall be washable and resistant against disinfectants.

n) Mechanical air-venting is necessary in general.

o) The windows shall be closed, and shall be opened only in case of emergency.

p) As a minimum, the following equipment shall be available:

   1) device for performing electrocoagulation;

   2) facilities for infusion and shock treatment;

   3) instrumentation table;

   4) lighting for examination and treatment;

   5) sphygmomanometer;

   6) stethoscope;

   7) couch suitable for shock positioning and cardiopulmonary resuscitation;

   8) basin.

To enhance patient safety use of the WHO Surgical Safety Checklist [86] is recommended.

5.12 Operating theatre (OP)

An operating theatre is for all major surgical procedures and at the same time suitable for all aesthetic surgical procedures. Requirements specific for an operating theatre shall include the following:

a) There shall be at least a fully qualified nurse or doctor's assistant present when aesthetic surgical procedures are being done. The anaesthesiologist shall be present in case of general anaesthesia or IV anaesthesia.

b) Appropriate transportation possibilities shall be provided, e.g. wheelchair, trolley or lift facilities.

c) The operating theatre 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 operating theatre shall have an emergency power source, (e.g. a generator or battery powered inverter), with capacity to operate 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 operating theatre within 3 s in case of a power failure. The emergency power device shall be checked regularly (e.g. monthly) to ensure function.

e) Appropriate surgical hand disinfection facilities shall be provided.

f) For aesthetic 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 in case of surgical complication.

g) The patient shall be monitored during and after the aesthetic surgical procedure.

h) Facilities shall have a minimum of 1,22 m 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.

j) Walls shall be washable and resistant against disinfectants. The junction between walls and floor shall 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 operating theatre shall be ensured. A device which prevents body heat loss and patient hypothermia during surgery may be used.

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) As a minimum, the following equipment shall be available in addition to those listed under 5.11 p):

    1) medication to treat malignant hyperthermia, if the aesthetic surgical procedure is performed under general anaesthesia or IV anaesthesia;

    2) operating light;

    3) operating table including accessories with appropriate positioning for the respective surgery;

    4) device for monitoring vital signs and resuscitation;

    5) instrument table and side table and storage space.

r) There shall be functional side rooms affiliated to the operating theatre with floor material covering the floor from wall to wall, i.e.:

    1) to be used for handing over the patient;

    2) room for post-operative monitoring;

    3) dressing room for patients including sanitary facilities;

    4) changing rooms for the staff;

    5) room for material supply and disposal;

6) storage rooms for medical products;

7) rooms for preparation of medical products (if not outsourced);

8) rooms for post-operative monitoring;

9) post recovery unit;

10) rooms for hand cleaning and disinfection;

11) dressing room for patients including sanitary facilities; and

12) 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.

To enhance patient safety use of the WHO Surgical Safety Checklist [86] is recommended.

6 Procedures

6.1 General

Aesthetic surgical procedures are subject to change. This clause sets out current practice and the generic groups of these treatments. For exact definitions of procedures peer reviewed journals, European and national competent organisations and authorities should be consulted.

6.2 Aesthetic surgical procedure categories

The following procedure categories apply:

— Category 1: **Minor aesthetic surgical procedures** undertaken under local anaesthetic in clinic/ minor ops environment

— Category 2: **Major aesthetic surgical procedures** undertaken under local/general anaesthesia in hospital/ clinic facility

6.3 Identifying factors

6.3.1 General

The following factors influence the outcome of an aesthetic surgical procedure:

— practitioner, see 6.3.2;

— facility, see 6.3.3,

— anaesthesia level, see 6.3.4,

— risk level of procedure, see 6.3.5,

— patient physical status and age, see 6.3.6, and

— duration of the procedure, see 6.3.7.

6.3.2 Practitioner

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

6.3.3 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.

The rooms, in which aesthetic surgical procedures are performed, are defined as follows:

— PR Procedure room for minor aesthetic surgical procedures (see 5.11),

— OP Operating theatre for major aesthetic surgical procedures (see 5.12).

6.3.4 Anaesthesia level

Anaesthesia levels are defined as follows:

— I Topical or no anaesthesia,

— II Local, loco-regional anaesthesia (peripheral nerve blocks) without sedation,

— III Local, loco-regional anaesthesia (peripheral nerve blocks) with sedation,

— IV General anaesthesia or loco-regional anaesthesia with sedation (plexus, nerve root or epidural).

6.3.5 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);

— E death.

There are no risk free procedures. Any aesthetic surgical procedure carries an element of risk of permanent scarring, permanent disability and even death. Procedures in Table 1 are categorized according to the most severe complication of the procedure, but excluding risk level E (death).

6.3.6 Patient physical status and age

All patients shall be assessed as described in 4.2.11. Three physical statuses are defined as follows:

— 1 normal healthy patient (ASA 1),

— 2 patient with mild systemic disease (ASA 2),

— 3 patient with severe systemic disease (ASA 3).

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.

For patients two age-levels are defined:

— A 18 years of age or above.

— B Below 18 years of age.

6.3.7 Duration of the procedure

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

6.4 Procedure identification

6.4.1 A list of procedures is identified from the UEMS syllabi of the relevant specialities (see Annex B) and is combined with the categories included in 6.2 and 6.3, resulting in the relations outlined in Figure 1.

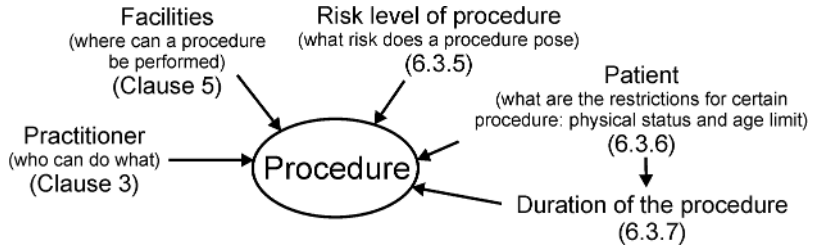

Figure 1 — Relations

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

6.4.2 Aesthetic surgical procedures, which are not included in Table 1 shall be allocated by the practitioner to an ‘equivalent’ procedure that is included in Table 1. Aesthetic surgical 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 surgical 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 surgical procedures shall be restricted to healthy individuals (physical status 1 according to 6.3.6).

6.5 Procedure list

Based on the factors identified in 6.3 aesthetic surgical procedures are classified in Table 1. In Table 1 aesthetic surgical procedures are categorized according to the most severe complication of the procedure, but excluding risk level E (death); it shall be noted, that all these aesthetic surgical procedures can lead to a risk of death.

Table 1 — Classification of aesthetic surgical procedures, excluding risk level E (death)

Procedures	Room type (6.3.3)	Risk level[a] (6.3.5)	Physical status of patient (6.3.6)	Patient age[b] (6.3.6)
General				
Free fat grafting facial	PR/OP	D	1–2	A
Free fat grafting other body (Breast, gluteal area)	OP	C	1–2	A
Free fat grafting other body (small defects)	PR	C	1–2	A
Body liposuction	PR/OP	D	1–2	A
Head and neck				
Blepharoplasty	PR/OP	D	1–3	A
Brow lift minor	PR	C	1–3	A
Brow lift extensive	OP	D	1–2	A
Limited Rhinoplasty (local)	PR	D	1–2	A
Rhinoplasty (sedation or general anaesthesia)	OP	D	1–2	A
Rhytidectomy (all facelift procedures including midface and neck)	OP	D	1–2	A
Liposuction face	PR	D	1–2	A
Alloplastic facial implants	OP	D	1–2	A
Hair flaps and scalp reduction	OP	D	1–2	A
Correction of prominent ears (otoplasty)	PR/OP	C	1–3	A, B
Genioplasty	OP	D	1–2	A
Chest and Breast				
Augmentation mammaplasty	OP	D	1–2	A
Correction of breast ptosis/mastopexy	OP	D	1–2	A
Breast reduction (mammaplasty)	OP	D	1–2	A, B
Nipple areola correction	PR	C	1–3	A, B
Pseudo Gynecomastia	OP	C	1–2	A
Breast asymmetry correction	OP	D	1–2	A
Upper limbs				
Liposuction	PR/OP	C	1–3	A
Brachioplasty	OP	D	1–2	A
Trunk, abdomen and Genitalia				
Abdominoplasty	OP	D	1–2	A
Liposuction	PR/OP	C	1–3	A
Body lift	OP	D	1–2	A

Procedures	**Room type (6.3.3)**	**Risk level[a] (6.3.5)**	**Physical status of patient (6.3.6)**	**Patient age[b] (6.3.6)**
Penis augmentation	OP	D	1–2	A
Nymphoplasty (correction of external female genitals)	PR	C	1–3	A
Lower limbs				
Liposuction	PR/OP	D	1–2	A
Thigh lift	OP	D	1–2	A
Buttock lift	OP	D	1–2	A
Implants	OP	D	1–2	A

[a] Procedures are categorized according to the most severe complication of the procedure, but excluding risk level E (death).

[b] For patients under the age of 18 years (B), see 4.3.2.9.

Annex A
(normative)

Code of Ethics for marketing and advertising

A.1 This annex applies only if marketing and advertising are legally permitted.

A.2 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.

A.3 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.

A.4 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 surgical procedures.

— Any advertisements in journals, newspapers, magazines or other print media should use photographs depicting real life results. Results from computer simulations should not be used. 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 surgical 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 be involved in group shopping services offering aesthetic surgical procedures, time-limited offers, money offers and offers such as nuy-and-get-one-free.

— A practitioner shall not participate in sweepstakes (lottery) of aesthetic surgical procedures.

— A practitioner shall not participate in makeover shows, as they can promote unrealistic expectations of what aesthetic surgical 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.

— Practitioners shall be honest about the science of any aesthetic surgical 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 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.

A.5 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)

Classification of practitioners

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

Defined UEMS monospeciality sections relevant for this European Standard are:

— dermatology;

— general surgery;

— gynaecology;

— ophthalmology;

— oro-maxillo-facial surgery and stomatology;

— otorhinolaryngology;

— plastic, reconstructive and aesthetic surgery;

— urology.

NOTE Information on UEMS syllabi is provided on the website of UEMS www.uems.net.

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

— medical doctors authorized by the national competent authority.

Annex C
(informative)

A–deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN member.

This European Standard does not fall under any Directive of the EU.

In the relevant CEN countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

Clause in EN 16372	**Deviation**
2.10 practitioner	**British deviation** The London Local Authorities Act 1991 allows certain local authorities (the London Boroughs and Nottingham) to require “special treatments” to be licensed before they can be offered to the public. This covers locations where cosmetic laser and ILS (Intense Pulsed Light Systems) services are provided. This includes the licensing of laser and ILS services offered by non-medical practitioners that provide treatments such as hair reduction and other non-surgical laser and ILS treatments. The Local Authorities recognize that the range of people who are suitably trained can be licensed to provide such services and many of those licensed come from the beauty therapy sector and also nurses using lasers and ILS. The Act ensures that these services provided by non-medical practitioners can be licensed and regulated. The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 allows a nurse independent prescriber. In addition dentists are appropriate practitioners according to the Medicines Act 1968 (as amended). **Applicable British regulations** London Local Authorities Act 1991 – Special Treatment Licensing NOTE 1 This regulation is available on web http://www.legislation.gov.uk/ukla/1991/13/part/I/enacted. The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 NOTE 2 This regulation is available on web http://www.legislation.gov.uk/uksi/2012/973/contents/made. Medicines Act 1968 (as amended) NOTE 3 This regulation is available on web http://www.legislation.gov.uk/ukpga/1968/67/contents.
2.10 practitioner	**Spanish deviation** The draft is exclusively directed at “practitioners” who, according to 2.11, are “medical doctors”, but not specialists in Aesthetic Surgery. In Spain there is no other way of being Aesthetic Surgeon than being officially specialists in Plastic, Aesthetic and Reconstructive Surgery. The draft under title “Aesthetic surgery services” is not exclusively directed to official specialists in aesthetic surgery and it is directed to non-specialists and general doctors too. This standard would cause confusion for patients in Spain.

Clause in EN 16372	**Deviation**
	Applicable Spanish regulations 1. REAL DECRETO, 127/1984, de 11 de enero, por el que se regula la formación médica especializada y la obtención del título de Médico Especialista. NOTE 1 This regulation is available on web http://www.boe.es/boe/dias/1984/01/31/pdfs/A02524-02528.pdf. 2. REAL DECRETO 139/2003, de 7 de febrero, por el que se actualiza la regulación de la formación médica especializada". NOTE 2 This regulation is available on web http://www.boe.es/boe/dias/2003/02/14/pdfs/A06026-06028.pdf.
2.10 practitioner Clause 3 Competencies	**Belgian deviation** The Belgian law of 23rd May 2013 regarding the qualifications for practicing aesthetic non-surgery and aesthetic surgery specifies the required titles/diplomas of the medical doctors or practitioner, for the non-surgical and surgical interventions. NOTE: Article 9 to 16 of this regulation is available on web: http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?N=&=&sql=(text+contains+(''))&rech=1&language=nl&tri=dd+AS+RANK&numero=1&table_name=wet&cn=2013052321&caller=image_a1&fromtab=wet&la=N&pdf_page=7&pdf_file=http://www.ejustice.just.fgov.be/mopdf/2013/07/02_1.pdf.
Clause 3 Competencies Annex B (informative) Classification of practitioners	**French deviation** In the French Code of Public Health (Code de la santé publique), Article D6322–43 it is regulated, that the medical staff practising aesthetic surgery in these facilities must consist only of: 1) one or more qualified doctors holding a national diploma of speciality in plastic, reconstructive and aesthetic surgery, or with a training and professional experience recognized as equivalent by the national competent authority (conseil de l'ordre des médecins); 2) one or more qualified doctors holding a diploma of speciality in maxillofacial surgery, maxillofacial surgery and stomatology, stomatology, ear nose and throat, ear nose and throat and face and neck surgery, face and neck surgery, ophthalmology, obstetrics and gynaecology or urological surgery or with a training and professional experience recognized as equivalent by the national competent authority (conseil de l'ordre des médecins); the doctors must only practise aesthetic surgery within the limits of the speciality for which they are registered with the medical board; 3) one or more qualified doctors holding a diploma of speciality in Anaesthetics or with a training and professional experience recognized as equivalent by the national competent authority (conseil de l'ordre des médecins). In Code de la santé publique, Article D6322–44 it is regulated, that when one or more patients are using the facilities for an aesthetic surgery procedure, the paramedical staff, both day and night, in addition to the specialist staff participating in the operating sector and the post-operative monitoring room, must consist of: 1) at least one nurse; 2) at least one nursing auxiliary. In Code de la santé publique, Article D6322–45 it is regulated, that If the facilities are not served by an in-house pharmacy, a pharmacist must be in charge of supervising the medical gases. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.

Clause in EN 16372	**Deviation**
Clause 3 Competencies	**Spanish deviation** Competences are defined in Clause 3 of Orden SAS/1257/2010 by Ministry of Health and Social Services in Spain. **Applicable Spanish regulations** Orden SAS/1257/2010, de 7 de mayo, por la que se aprueba y publica el programa formativo de la especialidad de Cirugía Plástica, Estética y Reparadora. NOTE This regulation is available on web http://www.boe.es/boe/dias/2010/05/15/pdfs/BOE-A-2010-7855.pdf.
3.1 General	**German deviation** According to the (Model) Specialist Training Regulation (MSTR), Section 7.6 in conjunction with MPC, Art. 2 para. 3 it is required that plastic aesthetic surgery is to be performed by plastic aesthetic surgeons. NOTE These regulations are available on web http://www.bundesaerztekammer.de/downloads/MWBOengl20130628.pdf, http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf.
3.1 General 3.1.3	**German deviation** According to the Federal Medical Regulation Art. 2, Chamber Registration Regulations; Art. 95a Social Code Book V registration is obligatory; additionally, statutory health insurance physicians are registered.
3.1 General	**German deviation** Training: Federal Medical Regulation Art. 2 and Art. 4 in conjunction with Approbation Regulation. It is the approbation awarded by the competent authority which provides for the guarantee of basic medical training, see note on German Legal Setting on page 1. Speciality Training: (Model) Specialist Training Regulation (MSTR) Section 7.6 in conjunction with MPC Art. 2 para. 3, Art. 95a Social Code Book V (as applicable for SHI physicians) It is becoming a specialist as awarded by the competent authority which provides for the guarantee of specialist training. NOTE These regulations are available on web http://www.bundesaerztekammer.de/downloads/MWBOengl20130628.pdf, http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf.
3.2 Training	**Spanish deviation** Duration and content of speciality training in Plastic, Aesthetic and Reconstructive Surgery is defined by Ministry of Health and Social Services in Spain. **Applicable Spanish regulations** Orden SAS/1257/2010, de 7 de mayo, por la que se aprueba y publica el programa formativo de la especialidad de Cirugía Plástica, Estética y Reparadora. NOTE This regulation is available on web http://www.boe.es/boe/dias/2010/05/15/pdfs/BOE-A-2010-7855.pdf.

Clause in EN 16372	**Deviation**
3.2 Training	**German deviation** MSTR Section 7.6 in conjunction with MPC Art. 2 para.3: The 108 German Medical Assembly in 2005 resolved to add the word “aesthetic” to the specialist designation “plastic surgery” in the speciality training regulations of the state chambers of physicians. This adjustment of the designation demonstrated clearly that the German medical profession has a uniform national specialist qualification for carrying out aesthetic plastic surgery. The adjunct “aesthetic surgery” aids transparency, enabling patients to differentiate more easily between highly qualified specialists and self-proclaimed “cosmetic surgeons”. At the 2011 German Medical Assembly it was made clear within the framework of the revision of the (Model) Professional Code that physicians who carry out, for example, cosmetic surgery without a sufficient level of qualification are practising unethically. Article 2, paragraph 3 of the (M)PC stipulates that “…Conscientious practise of the profession requires, in particular, the necessary professional qualification and compliance with the accepted state of medical knowledge”. The explanation for the alteration states “… The new version of this paragraph should make clear that physicians without sufficient qualifications, and who have in this respect sometimes forgone the limitations of recognition as a specialist, who carry out, for example, so-called cosmetic surgery during which a patient is harmed, also violate professional ethics and may therefore be prosecuted.” Section 7.6 covers more requirements than stipulated in 3.2. NOTE These regulations are available on web http://www.bundesaerztekammer.de/downloads/MWBOengl20130628.pdf, http://www.bundesaerztekammer.de/downloads/MBOen2012.pdf.
3.3 Continuous professional development (CPD) and continuous medical education (CME)	**German deviation** Chamber Laws and MPC Art. 4; (Model) Continuous Medical Education regulation (CME Regulation) Art. 6; Additionally, Social Code Book V Art. 95 d applies to statutory health insurance physicians (SHI physicians) Also, surgeons (see 2.13 - “aesthetic plastic surgeons”) are subject to CME requirements. The continuing education measures are rated using a point system which is not to be mixed with speciality training. There is no requirement for relicensing but for CME as stipulated by Chamber Laws and MPC Art. 4; (Model) Continuous Medical Education regulation (CME Regulation) NOTE This regulation is available on web http://www.baek.de/downloads/ADFBSatzungEn.pdf.
4.1 Office staff/Booking arrangements	**German deviation** Chamber Laws and MPC Art. 30 and 12 and Medical Fee Schedule The section covers different treatment principles which have to stand on its own. According to Art. 30 MPC physicians are obliged to preserve their medical independence for the treatment of patients in all contractual and other professional relationships with third parties. Detailed provisions in the Medical Fee Schedule regulate prices and conditions for deviating agreements. Subject to Art. 12 para. 2 free consultation is prohibited by Art. 12 MPC.

Clause in EN 16372	**Deviation**
4.2 Patient consultation and assessment	**French deviation** In the French Code of Public Health (Code de la santé publique), Article L6322–2 it is regulated, that the practitioner responsible must inform all individuals considering undergoing aesthetic surgery and where applicable the individual's legal representative, of the nature of the surgical procedure, the risks it entails and any possible after-effects or complications. The person must be provided with an itemised estimate at the same time as this information. The practitioner must allow for a minimum interval between the delivery of the said estimate and the procedure being considered. During this period, the person may not be asked for any payment or commitment, except fees incurred for the pre-operative consultations. In Article D6322–30 it is regulated, that pursuant to Article L6322–2, a minimum period of two weeks must be allowed after the patient has received the itemised estimate, signed and dated by the practitioner(s) listed in Article D6322–43, paragraphs 1, 2 and 4, who will be performing the aesthetic surgery procedure. There may be no adjustments to this period, even at the patient's request. The surgeon who has met with the patient must perform the surgical procedure him or herself, or must inform the patient during the meeting that he or she will not be performing part or all of the procedure him or herself. This information must be stated on the estimate. The provisions set out in this article must be reproduced on every estimate. In Article R6322–27 it is regulated, that the provisions contained in Articles R.1112–1 to R.1112–3, Article R.1112–5 and Articles R.1112–7 to R.1112–9 on information for users and informing users of the health-related information stipulated in Article L.1111–7 shall apply to aesthetic surgery facilities. If the licence holder is not a facility, the licence holder must implement the above provisions as applicable to private facilities not involved in public healthcare service. However, if the facilities do not have a medical conference, the doctors mentioned in Articles R.1112–1 and R.1112–7 shall be appointed by the licence holder or the licence holder's legal representative. In Article D6322–41 it is regulated, that the provisions set out in Articles D.6124–91 to D.6124–103 on performing anaesthesia shall apply to aesthetic surgery facilities. The pre-anaesthesia consultation set out in Article D.6124–92 shall be carried out either in the consultation facilities provided in the reception area, or in the anaesthetist's office. As an exemption form the requirements set out in Article D.6124–100, if the post-operative monitoring room is reserved for aesthetic surgery patients, it may have a minimum capacity of two stations. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.2 Patient consultation and assessment, 4.2.2	**German deviation** Art. 630e para. 2 of the Civil Code and the related jurisprudence according to which the delegation of undertaking consent might be delegated to other doctors than the treating doctor: Consent must always be carried out by a doctor; it is not permissible for it to be carried out by non-medical personnel.

Clause in EN 16372	**Deviation**
4.3 Consent	**French deviation** **Applicable French regulation** Arrêté du 17 octobre 1996 relatif à la publicité des prix des actes médicaux et chirurgicaux à visée esthétique: NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.3 Consent, 4.3.2.9	**Austrian deviation** According to the Austrian law on aesthetic treatments and surgeries, § 7 (1) aesthetic procedures are not permitted for patients under the age of 16 years without any exception. NOTE This regulation is available on web http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&Dokumentnummer=BGBLA_2012_I_80.
4.4 Documentation, 4.4.11	**German deviation** In view of data protection and confidentiality provisions, also, the release of data within a clinical care setting is not permissible as such, see p. A 1029 under 5.2. Minors and incompetent patients are not subject to aesthetic or non-aesthetic surgery, i.e. there is no room for legal representatives. NOTE This regulation is available on web http://www.bundesaerztekammer.de/downloads/Schweigepflicht_2014.pdf.
4.4 Documentation, 4.4.11	**French deviation** In case of death, according to L1110–4 of the Code of Public Health (Code de la Santé Publique) the eligible parties should have access to medical data, in so far as they are necessary to enable them to know the causes of death to defend the memory of deceased or their rights unless contrary intention by the person before his death. NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000020886954&cidTexte=LEGITEXT000006072665.
4.6 Cooling off period	**Austrian deviation** According to the Austrian law on aesthetic treatments and surgeries, § 6 (1) the cooling off period for category 1 and category 2 has to be two weeks. For patients not having their residence in Austria this cooling off period can be reduced to at least one week. NOTE This regulation is available on web http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&Dokumentnummer=BGBLA_2012_I_80.
4.6 Cooling off period	**Belgian deviation** The Belgian law of 23rd May 2013 requires minimum 15 days for aesthetic surgery interventions NOTE Article 20 of this regulation is available on web: http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?N=&=&sql=(text+contains+(''))&rech=1&language=nl&tri=dd+AS+RANK&numero=1&table_name=wet&cn=2013052321&caller=image_a1&fromtab=wet&la=N&pdf_page=7&pdf_file=http://www.ejustice.just.fgov.be/mopdf/2013/07/02_1.pdf.

Clause in EN 16372	**Deviation**
4.6 Cooling off period	**French deviation** In the Code de la santé publique, Article D6322–30 it is regulated, that pursuant to Article L6322–2, a minimum period of two weeks must be allowed after the patient has received the itemised estimate, signed and dated by the practitioner(s) listed in Article D6322–43, paragraphs 1, 2 and 4, who will be performing the aesthetic surgery procedure. There may be no adjustments to this period, even at the patient's request. The surgeon who has met with the patient must perform the surgical procedure him or herself, or must inform the patient during the meeting that he or she will not be performing part or all of the procedure him or herself. This information must be stated on the estimate. The provisions set out in this article must be reproduced on every estimate. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.7 Post-operative follow up and dressings, 4.7.2	**French deviation** According to section L1111–2 of the Code of Public Health and in order to ensure a quality follow up, the surgeon who performed the procedure should ensure follow up himself except absolute and justified impossibility (sickness, holidays, conferences, participation in specialist committees...) **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000020890189&cidTexte=LEGITEXT000006072665.
4.8 Publicity and advertising Annex A (normative) Code of Ethics for marketing and advertising	**French deviation** In the Code de la santé publique, Article L6322–1 it is regulated, that Aesthetic surgery procedures and operations, including those carried out in the type of healthcare facility mentioned in Book 1, may only be performed in facilities that meet certain technical operating requirements. The operating conditions must be certified in accordance with the procedures set outset out in Article L.6113–3. The licence shall be withdrawn if the facility it covers is the object of any direct or indirect advertising, whatever the nature. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.8 Publicity and advertising	**German deviation:** Chamber Laws and MPC Art. 27 and Recommendations by State Chambers and the German Medical Association Art. 1 para. 1 No. 2 Medical Products Advertising Act in conjunction with other provisions of the Medical Products Advertising Act if applicable: Advertising in breach of professional ethic is prohibited. The purpose of Art. 27 "is to ensure patient protection by means of appropriate and reasonable information, and to avoid any commercialisation of the medical profession, which is contrary to the self-perception of the physician. (2) On this basis, physicians are permitted to provide objective professionally related information. (3) Advertising by physicians which breaches professional ethics is banned. This refers particularly to advertising

Clause in EN 16372	**Deviation**
	that is praising, misleading or comparative." (…) According to the Medical Products Advertising Act it is even prohibited to promote aesthetic surgery procedures.
4.10 Medical indemnity and insurance	**French deviation** In the Code de la santé publique, Article R6322–4 it is regulated, that Licence and licence renewal applications will not be examined by the Chief Executive of the Regional Health Authority unless application they are complete. According to this Article the application must include the following documents among others: 1) An administrative application containing: … g) a declaration by the applicant and the applicant's insurer acknowledging awareness of their obligation to inform the patient's health insurance fund(s), under Article L.376–1 of the Social Security Code in the event of any accident or harm caused to the patient covered by the fund(s). **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.12 Arrangements for out of hours and emergency cover	**French deviation** In the Code de la santé publique, Article D6322–42 it is regulated, that should a vacancy for a physician mediator on the Committee as defined in Article R.6322–20 remain unfilled for over six months, the Chief Executive of the Regional Health Authority shall appoint a replacement member from among the practitioners who meet the practice conditions set out in Article R.6322–20, upon a proposal by the local medical department board. One person may not perform the duties of physician mediator or substitute member in more than three facilities at once. In Article D6322–46 it is regulated, that the holder of the licence for the aesthetic surgery facilities must guarantee off-hours care and continuity of care for the patients who are and have been treated at the facilities. If the holder of the licence for the aesthetic surgery facilities, or where applicable, the health care facility in which the aesthetic surgery facilities are housed, is not able to handle emergency medical complications should they arise, the licence holder must conclude a convention to cover such circumstances with a public or private facility holding the licences referred to in Articles R.6123–1 and R. 6123–37. The agreement must describe the conditions for transfer of patients to the public or private healthcare facility when necessary. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.14 Complaints	**French deviation** In the Code de la santé publique, Articles R6322–19 to R6322–26 the creation, membership and terms of reference of the user relations and quality of care Committee in aesthetic surgery facilities, where the licence holder is a healthcare facility, is regulated in detail. **Applicable French regulation** Code de la santé publique

Clause in EN 16372	**Deviation**
	NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
4.18 Registration	**French deviation** In the Code de la santé publique, Articles L6322–1, R6322–1 to R6322–14 and D6322–48 as well as R6322–29 the authorization and licensing of the facility from the competent local administrative authority is regulated. In Article R622–28 the certification of the aesthetic surgery facilities is regulated. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
Clause 5 Facilities	**Italian deviation** The Italian Decree No. 42 issued on 14.January 1997 covers provisions for structural, organizational and technical requirements applicable to public and private healthcare facilities. **Applicable Italian regulation** Decreto del Presidente della Repubblica 14 gennaio 1997 – Approvazione dell'atto di indirizzo e coordinamento alle regioni e alle province autonome di Trento e di Bolzano, in materia di requisiti strutturali, tecnologici ed organizzativi minimi per l'esercizio delle attività sanitarie da parte delle strutture pubbliche e private NOTE This regulation is available on web http://www.salute.gov.it/imgs/C_17_normativa_1163_allegato.pdf.
5.2 Personnel	**French deviation** In the Code de la santé publique, Article R6322–44 D.6322–43 and D.6322–45 the required documentation for Licence and licence renewal applications is regulated. Among others a case file regarding the personnel employed, stating the applicant's commitment to maintain appropriate staffing levels and suitably qualified staff, in particular the medical, pharmaceutical and non-medical personnel required to implement the project and to carry out the aesthetic surgery is required. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
5.4 Facility 6.3.3 Facility	**French deviation** In the Code de la santé publique Articles D6322–31 to D6322–47 the technical operating conditions are regulated in detail. In Article R6322–15 it is specified that if the aesthetic surgery facilities are not served by a healthcare facility's in-house pharmacy under Article R5126–3(4), it may establish its own in-house pharmacy, in accordance with the conditions set out in Article L5126–1 and Articles R5126–2 to R5126–51. Otherwise, they must comply with the provisions set out in Articles R. 5126–111 to R.5126–115 with respect to the purchase, storage and provision of pharmaceutical products and drugs. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.

Clause in EN 16372	**Deviation**
5.7 Safety and security	**French deviation** In the Code de la santé publique, Article R6322–18 it is regulated, that the provisions set out in Articles R.1113–1 to R.1113–9 regarding the responsibility of facilities for personal belongings possessions shall apply to aesthetic surgery facilities. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
5.8 Anaesthesia Device	**French deviation** In the Code de la santé publique, Article D6322–41 it is regulated, that the provisions set out in Articles D.6124–91 to D.6124–103 on performing anaesthesia shall apply to aesthetic surgery facilities. The pre-anaesthesia consultation set out in Article D.6124–92 shall be carried out either in the consultation facilities provided in the reception area, or in the anaesthetist's office. As an exemption form the requirements set out in Article D.6124–100, if the post-operative monitoring room is reserved for aesthetic surgery patients, it may have a minimum capacity of two stations. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
5.9 Hygiene standards for procedure rooms and operating theatres	**French deviation** In the Code de la santé publique, Article R6322–16 it is regulated, that The holder of the licence for the aesthetic surgery facilities shall ensure that sterilization standards for medical devices are met, in accordance with the provisions set out in Articles R.6111–18 to R.6111–21. According to Article R6322–17, waste from the aesthetic surgery procedures shall be treated as clinical waste, as defined under and pursuant to Article R. 1335–1. The provisions set out in Articles R.1335–2 to R.1335–8 and Articles R.1335–13 and R.1335–14 regarding the disposal of clinical waste carrying infectious or similar hazards, shall apply to aesthetic surgery facilities. **Applicable French regulation** Code de la santé publique NOTE This regulation is available on web http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&dateTexte=20080506&fastPos=1&fastReqId=867835098&oldAction=rechTexte.
Annex A	**German deviation** It is the medical self-administration agreeing on ethical frameworks and incorporating them into law by issuing chamber regulations such as the enforceable professional codes. Furthermore, advertising in breach of professional ethic is prohibited, see 4.7.

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[4] EN 455-2, *Medical gloves for single use - Part 2: Requirements and testing for physical properties*

[5] EN 455-3, *Medical gloves for single use - Part 3: Requirements and testing for biological evaluation*

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[11] EN 1500, *Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)*

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[14] EN 12470 (all parts), *Clinical thermometers*

[15] EN 13060, *Small steam sterilizers*

[16] 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*

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[18] CEN/TR 15133, *Nomenclature - Collective terms and codes for groups of medical devices*

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