



BSI Standards Publication

**Aesthetic medicine services —  
Non-surgical medical treatments**

---

## National foreword

This British Standard is the UK implementation of EN 16844:2017.

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.

© The British Standards Institution 2017  
Published by BSI Standards Limited 2017

ISBN 978 0 580 89122 9

ICS 03.080.99; 11.020.10

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2017.

### Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

---

EUROPEAN STANDARD

**EN 16844**

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2017

ICS 03.080.99; 11.020.10

English Version

## Aesthetic medicine services - Non-surgical medical treatments

Services en médecine esthétique - Traitements médicaux, non chirurgicaux

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

This European Standard was approved by CEN on 27 February 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Contents

Page

European foreword .....	4
Introduction.....	5
<b>1 Scope .....</b>	<b>6</b>
<b>2 Terms and definitions.....</b>	<b>6</b>
<b>3 Competencies .....</b>	<b>8</b>
<b>3.1 General .....</b>	<b>8</b>
<b>3.2 Training.....</b>	<b>8</b>
<b>3.3 Continuous professional development (CPD) and continuous medical education (CME).....</b>	<b>9</b>
<b>4 Management and communication with patients.....</b>	<b>9</b>
<b>4.1 Office staff/Booking arrangements.....</b>	<b>9</b>
<b>4.2 Patient consultation and assessment.....</b>	<b>10</b>
<b>4.3 Consent.....</b>	<b>11</b>
<b>4.4 Documentation .....</b>	<b>12</b>
<b>4.5 Post-treatment follow up and patient satisfaction.....</b>	<b>13</b>
<b>4.6 Advertising.....</b>	<b>13</b>
<b>4.7 Medical tourism and travelling long distance for treatment.....</b>	<b>14</b>
<b>4.8 Medical indemnity and insurance .....</b>	<b>14</b>
<b>4.9 Fees .....</b>	<b>15</b>
<b>4.10 Arrangements for out of hours and emergency cover .....</b>	<b>15</b>
<b>4.11 Complaints .....</b>	<b>15</b>
<b>4.12 Confidentiality .....</b>	<b>15</b>
<b>4.13 Safe timing of treatments.....</b>	<b>16</b>
<b>4.14 Registration .....</b>	<b>16</b>
<b>5 Facilities .....</b>	<b>16</b>
<b>5.1 Evaluation of compliance and risk management .....</b>	<b>16</b>
<b>5.2 Personnel.....</b>	<b>16</b>
<b>5.3 Documentation of medical records.....</b>	<b>17</b>
<b>5.4 Facility .....</b>	<b>17</b>
<b>5.5 Administrative and waiting area .....</b>	<b>17</b>
<b>5.6 General requirements and recommendations for treatment rooms and procedure rooms .....</b>	<b>17</b>
<b>5.7 Patient safety and security.....</b>	<b>18</b>
<b>5.8 Hygiene standards for treatment rooms and procedure rooms .....</b>	<b>19</b>
<b>5.9 Medicines Management.....</b>	<b>20</b>
<b>5.10 Treatment room (TR).....</b>	<b>21</b>
<b>5.11 Procedure room (PR) .....</b>	<b>21</b>
<b>6 Treatments.....</b>	<b>22</b>
<b>6.1 General .....</b>	<b>22</b>
<b>6.2 Aesthetic medical treatment categories.....</b>	<b>22</b>
<b>6.3 Identifying factors .....</b>	<b>23</b>
<b>6.3.1 General .....</b>	<b>23</b>
<b>6.3.2 Practitioner.....</b>	<b>23</b>
<b>6.3.3 Facility .....</b>	<b>23</b>
<b>6.3.4 Anaesthesia level .....</b>	<b>24</b>

<b>6.3.5</b>	<b>Risk level of treatment.....</b>	<b>24</b>
<b>6.3.6</b>	<b>Patient physical status and age .....</b>	<b>24</b>
<b>6.3.7</b>	<b>Mental status and patient expectations.....</b>	<b>25</b>
<b>6.4</b>	<b>Treatment identification.....</b>	<b>25</b>
<b>6.5</b>	<b>Cooling off period .....</b>	<b>25</b>
<b>6.6</b>	<b>Aesthetic medical treatments .....</b>	<b>25</b>
<b>Annex A</b>	<b>(normative) Code of Ethics for marketing and advertising .....</b>	<b>28</b>
<b>Annex B</b>	<b>(informative) A-deviations.....</b>	<b>30</b>
<b>Bibliography</b>	<b>.....</b>	<b>45</b>

## **European foreword**

This document (EN 16844:2017) has been prepared by Technical Committee CEN/TC 403 “Aesthetic surgery and aesthetic non-surgical medical services”, the secretariat of which is held by ASI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Introduction

This European Standard provides a set of requirements, which are deemed to be essential for the provision of aesthetic medicine services (non-surgical medical treatments).

However, attention is drawn to the fact that in certain countries specific national regulations apply and take precedence over this European Standard. Users of this European Standard are advised to inform themselves of the applicability or non-applicability for this European Standard by their national responsible authorities.

Furthermore, recommendations for other aspects of good practice are provided. The Bibliography provides a list of European and International Standards and other documents of general interest for aesthetic medicine services. This list is not intended to be exhaustive.

Emphasis is placed on defining requirements for the quality of the aesthetic medicine services offered in order to ensure patient safety.

Other factors which influence the overall quality of service include: qualifications and professional competencies, staff behaviour, facility design and choice of products and suppliers.

This European Standard is designed to bring the following advantages to those that adopt it:

- improvement in aesthetic medicine services which can enhance patient safety and reduce the risk of complications;
- to promote consistently high standards for aesthetic medicine service providers across Europe;
- enhance patient satisfaction.

Requirements for a quality management system based on EN ISO 9001 for health care services are provided in EN 15224.

Requirements concerning the occupational health and safety of service providers and their staff at work are provided in relevant EU-Directives and national occupational health and safety legislation.

## 1 Scope

This European Standard addresses the requirements for certain aesthetic non-surgical medical treatments:

- treatments with resorbable injectables, botulinum toxin and micro needling;
- treatments with non-ablative fractional resurfacing and superficial peels, lasers and comparable energy based devices;
- treatments with fractional ablative lasers and comparable energy based devices and medium depth peels; and
- other treatments such as deep chemical peels, full ablative lasers and thread lifts.

This European Standard provides recommendations for aesthetic non-surgical medical treatments, including the ethical framework and general principles according to which aesthetic medicine services are provided by all practitioners and stakeholders of the aesthetic medical field. These recommendations apply before, during and after the treatment.

Any aesthetic medical treatment that goes deeper than the stratum corneum or which has, or claims to have, a biological effect beyond the stratum corneum (with or without instrument or devices) is included in the scope of this European Standard.

Aesthetic surgical procedures covered by EN 16372 and dentistry<sup>1)</sup> procedures are excluded from the scope of this European Standard.

Aesthetic non-medical treatments (tattooing and any treatment not affecting tissue deeper than the stratum corneum) which can be legally performed by non-physicians (e.g. tattooist, beauty therapists) are excluded from the scope of this European Standard.

## 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 2.1

#### **aesthetic medicine services**

services related to non-surgical medical treatments where the primary aim is the aesthetic change, restoration or improvement of the appearance, the function and/or well-being at the request of an individual with medical treatments, including the prevention and treatment of all kind of aesthetic concern, aging process, as well as the promotion of health

### 2.2

#### **adverse event**

unfavourable, unexpected or unintended temporary or permanent medical outcome to the patient

Note 1 to entry: “Adverse event” is defined in ISO/TS 19218-1:2011, 2.1 as an event associated with a medical device that led to death or serious injury of a patient, user or other person, or that might lead to death or serious injury of a patient, user or other person if the event recurs. This definition is consistent with the guidance in GHTF/SG2/N54/R8:2006 and definition includes malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

---

1) As defined in EN ISO 1942.



Note 2 to entry: “Adverse event” is defined in 2001/20/EC, Article 2 (m) as any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

### 2.3

#### **competence**

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

### 2.4

#### **complaint**

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

### 2.5

#### **“cooling off” period**

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

### 2.6

#### **facility**

medical establishment where aesthetic medical treatments and procedures are performed

### 2.7

#### **health**

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

Note 1 to entry: This definition is from the preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19–22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

### 2.8

#### **patient satisfaction**

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

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

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

Note 3 to entry: This definition was adapted from EN ISO 9000:2015, 3.9.2.

### 2.9

#### **practitioner**

medical doctor authorized by national competent authority to practice medicine autonomously

### 2.10

#### **reporting**

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

### **3 Competencies**

#### **3.1 General**

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

- determine the necessary competence of person(s) doing work under its control,
- ensure these persons are competent on the basis of training, skills and experience,
- where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken,
- retain documented information as evidence of competence,
- check the professional credentials and certified training of any professional applying to provide services under its responsibility.

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

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

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

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

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

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

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

#### **3.2 Training**

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

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

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

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

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

**3.3.1** The practitioner shall:

- a) maintain a valid registration by the national competent authorities of the country of practice and shall be involved in aesthetic practice on a regular basis; and
- b) attend at least two CME accredited scientific events per year relevant to the sphere of aesthetic practice he/she performs or accreditation by the recognized national profession society.

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

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

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

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

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

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

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

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

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

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

## **4.2 Patient consultation and assessment**

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

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

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

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

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

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

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

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

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

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

**4.2.11** The initial consultation(s) shall include

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

- b) explore the specific aesthetic concerns;
- c) assessment of patient's mental health/psychological state, including past psychological/mental health history where possible;
- d) assessment of patient's expectations;
- e) request relevant blood tests, if necessary;
- f) request other relevant investigations;
- g) request to communicate with relevant medical colleagues;

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

- h) if the patient is diagnosed with dysmorphobia no aesthetic medical treatments shall be performed;
- i) pre-treatment tests and investigations shall be performed where appropriate. The practitioner shall inform the patient of the financial implications.

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

NOTE 2 For consultation documentation, see 4.4.

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

### **4.3 Consent**

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

**4.3.2** The process shall include the following:

- a) A clear explanation of the limitations of the aesthetic medical treatment and alternative treatments that may be available (including those not offered by the practitioner).
- b) A clear explanation of the implications of the aesthetic medical treatment, including a clear explanation of the recovery time, duration of recommended absence from work and follow up plans.
- c) The practitioner shall ensure that the patient clearly understands the risks involved with the planned treatment. The frequently occurring and the rare, but serious, complications should be fully explained and understood. A personal low rate of complication shall not be used to entice patient to undertake aesthetic medical treatment.

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

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

- e) Written information shall be given as additional material and shall not take the place of an informed discussion. Practitioners should keep a record of both the discussions and of the information given to the patient. Both parties shall sign the informed consent form.
- f) The practitioner shall ensure that the patient is informed of the limitation, implications and potential complications of the aesthetic medical treatment before booking it.
- g) Until the initial consent process is complete (the time at which the patient fully understands the limitation, implications and potential complications of the aesthetic medical treatment) all monies, except for any previously declared non-refundable deposit, shall remain refundable.
- h) No patient shall undergo an aesthetic medical treatment without completion of the consent process.
- i) Aesthetic medical treatments for patients under the age of 18 years should be exceptional and linked to a documented medical assessment of the risks and benefits (health, social consequences). In those cases where it is clinically or psychologically necessary, the consent form shall be available in a legal form of words appropriate to the patient and/or their parents or guardians prior to the aesthetic medical treatment. Parental or guardian written agreement is mandatory.
- j) The consent forms should be legible, understandable and signed by both parties.
- k) The patient's consent shall be performed in a language both parties can understand and agree on.

#### **4.4 Documentation**

**4.4.1** Medical records and notes shall be legible and understandable.

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

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

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

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

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

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

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

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

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

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

#### **4.5 Post-treatment follow up and patient satisfaction**

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

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

**4.5.3** Follow up shall be ensured, if necessary.

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

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

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

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

#### **4.6 Advertising**

Advertising should be avoided.

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

- a) National advertising rules and prohibition shall be followed by any individual, group or business wishing to communicate with, or advertise to, patients in the country concerned.
- b) Advertising and marketing in any form shall be legal, decent, honest, truthful and socially responsible.

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

- c) Advertorial transparency shall be assured and patients shall be aware from the text when an article is an advertorial.
- d) Free consultation shall not be used as a marketing tool.
- e) No models shall be used either in advertising or marketing and a declaration of conflict of interest shall be prominent.
- f) Web, blog and any social media transparency shall be assured and if practitioners, or their employees, are involved in blog/web communications they shall declare their true identity.
- g) The official professional status/qualification of the practitioner shall be clearly stated.

- h) Practitioner's qualifications shall not be misrepresented and only the speciality listed in EU-Directive 2005/36/EC in which the practitioner is qualified shall be used. No terms shall be used that give patients or the public the wrong impression of a qualification in a speciality listed in EU-Directive 2005/36/EC or specialities recognized at national level, in the respective country.
- i) Commission based patient advisors shall not be used. 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) Patient's testimonial used by practitioners for public information shall be verifiable, traceable and unpaid.
- k) For further details, see Annex A.

#### **4.7 Medical tourism and travelling long distance for treatment**

Medical tourism and travelling long distance for treatment are rarely in the patient's best interest. In addition to the other subclauses in Clause 4 the medical establishment and the practitioner:

- a) shall make patients fully aware of the implications and risks of long distance travelling for treatment and that follow up, and the management of even minor complications/ dissatisfaction becomes a complicated process;
- b) should not reassure patients that pre- and post-treatment appointments made with other, local, practitioners are equivalent to seeing the practitioner performing the treatment at any time that may be necessary in the future;
- c) should emphasize the importance of follow up. Documentation shall be made of discussions explaining the difficulties in the case of complications/ dissatisfaction with the result. It is advised this is presented as a risk disclosure document and that it is signed by the patient;
- d) shall inform the patient in the case of category 3 and 4 aesthetic medical treatments (see 6.2) about the risk of long distance travelling in the pre- and post-treatment period;
- e) should not recommend insurance schemes that hand over the responsibility for looking after complications to third parties. They act as an inducement by making a dangerous process slightly more attractive but no less dangerous;
- f) shall inform patients travelling long distances for treatment of the professional indemnity arrangements of the practitioner and, if applicable, the medical establishment where treatments are performed;
- g) should inform patients of tiers of responsibility should problems arise. Patients shall not be misled into believing that the company making the arrangements for their trip carries medical liability insurance;
- h) shall inform patients if the practitioner is travelling long distance to provide treatment. Requirements in this European Standard also apply to travelling practitioners.

#### **4.8 Medical indemnity and insurance**

**4.8.1** Practitioners shall hold a medical indemnity insurance for each kind of treatments they perform. This insurance should also cover damages or problems that are unexpected or unforeseeable at the time of treatment.



**4.8.2** Patients shall be informed that the practitioner undertaking their aesthetic medical treatment 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.

**4.8.3** Patients shall be informed that their practitioner/practitioners possesses adequate and appropriate indemnity for the treatments being undertaken, registered in the country where the treatment is performed.

**4.8.4** The practitioner shall honestly declare all information regarding scope and location of the aesthetic medical treatments he/she performs to the insurer, thus ensuring that he/she remains insured.

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

#### **4.9 Fees**

**4.9.1** Fees shall be transparent and a detailed and written quote shall be delivered prior consent being obtained.

**4.9.2** Long term financial implications should be clear.

**4.9.3** Financial arrangement for complications should be explicit.

**4.9.4** Financial discounts shall not be used to encourage patients to consider aesthetic medical treatment or further treatments.

**4.9.5** Patients shall be informed of the terms and conditions of any payment made, particularly deposits.

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

**4.10.1** Patients shall be provided with contact details for their practitioner/ medical establishment in the case of emergency.

**4.10.2** Out of hours care would normally be expected to be provided by the practitioner involved in the treatment, unless other arrangements have been clearly defined with healthcare staff/ facilities and explained to the patient.

**4.10.3** 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. For treatments with higher risk a thorough handover of patients is expected.

#### **4.11 Complaints**

**4.11.1** All practices/ medical establishments offering aesthetic medicine services shall have a clear complaints procedure and process, including timeframe for responding.

**4.11.2** Patients should be made aware of the practice/ medical establishments' complaints procedure.

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

#### **4.12 Confidentiality**

Patient confidentiality shall be respected at all times.

### **4.13 Safe timing of treatments**

**4.13.1** The practitioner shall inform the patient if the timing, complexity, or duration of their aesthetic medical treatment could introduce additional risks/complications (e.g. peeling before sun exposure).

**4.13.2** The practitioner shall inform the patient of additional risks associated with the aesthetic medical treatment if patient behaviour may modify these, e.g. smoking cessation and weight loss.

**4.13.3** The practitioner shall inform the patient if stopping or taking any medication would modify risk of the aesthetic medical treatment.

**4.13.4** The practitioner shall carefully consider the age of patient, his/her health condition and psychological state when considering whether aesthetic medical treatment is appropriate.

### **4.14 Registration**

All practitioners and medical establishments 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 and good clinical practice 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 medical treatment 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 medical treatment and that meet the definitions of Directives 2001/83/EC and 93/42/EEC shall be reported to the vigilance contact point in the national competent authorities. Where appropriate, provisions shall be in place if such adverse events occur 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 to recall patients shall be regularly updated.

### **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 and whenever necessary, i.e. due to change(s) in national regulations or medical recommendations for given treatments.

**5.2.3** All medical personnel directly involved in patient care should be trained in cardiovascular resuscitation and in specific emergencies relevant to aesthetic medical treatments.

**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 securely kept and only accessible to 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 (if needed) for patients. The lavatory facilities shall accommodate patients' 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, devices and equipment shall be stored in a safe manner to both maintain their cleanliness, sterility, functionality and to prevent injury to patients.

**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 lighting.

### **5.5 Administrative and waiting area**

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

**5.5.2** If needed, there should be an area for administrative activities. This area shall be ventilated, temperature controlled for personnel comfort, cleaned, maintained and lit.

### **5.6 General requirements and recommendations for treatment rooms and procedure rooms**

**5.6.1** The practitioner or the medical establishment shall determine, provide and maintain the facilities needed to ensure the safety of the patient during provision of aesthetic medicine services.

**5.6.2** All treatment and procedure rooms 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 medical treatments.

**5.6.7** Each room shall have wiring that meets the 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.

NOTE Particular requirements for the basic safety and essential performance of operating tables are provided in EN 60601-2-46.

**5.6.9** Facilities for hand washing, waste disposal and work surfaces shall be available.

## **5.7 Patient safety and security**

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

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

**5.7.3** A process shall be implemented to assess the medical facility's ability to meet patient, statutory, regulatory and the organization's own requirements applicable to all devices used in the medical facility. In addition, the person responsible of the medical establishment (including the practitioner when he/she manages the medical establishment) shall ensure that all findings from inspections and audits required by that process are recorded. When equipment is not found to conform to the requirements, the practitioner shall take appropriate action on the equipment or any device affected.

**5.7.4** 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.

**5.7.5** All medical hazardous wastes and their packaging shall be stored in suitable containers, and separated from general waste/refuse for special collection and handling.

**5.7.6** All medical hazardous wastes and their packaging shall be disposed of in sealed, labelled containers.

**5.7.7** 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.

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

**5.7.9** If a laser of class 1C, 3B or 4 or intense pulsed light (IPL) device is used, all applicable laser safety standards shall be implemented and followed.

NOTE 1 Further guidance for the safe use of laser beams and IPL devices on humans and laser equipment is provided in IEC/TR 60825-8 and IEC/TR 62471-3 respectively. Equipment classification and requirements for laser products are provided in EN 60825-1 and EN 60601-2-22. Equipment classification and requirements for IPL devices are provided in EN 62471 and EN 60601-2-57.

NOTE 2 See EU-Directives 93/42/EEC, 2006/25/EC and 2006/95/EC.

**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, if present, shall be stored and handled in a safe manner.

**5.7.12** There shall be a written policy specifying and mandating the use of appropriate personal protective equipment for the protection of the patient 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. In case of power failure there shall be emergency lights for exit routes and patient care areas. Passage and hallways shall allow evacuation of a patient by emergency personnel (including stretchers, etc.). 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 for the evacuation of a patient.

**5.7.15** 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 his/her the room and,
- if applicable, for immediate or timely return to the treatment room for patient emergencies.

**5.7.16** There shall be a written protocol for:

- a) cardiopulmonary resuscitation,
- b) situation in which the practitioner becomes incapacitated,
- c) response to power failure emergencies,
- d) transferring patients in an emergency,
- e) plan for emergency evacuation of facility.

## **5.8 Hygiene standards for treatment rooms and procedure rooms**

**5.8.1** The arrangements concerning hygiene and infection protection shall comply with legal requirements.

**5.8.2** In order to protect the patient, aseptic conditions shall be ensured by using sterile, protective gowns, aprons, masks, eye protection and gloves as appropriate.

**5.8.3** Disposable materials and devices should be used. If this is not possible re-sterilizable materials and devices shall be used.

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

**5.8.5** In order to protect the patient, any risk of contamination induced by blood and body fluids shall be prevented by effective cleaning and disinfection using appropriate germicides indicated as virucidal, bactericidal, tuberculocidal, fungicidal, levuricidal, mycobactericidal, sporicidal.

**5.8.6** 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.

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

NOTE Requirements for sharps containers are included in EN ISO 23907.

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

**5.8.9** 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.

**5.8.10** Dirty devices and instruments shall be strictly separated from those which have been cleaned.

**5.8.11** Re-usable medical devices shall be processed in accordance with validated procedures and appropriate records shall be kept.

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

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

## **5.9 Medicines Management**

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

**5.9.2** If narcotics are used, there shall be a dated, sequential narcotic inventory and control record which includes the use of narcotics on individual patients. Such records shall be kept in a retrievable format.

**5.9.3** All narcotics and controlled substances, if present, shall be secured and locked, not portable, and under supervised access.

**5.9.4** Medications shall be routinely reviewed and outdated drugs shall be removed and replaced. Medications shall be stored in a temperature controlled environment. Refrigerators shall be equipped with a temperature alarm.

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

**5.9.6** At least the following emergency medications shall be available in the facility at all times:

- epinephrine,
- amiodarone,
- seizure arresting medication (a benzodiazepine),
- bronchospasm arresting medication (inhaled beta agonist),
- intravenous or intramuscular corticosteroids,
- antihistamines,

- short-acting beta-blocker,
- atropine,
- oxygen, and
- hyaluronidase.

### **5.10 Treatment room (TR)**

In addition to 5.6 requirements specific for a treatment room are:

- a) There shall be space and all necessary equipment to ensure safe and aseptic treatment of the patient. Personal protective equipment, which shall be worn for the protection of the patient, shall be available and room to put it on is provided.
- b) An automated external defibrillator (AED) should be present in close proximity and staff members trained to use it.
- c) As a minimum, the following shall be available:
  - 1) lighting for examination and treatment;
  - 2) sphygmomanometer;
  - 3) stethoscope;
  - 4) couch suitable for shock positioning and cardiopulmonary resuscitation;
  - 5) basin.

### **5.11 Procedure room (PR)**

In addition to 5.6 requirements specific for a procedure room are:

- a) If the practitioner performing the aesthetic medical treatment leaves the room during the treatment there shall be at least a fully qualified nurse or doctor's assistant present. No patient can be left alone without medical supervision during a treatment.
- 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. battery powered inverter), with sufficient capacity to operate medical electrical equipment, cautery and lighting until the treatment can be stopped in a safe manner. This emergency power source shall be able to begin generating ample power to operate all the essential electrical device being used in the treatment within 3 s in case of a power failure. The emergency power device shall be checked regularly (e.g. monthly) to insure function.
- e) Appropriate scrub facilities for hand disinfection shall be provided necessary to ensure the safety of the patient.
- f) The procedure room shall be at least 12 m<sup>2</sup>.

- g) For aesthetic medical treatment performed under sedation, there shall be a transfer agreement with a local accredited or licensed acute care hospital which is approved by the facility's medical staff or the practitioner has privileges to admit patients to such a hospital after having performed the aesthetic medical treatment in the facility.
- h) The patient shall be monitored during and after the aesthetic medical treatment.
- i) O<sub>2</sub> and suction shall be provided.
- j) Emergency Cart shall be available with defibrillator, necessary drugs and other devices needed for cardiopulmonary emergency. An automated external defibrillator (AED) shall be present and staff members trained to use it.
- 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 and floors 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) facilities for infusion and resuscitation;
  - 2) lighting for examination and treatment;
  - 3) sphygmomanometer;
  - 4) stethoscope;
  - 5) pulse oximeter;
  - 6) couch suitable for shock positioning and cardiopulmonary resuscitation;
  - 7) basin.

## 6 Treatments

### 6.1 General

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

### 6.2 Aesthetic medical treatment categories

The following aesthetic medical treatment categories apply:

Category 1: Aesthetic medical treatments with resorbable injectables, botulinum toxin and micro needling;

Category 2: Aesthetic medical treatments with non-ablative fractional resurfacing and superficial



peels, lasers and comparable energy based devices;

Category 3: Aesthetic medical treatments with fractional ablative lasers and comparable energy based devices and medium depth peels;

Category 4: Aesthetic medical treatments not categorized in Categories 1, 2 or 3, such as deep chemical peels, full ablative lasers and thread lifts.

## 6.3 Identifying factors

### 6.3.1 General

The following factors influence the outcome of an aesthetic medical treatment:

- practitioner, see 6.3.2;
- facility, see 6.3.3;
- anaesthesia level, see 6.3.4;
- risk level of treatment, see 6.3.5;
- patient physical status and age, see 6.3.6;
- patient mental status and expectations, see 6.3.7.

The relation between aesthetic medical treatments and categories is outlined in Figure 1.

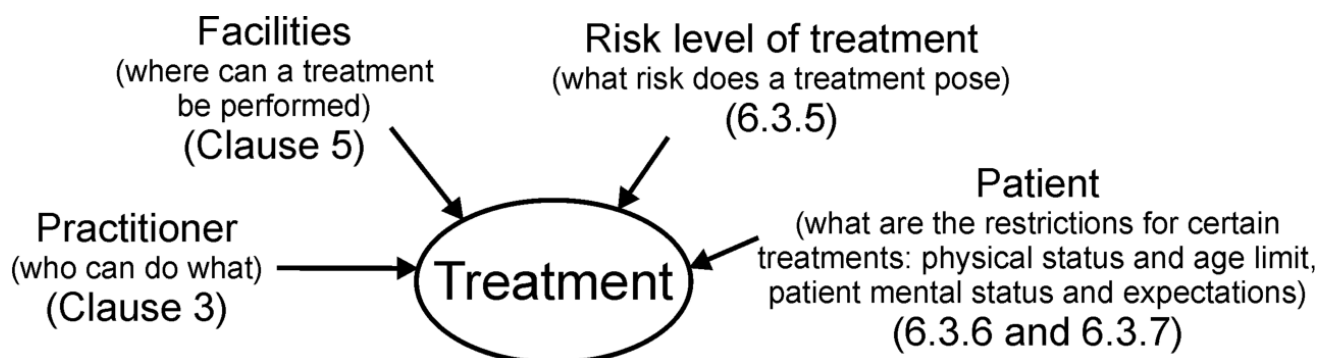


Figure 1 — Relations

### 6.3.2 Practitioner

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

### 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 and medication, infrastructure and personal competencies as presented in Clause 5.

The rooms, in which aesthetic medical treatments are performed, are defined as follows:

TR Treatment room for aesthetic medical treatments of categories 1, 2 and 3 as defined in 6.2 (see Clause 5, especially 5.10),

PR Procedure room for aesthetic medical treatments of category 4 as defined in 6.2 (see Clause 5, especially 5.11).

#### 6.3.4 Anaesthesia level

- I Topical or no anaesthesia,
- II Local, loco-regional anaesthesia (peripheral nerve blocks) without sedation.

#### 6.3.5 Risk level of treatment

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 treatments. Any aesthetic medical treatment carries an element of risk of permanent scarring, permanent disability and even death.

Treatments in Table 1 are categorized according to the most severe complication of the treatment, 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. Patients' physical status is defined as follows:

- 1 normal healthy patient (no organic, physiologic or psychiatric disturbance, healthy with good exercise tolerance),
- 2 patient with mild systemic disease (no functional limitations; patient has a well-controlled disease of one body system; controlled hypertension or diabetes without systemic effects, cigarette smoking without chronic obstructive pulmonary disease (COPD); mild obesity, pregnancy),
- 3 patients with severe systemic disease (some functional limitation; patient has a controlled disease of more than one body system or one major system; no immediate danger of death; controlled congestive heart failure (CHF), stable angina, old heart attack, poorly controlled hypertension, morbid obesity, chronic renal failure; bronchospastic disease with intermittent symptoms),
- 4 patients with severe systemic disease that is a constant threat to life (patient has at least one severe disease that is poorly controlled or at end stage; possible risk of death; unstable angina, symptomatic COPD, symptomatic CHF, hepatorenal failure),
- 5 moribund patients who are not expected to survive without surgery (not expected to survive after 24 h without surgery; imminent risk of death; multiorgan failure, sepsis syndrome with haemodynamic instability, hypothermia, poorly controlled coagulopathy),
- 6 declared brain-dead patients whose organs are being removed for donor purposes.

Patients' physical status 4, 5 and 6 are not used for the purpose of this European Standard.

For patients two age-levels are defined:

- Y Below 18 years of age.
- O 18 years of age or above.

### 6.3.7 Mental status and patient expectations

All patients shall be assessed as described in 4.2.11 to exclude unrealistic expectations and some mental disorders such as dysmorphobia.

### 6.4 Treatment identification

Since Table 1 is not intended to be exhaustive, aesthetic medical treatments not included in Table 1 shall be allocated by the practitioner to an 'equivalent' treatment that is included in Table 1. Aesthetic medical treatments that cannot be allocated shall be listed separately. These treatments and treatments that do not yet exist at this time shall be classified as follows:

- Every new or unmentioned aesthetic medical treatment shall be judged compared to already existing or mentioned treatments, using an evidence based approach.
- New aesthetic medical treatments shall be restricted to normal healthy patients and patients suffering of mild systemic diseases (physical status 1 or 2 according to 6.3.6).

### 6.5 Cooling off period

The "cooling off" period depends on the aesthetic medical treatment category (see 6.2) and on the risk levels (see 6.3.5). The minimum "cooling off" period should be:

- a) for treatment categories 1 and 2: No "cooling off" period;
- b) for treatment categories 3 and 4:
  - 1) risk level A to C: 24 h;
  - 2) risk level D: 1 week;
- c) for patients with mental health impairment: 4 weeks.

### 6.6 Aesthetic medical treatments

Some phenol peels and ablative non-fractional resurfacing of the face might require general anaesthesia or loco-regional anaesthesia with sedation. In such cases, even though general anaesthesia and loco-regional anaesthesia with sedation are not covered in this European Standard, these treatments shall be carried out in an operating theatre environment with an anaesthesiologist.

Non-resorbable fillers shall not be used until ongoing clinical trials prove long term safety.

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

In order to ensure patient safety all treatments shall be carried out according to best clinical practice with special attention to sterility and safety of the equipment used (see 5.8).

**Table 1 — Classification of aesthetic medical treatments, excluding risk level E (death)**

<b>Treatments</b>	<b>Room type (6.3.3)</b>	<b>Risk level<sup>a</sup> (6.3.5)</b>	<b>Physical status of patient (6.3.6)</b>	<b>Treatment category (6.2)</b>
<b>Chemical peels</b>				
Superficial	TR	A	1-3	2
Medium	TR	C	1-2	3
<b>Fillers</b>				
Filler resorbable	TR	D	1-3	1
Filler non-resorbable	shall not be used until ongoing clinical trials prove long term safety			
<b>Botulinum toxin injection</b>	TR	B	1-3	1
<b>(Micro) needling</b> (exceeding stratum corneum, or 0,2 mm around the nose and the eyes, 0,5 mm for the rest of the face and the neck and 1 mm for the rest of the body)	TR	B	1-3	1
<b>Electromagnetic radiations</b>				
Lasers for skin pigmentation, except the eyes region	TR	C	1-3	2
Lasers for hair removal, except the eyes region	TR	C	1-3	2
Lasers for tattoo removal	TR	C	1-3	3
Non-Ablative Fractional resurfacing	TR	B	1-3	2
Ablative Fractional resurfacing	TR	C	1-3	3
Intense pulse light (IPL) treatments, except the eyes region	TR	C	1-3	3
Photodynamic therapy	TR	B	1-3	2
Radiofrequency for skin tightening	TR	C	1-3	3
Infrared and other devices e.g. for skin tightening treatments	TR	C	1-3	3
Lasers, infrared, radiofrequencies, intense pulse light (IPL) treatment and other sources of equivalent power and energy applied in the eyes region	TR	D	1-3	3
High frequency, radiofrequency and other treatments with energy based devices increasing skin temperature above 42 °C	TR	C	1-3	2

Treatments	Room type (6.3.3)	Risk level <sup>a</sup> (6.3.5)	Physical status of patient (6.3.6)	Treatment category (6.2)
Treatments with LED (Light Emitting Diodes) or equivalent electromagnetic sources (output exceeding 500 mW·cm <sup>-2</sup> ) for biomodulation	TR	B	1-3	2
<b>Focalized ultrasound</b>	TR	C	1-3	3
<b>Sclerotherapy of reticular veins</b>	TR	C	1-2	2
<b>Mesotherapy</b>	TR	C	1-3	1
<b>Carboxytherapy</b>	TR	C	1-3	1
<b>Platelet Rich Plasma injections and comparable techniques in a closed system</b>	TR	A	1-3	1
<b>Platelet Rich Plasma injections and comparable techniques in an open system</b>	PR	B	1-3	1
<b>Cryolipolysis with continuous temperature monitoring</b>	TR	B	1-3	2
<b>Cryolipolysis without continuous temperature monitoring</b>	TR	C	1-3	3
<b>Subcutaneous resorbable threads to stimulate collagen</b>	TR	C	1-3	2
<b>Thread lifts</b>	PR	D	1-3	4
<b>Dermabrasion (exceeding stratum corneum)</b>	PR	C	1-3	4
<b>Deep chemical peels (Phenol or other)</b>	PR	D	1	4
<b>Ablative Laser Skin Resurfacing</b>	PR	D	1-3	4
Aesthetic medical treatments not included in Table 1 shall be judged compared to those included in Table 1, using an evidence based approach. See further guidance provided in 6.4.				
<sup>a</sup> Treatments are categorized according to the most severe complication of the treatment, but excluding risk level E (death).				

## **Annex A** (normative)

### **Code of Ethics for marketing and advertising**

**A.1** Any marketing towards patients residing in a country, where marketing and advertising are not allowed, shall not be done. 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 medical treatments;
- any advertisements in journals, newspapers, magazines or other advertising 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 treatment, this shall be stated clearly;
- the information published shall not make unjustifiable claims or offer cures/guarantees;
- services shall not be advertised by visiting or telephoning prospective patients, either in person or through a deputy;
- advertisements shall not offer discounts linked to a deadline date for booking appointments for aesthetic medical treatment 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 medical treatments, time-limited offers, money offers and offers such as buy one and get one free;
- a practitioner shall not participate in sweepstakes (lottery) of aesthetic medical treatments;
- a practitioner shall not participate in makeover shows, as they can promote unrealistic expectations of what aesthetic medical treatment 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 data related to complications and their own complication rate;
- practitioners shall be honest about the science of any aesthetic medical treatment 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)

### A-deviations

**A-deviation:** National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN national 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/subclause/section in EN 16844	Deviation
Clause 1 Scope	<p><b>French deviation</b></p> <p>Marketing authorization (AMM) in France reserves the prescription of botulinum toxin:</p> <ul style="list-style-type: none"> <li>- to specialists of plastic, reconstructive and aesthetic Surgery, dermatology, surgery of the face and neck, maxillofacial surgery and ophthalmology</li> <li>- to certain anatomical areas.</li> </ul> <p>Botulinum toxin, whatever its packaging must be used only for a single patient, in a single session, and the procedures to follow for a safe disposal of vials, syringes and materials used, should follow the recommendations contained in the recommendations of product characteristics (RCP).</p> <p>NOTE This regulation is available on the web at <a href="http://www.has-sante.fr/portail/upload/docs/application/pdf/2008-06/ct_2918_dysport_ang.pdf">http://www.has-sante.fr/portail/upload/docs/application/pdf/2008-06/ct_2918_dysport_ang.pdf</a></p>
2.9 practitioner	<p><b>British deviation</b></p> <p>The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 allows a registered nurse to act as an independent prescriber. When considering which procedures in EN 16844 a registered nurse is allowed to perform, the registered nurse must meet the regulations set out in the Nursing and Midwifery Council (NMC) Code in respect of only performing procedures that they are specifically qualified to deliver.</p> <p>Dentists are appropriate practitioners according to the Medicines Act 1968 (as amended). In practising non-surgical cosmetic procedures, dentists must have regard to the national professional regulations and guidance set by the General Dental Council (GDC).</p> <p>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 (e.g. Intense Pulsed Light Systems) services are provided.</p> <p>This includes the licensing of laser and ILS services offered by non-medical practitioners that provide treatments such as hair reduction</p>



Clause/subclause/section in EN 16844	Deviation
	<p>and other 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. In the jurisdictions listed below clinics with Class 3B lasers and above, and IPLs, shall appoint a certificated Laser Protection Adviser (LPA) to advise on safe use of the lasers / IPLs.</p> <p><b>Applicable UK regulation</b></p> <p>London Local Authorities Act 1991 – Special Treatment Licensing</p> <p>NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/ukla/1991/13/part/I/enacted">http://www.legislation.gov.uk/ukla/1991/13/part/I/enacted</a> and under Paragraph 6 (2) “The borough council may grant to an applicant and from time to time renew or transfer a licence on such terms and conditions and subject to such restrictions as may be specified.” and under Paragraph 10 (1) Power to prescribe standard terms, conditions and restrictions. “The borough council may make regulations prescribing standard conditions applicable to all, or any class of, licences, that is to say terms, conditions and restrictions on or subject to which licences, or licences of that class, are in general to be granted, renewed or transferred by them.” These regulations are usually implemented by London boroughs through the issue of 'Codes of Practice' or 'Special Treatment Conditions' which specify the appointment of an LPA a typical example of which is available on the web at: <a href="http://www.camden.gov.uk/ccm/content/business/business-regulations/licensing-and-permits/licences/other-licences/massage-and-special-treatments/massage-and-special-treatments/">http://www.camden.gov.uk/ccm/content/business/business-regulations/licensing-and-permits/licences/other-licences/massage-and-special-treatments/massage-and-special-treatments/</a>.</p> <p>The Independent Healthcare (Wales) Regulations 2011</p> <p>NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/wsi/2011/734/regulation/45/made">http://www.legislation.gov.uk/wsi/2011/734/regulation/45/made</a> and is enforced through the 'Registration under the Care Standards Act 2000 Guide to the application process for new providers' issued by Health Inspectorate Wales (October 2013) which can be accessed at: <a href="http://www.hiw.org.uk/sitesplus/documents/1047/Independent%20health%20%2D%20Application%20guidance%2De.pdf">http://www.hiw.org.uk/sitesplus/documents/1047/Independent%20health%20%2D%20Application%20guidance%2De.pdf</a> and through implementation of the 'National Minimum Standards for Independent Health Care Services in Wales' which can be accessed at: <a href="http://gov.wales/docs/legislation/inforcenonsi/nationalhealth/110401nmstandards16.pdf">http://gov.wales/docs/legislation/inforcenonsi/nationalhealth/110401nmstandards16.pdf</a> (see page 10 regarding appointment of an LPA).</p> <p>The Independent Healthcare Regulations (Northern Ireland) 2005</p> <p>NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/nisr/2005/174/regulation/39/made">http://www.legislation.gov.uk/nisr/2005/174/regulation/39/made</a> and is enforced through the Independent Healthcare Minimum Standards issued by the Department of Health, Social Services and Public Safety (July 2014) which can be accessed at: <a href="http://www.rqia.org.uk/cms_resources/Independent_Healthcare_Minimum_Standards.pdf">http://www.rqia.org.uk/cms_resources/Independent_Healthcare_Minimum_Standards.pdf</a> and which require that “There is written confirmation of the appointment and duties of a certificated Laser Protection Advisor that is renewed annually.” (paragraph 48.6)</p> <p>NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/wsi/2011/734/regulation/45/made">http://www.legislation.gov.uk/wsi/2011/734/regulation/45/made</a> and is enforced through the 'Registration under the Care Standards Act 2000 Guide to the application process for new providers' issued by Health Inspectorate Wales (October 2013) which can be accessed at:</p>

Clause/subclause/section in EN 16844	Deviation
	<p><a href="http://www.hiw.org.uk/sitesplus/documents/1047/Independent%20health%20%2D%20Application%20guidance%2De.pdf">http://www.hiw.org.uk/sitesplus/documents/1047/Independent%20health%20%2D%20Application%20guidance%2De.pdf</a> and through implementation of the 'National Minimum Standards for Independent Health Care Services in Wales' which can be accessed at: <a href="http://gov.wales/docs/legislation/inforcenonsi/nationalhealth/110401nmstandards16.pdf">http://gov.wales/docs/legislation/inforcenonsi/nationalhealth/110401nmstandards16.pdf</a> (see page 10 regarding appointment of an LPA).</p> <p>The Independent Healthcare Regulations (Northern Ireland) 2005</p> <p>NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/nisr/2005/174/regulation/39/made">http://www.legislation.gov.uk/nisr/2005/174/regulation/39/made</a> and is enforced through the Independent Healthcare Minimum Standards issued by the Department of Health, Social Services and Public Safety (July 2014) which can be accessed at: <a href="http://www.rqia.org.uk/cms_resources/Independent_Healthcare_Minimum_Standards.pdf">http://www.rqia.org.uk/cms_resources/Independent_Healthcare_Minimum_Standards.pdf</a> and which require that "There is written confirmation of the appointment and duties of a certificated Laser Protection Advisor that is renewed annually." (paragraph 48.6).</p>
2.9 practitioner Clause 3 Competencies	<p><b>Belgian deviation</b></p> <p>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.</p> <p>NOTE Article 9 to 16 of this regulation is available on web: <a "))&amp;rech='1&amp;language=nl&amp;tri=dd+AS+RANK&amp;numero=1&amp;table_name=wet&amp;cn=2013052321&amp;caller=image_a1&amp;fromtab=wet&amp;la=N&amp;pdf_page=7&amp;pdf_file=http://www.ejustice.just.fgov.be/mopdf/2013/07/02_1.pdf"' href="http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?N=&amp;=&amp;sql=(text+contains+(">http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?N=&amp;=&amp;sql=(text+contains+(""))&amp;rech=1&amp;language=nl&amp;tri=dd+AS+RANK&amp;numero=1&amp;table_name=wet&amp;cn=2013052321&amp;caller=image_a1&amp;fromtab=wet&amp;la=N&amp;pdf_page=7&amp;pdf_file=http://www.ejustice.just.fgov.be/mopdf/2013/07/02_1.pdf</a></p>
2.9 practitioner Clause 3 Competencies 3.1 General	<p><b>Irish deviation</b></p> <p>Prescriptive authority of medicinal products is extended to nurses and midwives in Ireland as per the legislative framework – IMB Miscellaneous Provisions Act 2006 and supporting regulations, SI 200 and SI 201 of 2007 and the NMBI regulatory framework for registered nurse prescribers.</p> <p>Medicines regulations of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (Statutory Instrument (SI) No. 201 of 2007) and the Misuse of Drugs (Amendment) Regulations 2007 (SI No. 200 of 2007). The medicines legislation provides the legal authority to nurses and midwives to prescribe. This authority is based upon the following conditions being satisfied:</p> <ul style="list-style-type: none"> <li>- The nurse/midwife is employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home).</li> </ul> <p>The medicinal product is one that would be given in the usual course of the service provided in the health service setting in which the nurse/midwife is employed.</p> <ul style="list-style-type: none"> <li>- The prescription is issued in the usual course of the provision of that health service.</li> </ul> <p>NMBI Personal Identification Number (PIN) of the registered nurse/midwife must also be stated on the prescription.</p>

Clause/subclause/section in EN 16844	Deviation
	In addition, the 2007 Regulations allow a health service provider to determine further conditions for the prescriptive authority of the RNP.
3.1 General	<p><b>German deviation</b></p> <p>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.</p> <p>NOTE These regulations are available on web <a href="http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MWBOengl20130628.pdf">http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MWBOengl20130628.pdf</a></p>
3.1 General 3.1.3	<p><b>German deviation</b></p> <p>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.</p>
3.1 General	<p><b>German deviation</b></p> <p>Training: Federal Medical Regulation Art. 2 and Art. 4 in conjunction with Approbation Regulation.</p> <p>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.</p> <p>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)</p> <p>It is becoming a specialist as awarded by the competent authority which provides for the guarantee of specialist training.</p> <p>NOTE These regulations are available on web <a href="http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MWBOengl20130628.pdf">http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MWBOengl20130628.pdf</a></p>
3.1.5	<p><b>Applicable Norwegian regulation</b></p> <p>Norwegian Health Personnel Act of 2 July 1999 No. 64 relating to Health Personnel, etc. (<i>Helsepersonelloven</i>). With amendments made previous to 1 July 2002 from the Ministry of Health and Care Services and which came into force on the 2001-01-01.</p> <p>Chapter II, Use of assistants:</p> <p>Health personnel may in their work assign certain tasks to other personnel if it is considered safe to do so based on the nature of the assigned task, the qualification of the assigned personnel and the guidance that is being provided. Pupils and students shall as a rule only be assigned tasks based on their need for training.</p> <p><b>Norwegian deviation</b></p> <p>In addition to medical doctors, nurses may perform treatments with resorbable injectables and botulinum toxin after attending a course in botox treatment.</p> <p>However nurses do not have prescription authority in Norway, and the prescribing medical doctor is therefore medically responsible for the</p>

Clause/subclause/section in EN 16844	Deviation
	<p>treatment without the requirements of supervision. Nurses may independently assess and proceed with patient consultations without supervision of a medical doctor.</p>
3.1.7	<p><b>Dutch deviation</b> In accordance with the wet BIG skin therapists with appropriate, nationally recognized, training can use lasers class 2 and higher, IPL and LED. Dutch skin therapists cannot apply lasers, IPL and LED for purposes of incision or injecting without medical supervision. NOTE This regulation is available on web <a href="http://wetten.overheid.nl/BWBR0006251/geldigheidsdatum_20-01-2016">http://wetten.overheid.nl/BWBR0006251/geldigheidsdatum_20-01-2016</a></p>
3.1.7	<p><b>German deviation</b> The authorization of a healthcare professional for medical treatments with the use of lasers (class 3B and higher) is not possible. In Germany occupational safety and health of employees using lasers is regulated on the basis of Verordnung zum Schutz der Beschäftigten vor Gefährdungen durch künstliche optische Strahlung (Arbeitsschutzverordnung zu künstlicher optischer Strahlung – OstrV) which is the German version <a href="http://www.gesetze-im-internet.de/bundesrecht/ostrv/gesamt.pdf">http://www.gesetze-im-internet.de/bundesrecht/ostrv/gesamt.pdf</a> of Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) <a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006L0025">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006L0025</a> as well as DGUV Vorschrift 11 <a href="http://publikationen.dguv.de/dguv/pdf/10002/vorschrift11.pdf">http://publikationen.dguv.de/dguv/pdf/10002/vorschrift11.pdf</a>. Additionally, §1 (2) HeilprG <a href="http://www.gesetze-im-internet.de/bundesrecht/heilprg/gesamt.pdf">http://www.gesetze-im-internet.de/bundesrecht/heilprg/gesamt.pdf</a> in combination with §§2, 2a (BÄO) <a href="http://www.gesetze-im-internet.de/bundesrecht/b_o/gesamt.pdf">http://www.gesetze-im-internet.de/bundesrecht/b_o/gesamt.pdf</a> mandates medical procedures are only to be carried out by medical practitioners. Treatments with the use of lasers (class 3B and higher) are considered to be medical procedures according to The Federal Administrative Court decision <a href="http://www.bverwg.de/entscheidungen/pdf/260810U3C28.09.0.pdf">http://www.bverwg.de/entscheidungen/pdf/260810U3C28.09.0.pdf</a> (ECLI:DE:BVerwG:2010:260810U3C28.09.0) because they can induce negative health effects. Based on decision of the Bundesärztekammer authorization of a healthcare professional for medical treatments that are likely to induce negative health effects is not possible. <a href="http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/Empfehlungen_Persoенliche_Leistungserbringung.pdf">http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/Empfehlungen_Persoенliche_Leistungserbringung.pdf</a> (<a href="http://www.kammerrecht.de/kammergesetze/berufskammern.html#Heilberufskammern">http://www.kammerrecht.de/kammergesetze/berufskammern.html#Heilberufskammern</a>)</p>

Clause/subclause/section in EN 16844	Deviation
3.2 Training	<p><b>German deviation</b></p> <p>MSTR section 7.6 in conjunction with MPC Art. 2 para.3</p> <p>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 <u>surgery</u>. 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.”</p> <p>Section 7.6 covers more requirements than stipulated in 3.2.</p> <p>NOTE These regulations are available on web <a href="http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MWBO_engl20130628.pdf">http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MWBO_engl20130628.pdf</a></p>
3.3 Continuous professional development (CPD) and continuous medical education (CME)	<p><b>German deviation</b></p> <p>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)</p> <p>Also, surgeons (see 2.13 - “aesthetic plastic surgeons”) are subject to CME requirements.</p> <p>The continuing education measures are rated using a point system which is not to be mixed with speciality training.</p> <p>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)</p> <p>NOTE This regulation is available on web <a href="http://www.baek.de/downloads/ADFBSatzungEn.pdf">http://www.baek.de/downloads/ADFBSatzungEn.pdf</a></p>

Clause/subclause/section in EN 16844	Deviation
4.1 Office staff/Booking arrangements	<p><b>German deviation</b></p> <p>Chamber Laws and MPC Art. 30 and 12 and Medical Fee Schedule</p> <p>The section covers different treatment principles which have to stand on its own.</p> <p>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.</p>
4.2.2 Patient consultation and assessment “Nurses and non-medical professionals shall not be used as a shortcut for the practitioner who remains responsible for carefully assessing the patients...”	<p><b>French deviation</b></p> <p>Anyone who takes part in the facility diagnosis or treatment without being the holder of a medical degree unlawfully practicing medicine</p> <p><b>Applicable French regulation</b></p> <p>Article L.4161-1 of the Code of Public Health</p> <p>NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000021709047&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1650607943&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000021709047&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1650607943&amp;nbResultRech=1</a>.</p>
4.2 Patient consultation and assessment 4.2.2	<p><b>German deviation</b></p> <p>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</p> <p>Consent must always be carried out by a doctor; it is not permissible for it to be carried out by non-medical personnel.</p>
4.2 Patient consultation and assessment 4.2.2	<p><b>Applicable Norwegian regulation</b></p> <p>Norwegian Health Personnel Act of 2 July 1999 No. 64 relating to Health Personnel, etc. (<i>Helsepersonelloven</i>). With amendments made previous to 1 July 2002 from the Ministry of Health and Care Services and which came into force on the 2001-01-01.</p> <p>Chapter II, Use of assistants:</p> <p>Health personnel may in their work assign certain tasks to other personnel if it is considered safe to do so based on the nature of the assigned task, the qualification of the assigned personnel and the guidance that is being provided. Pupils and students shall as a rule only be assigned tasks based on their need for training.</p> <p><b>Norwegian deviation</b></p> <p>In addition to medical doctors, nurses may perform treatments with resorbable injectables and botulinum toxin after attending a course in botox treatment.</p> <p>However nurses do not have prescription authority in Norway, and the prescribing medical doctor is therefore medically responsible for the treatment without the requirements of supervision.</p> <p>Nurses may independently assess and proceed with patient consultations without supervision of a medical doctor.</p>

Clause/subclause/section in EN 16844	Deviation
4.3 Consent	<p><b>French deviation</b></p> <p>For any service for aesthetic purposes, whose estimated value is greater than or equal to 300 euros the practitioner submits a detailed estimate.</p> <p><b>Applicable French regulation</b></p> <p>Arrêté 17th of October 1996 on price advertising of medical and surgical aesthetic acts.</p> <p>NOTE This regulation is available on web  <a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&amp;fastPos=1&amp;fastReqId=482025125&amp;categorieLien=cid&amp;oldAction=rechTexte">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000177122&amp;fastPos=1&amp;fastReqId=482025125&amp;categorieLien=cid&amp;oldAction=rechTexte</a></p> <p>If patient is received in a health facility, patient information is governed by articles L.1111-1 à 9, R.1112-1 à 3, R.1112-5 et R.1112-7 of the code of public health</p> <p>NOTE This regulation is available on web  <a href="https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006185255&amp;cidTexte=LEGITEXT000006072665">https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006185255&amp;cidTexte=LEGITEXT000006072665</a>  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006908159&amp;dateTexte=&amp;categorieLien=cid">https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006908159&amp;dateTexte=&amp;categorieLien=cid</a>  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006908160&amp;dateTexte=&amp;categorieLien=cid">https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006908160&amp;dateTexte=&amp;categorieLien=cid</a>  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006908162&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20150115">https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006908162&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20150115</a>  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006908164&amp;dateTexte=&amp;categorieLien=cid">https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006908164&amp;dateTexte=&amp;categorieLien=cid</a>  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006908167&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20140404&amp;oldAction=rechCodeArticle">https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006908167&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20140404&amp;oldAction=rechCodeArticle</a>.</p>
4.3 Consent 4.3.2 i)	<p><b>Austrian deviation</b></p> <p>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.</p> <p>NOTE This regulation is available on web  <a href="http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&amp;Dokumentnummer=BGBLA 2012 I 80">http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&amp;Dokumentnummer=BGBLA 2012 I 80</a></p>
4.4 Documentation 4.4.11	<p><b>German deviation</b></p> <p>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 .</p> <p>Minors and incompetent patients are not subject to aesthetic or non-aesthetic surgery i.e. there is no room for legal representatives.</p> <p>NOTE This regulation is available on web  <a href="http://www.bundesaeztekammer.de/downloads/Schweigepflicht_2014.pdf">http://www.bundesaeztekammer.de/downloads/Schweigepflicht_2014.pdf</a></p>

Clause/subclause/section in EN 16844	Deviation
<p>4.4 Documentation 4.4.5 4.4.11 "... Medical records shall only be released to third parties in case of patient's death"</p>	<p><b>French deviation</b> Article L.1111–8 of the Code of Public Health, Harbouring health data needs the express consent of the person concerned. Harbouring health data centre must respect national specific requirements, like specific data access by a physician which ensure safety and legal protection. Harbouring health data by non-health organization will be done in France with a national agreement accorded by French health ministry.</p> <p><b>Applicable French regulation</b> Article L.1111–8 of the Code of Public Health NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000021941353&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=440462227&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000021941353&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=440462227&amp;nbResultRech=1</a>.</p> <p>The patient has access to documents concerning his health under conditions set by regulatory means under article L.1111–7 of the code of public health. NOTE This regulation is available on web <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006685776&amp;dateTexte=&amp;categorieLien=cid">https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006685776&amp;dateTexte=&amp;categorieLien=cid</a>.</p> <p>In case of death, in accordance with the article L.1110–4 of the Code of Public Health, it is appropriate that the eligible parties have access to medical data insofar as they are necessary to the parties to determine the cause of death to defend the memory of the deceased or their rights unless a contrary intention expressed by the individual before death. NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000024462526&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=513179286&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000024462526&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=513179286&amp;nbResultRech=1</a>.</p>
<p>4.5.2 Post-treatment</p>	<p><b>French deviation</b> It is a requirement in France "Once it has agreed to answer a request the physician commits himself to personally assure the patient care."</p> <p><b>Applicable French regulation</b> Article R.4127–32 of the Code of Public Health NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006912894&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1111625624&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006912894&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1111625624&amp;nbResultRech=1</a>.</p>
<p>4.6 Advertising Annex A (normative) Code of Ethics for marketing and advertising</p>	<p><b>Austrian deviation</b> According to the Austrian law on aesthetic treatments and surgeries, § 8 advertising is restricted and provisions are prohibited. NOTE This regulation is available on web <a href="http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&amp;Dokumentnummer=BGBLA_2012_I_80">http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&amp;Dokumentnummer=BGBLA_2012_I_80</a>.</p>



Clause/subclause/section in EN 16844	Deviation
4.6 Advertising “Advertising should be avoided ...”	<p><b>French deviation</b></p> <p>The article R.4127–19 of the Code of Public Health prohibits all direct or indirect methods of advertising</p> <p>NOTE This regulation is available on web  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006912881&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=602214013&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006912881&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=602214013&amp;nbResultRech=1</a>.</p>
4.6 Advertising	<p><b>German deviation:</b></p> <p>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.</p> <p>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 commercialization 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 that is praising, misleading or comparative.” (...)</p> <p>According to the Medical Products Advertising Act it is even prohibited to promote aesthetic surgery procedures.</p>
Clause 5 Facilities	<p><b>Italian deviation</b></p> <p>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.</p> <p><b>Applicable Italian regulation</b></p> <p>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</p> <p>NOTE This regulation is available on web  <a href="http://www.salute.gov.it/imgs/C_17_normativa_1163_allegato.pdf">http://www.salute.gov.it/imgs/C_17_normativa_1163_allegato.pdf</a>.</p>

Clause/subclause/section in EN 16844	Deviation
5.2 Personnel	<p><b>French deviation</b></p> <p>Mandatory vaccination personnel means under article L.3111-4 of the code of public health.</p> <p>NOTE This regulation is available on web  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000021709132">https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000021709132</a>.</p> <p>Procedure in the event of accidental exposure to blood and other body fluids under the order 2013 July the 10th and ministerial circular DGS/RI/DGT/DSS n° 2008-91 of 13th March 2008</p> <p>NOTE This regulation is available on web  <a href="https://www.legifrance.gouv.fr/eli/arrete/2013/7/10/ETST1314972A/jo">https://www.legifrance.gouv.fr/eli/arrete/2013/7/10/ETST1314972A/jo</a>  <a href="http://social-sante.gouv.fr/IMG/pdf/circulaire_ste_20080005_0100_0079-2.pdf">http://social-sante.gouv.fr/IMG/pdf/circulaire_ste_20080005_0100_0079-2.pdf</a>.</p>
5.4 Facility	<p><b>French deviation</b></p> <p>The entire facility shall be accessible to disabled persons in accordance with the French regulations in articles L.111-7-3, L.111-7-5 à L.111-7-11 et R.111-19 à R.111-19-25 of the code of construction and housing relating to the accessibility of establishments open to the public</p> <p>NOTE This regulation is available on web  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978438&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=2085447203&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978438&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=2085447203&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000029506660&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=253141436&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000029506660&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=253141436&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978378&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=2004749911&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978378&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=2004749911&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978375&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=738228488&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978375&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=738228488&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978372&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=96597055&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978372&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=96597055&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000029506668&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1012468822&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000029506668&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1012468822&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978472&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1200496034&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978472&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=1200496034&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978462&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=70508283&amp;nbResultRech=1">http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000030978462&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202&amp;oldAction=rechCodeArticle&amp;fastReqId=70508283&amp;nbResultRech=1</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000029714007&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000029714007&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000029714026&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000029714026&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006195578&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006195578&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006195578&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006195578&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a></p>

Clause/subclause/section in EN 16844	Deviation
	<p><a href="http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006195579&amp;cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a>  <a href="http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074096&amp;dateTexte=20151202</a></p>
<p>5.7 Patient safety and security 5.7.9 If a laser of class 1C, 3B or 4 or intense pulsed light (IPL) device is used, all applicable laser safety standards shall be implemented and followed</p>	<p><b>French deviation</b> In France, the regulations are not limited to lasers for workers protection but are about all artificial optical radiation. <b>Applicable French regulation</b> Decree N° 2010-750 2th of July 2010 on the protection of workers against risks arising from optical radiation NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/jopdf/common/jo_pdf.jsp?numJO=0&amp;dateJO=20100704&amp;numTexte=11&amp;pageDebut=12149&amp;pageFin=12168">http://www.legifrance.gouv.fr/jopdf/common/jo_pdf.jsp?numJO=0&amp;dateJO=20100704&amp;numTexte=11&amp;pageDebut=12149&amp;pageFin=12168</a>. Decree n° 2007-665 2th of May 2007 on the use of lasers of a higher class 2 (notice, used, used instructions, warning notices on the precautions...) NOTE This regulation is available on web <a href="https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00000646998">https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00000646998</a>.</p>
<p>5.7 Patient safety and security 5.7.9</p>	<p><b>British deviation</b> In the jurisdictions listed below clinics with Class 3B lasers and above, and IPLs, shall appoint a certificated Laser Protection Adviser (LPA) to advise on safe use of the lasers / IPLs. <b>Applicable UK regulation</b> London Local Authorities Act 1991 – Special Treatment Licensing NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/ukla/1991/13/part/I/enacted">http://www.legislation.gov.uk/ukla/1991/13/part/I/enacted</a> and under Paragraph 6 (2), “The borough council may grant to an applicant and from time to time renew or transfer a licence on such terms and conditions and subject to such restrictions as may be specified”, and under Paragraph 10 (1) Power to prescribe standard terms, conditions and restrictions. “The borough council may make regulations prescribing standard conditions applicable to all, or any class of, licences, that is to say terms, conditions and restrictions on or subject to which licences, or licences of that class, are in general to be granted, renewed or transferred by them.” These regulations are usually implemented by London boroughs through the issue of 'Codes of Practice' or 'Special Treatment Conditions' which specify the appointment of an LPA a typical example of which is available on the web at: <a href="http://www.camden.gov.uk/ccm/content/business/business-regulations/licensing-and-permits/licences/other-licences/massage-and-special-treatments/massage-and-special-treatments/">http://www.camden.gov.uk/ccm/content/business/business-regulations/licensing-and-permits/licences/other-licences/massage-and-special-treatments/massage-and-special-treatments/</a>. The Independent Healthcare (Wales) Regulations 2011 NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/wsi/2011/734/regulation/45/made">http://www.legislation.gov.uk/wsi/2011/734/regulation/45/made</a> and is enforced through the 'Registration under the Care Standards Act 2000 Guide to the application process for new providers' issued by Health Inspectorate Wales (October 2013) which can be accessed at: <a href="http://www.hiw.org.uk/sitesplus/documents/1047/Independent%20health%20%2D%20Application%20guidance%2De.pdf">http://www.hiw.org.uk/sitesplus/documents/1047/Independent%20health%20%2D%20Application%20guidance%2De.pdf</a> and through implementation of the 'National Minimum Standards for Independent Health Care Services in</p>

Clause/subclause/section in EN 16844	Deviation
	<p>Wales' which can be accessed at: <a href="http://gov.wales/docs/legislation/inforcenonsi/nationalhealth/110401nmstandards16.pdf">http://gov.wales/docs/legislation/inforcenonsi/nationalhealth/110401nmstandards16.pdf</a> (see page 10 regarding appointment of an LPA).</p> <p>The Independent Healthcare Regulations (Northern Ireland) 2005 NOTE This regulation is available on the web at <a href="http://www.legislation.gov.uk/nisr/2005/174/regulation/39/made">http://www.legislation.gov.uk/nisr/2005/174/regulation/39/made</a> and is enforced through the Independent Healthcare Minimum Standards issued by the Department of Health, Social Services and Public Safety (July 2014) which can be accessed at: <a href="http://www.rqia.org.uk/cms_resources/Independent_Healthcare_Minimum_Standards.pdf">http://www.rqia.org.uk/cms_resources/Independent_Healthcare_Minimum_Standards.pdf</a> and which require that "There is written confirmation of the appointment and duties of a certificated Laser Protection Advisor that is renewed annually." (paragraph 48.6)</p>
5.7 Patient safety and security 5.7.9	<p>In Germany occupational safety and health of employees using lasers is regulated on the basis of Verordnung zum Schutz der Beschäftigten vor Gefährdungen durch künstliche optische Strahlung (Arbeitsschutzverordnung zu künstlicher optischer Strahlung – OstrV) which is the German version <a href="http://www.gesetze-im-internet.de/bundesrecht/ostrv/gesamt.pdf">http://www.gesetze-im-internet.de/bundesrecht/ostrv/gesamt.pdf</a> of Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), <a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006L0025">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006L0025</a>.</p> <p>Thus, Directive 2006/25/EC is not directly applicable as referenced in 5.7.9, NOTE 2. Additionally, there are specific requirements regarding the use of lasers class 2 and higher based on DGUV Vorschrift 11 <a href="http://publikationen.dguv.de/dguv/pdf/10002/vorschrift11.pdf">http://publikationen.dguv.de/dguv/pdf/10002/vorschrift11.pdf</a>.</p>
5.8.7 "Used disposable sharp items shall be placed in secure puncture-resistant containers which are located as close to the treatment area as is practical."	<p><b>French deviation</b></p> <p>According with the French regulation, it is not true, consideration of sharp is too limited. Indeed, in France, treatment of all medical activities waste with infectious risk must be in accordance with articles R.1335–1 à 8 and R.1335–13 and 14 of the Code of Public Health.</p> <p>They are considered hazardous waste and subject to special requirements in terms of storage, transport, processing, traceability and elimination. The elimination is not provided in the draft standard, this waste could be disposed of with household waste</p> <p>NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000022963923&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do;jsessionid=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000022963923&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202</a>.</p>
5.9 Medicines Management	<p><b>French deviation</b></p> <p>In a health facility, medicine management shall be processed in accordance with requirements of articles R.5126–1 and following of the code of Public Health.</p> <p>Otherwise, they conform to the supply, possession and delivery of pharmaceuticals and medicines to articles R.5126.111 to R.5126–115 of the code of Public Health.</p>

Clause/subclause/section in EN 16844	Deviation
	<p>NOTE This regulation is available on web  <a href="http://www.legifrance.gouv.fr/affichCode.do?sessionId=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006191026&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202">http://www.legifrance.gouv.fr/affichCode.do?sessionId=EE53F901B4B80B29C4A5F82BDFE3FDC8.tpdila14v_2?idSectionTA=LEGISCTA000006191026&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20151202</a>.</p>
6.5 Cooling off period	<p><b>Austrian deviation</b></p> <p>According to the Austrian law on aesthetic treatments and surgeries, § 6 (1) the cooling off period 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.</p> <p>NOTE This regulation is available on web  <a href="http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&amp;Dokumentnummer=BGBLA_2012_I_80">http://www.ris.bka.gv.at/Dokument.wxe?Abfrage=BgblAuth&amp;Dokumentnummer=BGBLA_2012_I_80</a>.</p>
6.5 Cooling off period	<p><b>Belgian deviation</b></p> <p>The Belgian law of 23rd May 2013 requires minimum 15 days for aesthetic surgery interventions</p> <p>NOTE Article 20 of this regulation is available on web:  <a "))&amp;rech='1&amp;language=nl&amp;tri=dd+AS+RANK&amp;numero=1&amp;table_name=wet&amp;cn=2013052321&amp;caller=image_a1&amp;fromtab=wet&amp;la=N&amp;pdf_page=7&amp;pdf_file=http://www.ejustice.just.fgov.be/mopdf/2013/07/02_1.pdf"' href="http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?N=&amp;sql=(text+contains+(">http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?N=&amp;sql=(text+contains+(""))&amp;rech=1&amp;language=nl&amp;tri=dd+AS+RANK&amp;numero=1&amp;table_name=wet&amp;cn=2013052321&amp;caller=image_a1&amp;fromtab=wet&amp;la=N&amp;pdf_page=7&amp;pdf_file=http://www.ejustice.just.fgov.be/mopdf/2013/07/02_1.pdf</a>.</p>
6.5 Cooling off period	<p><b>French deviation</b></p> <p>“Mental health impairment” is imprecise. In France, consent of “major under guardianship” is governed by articles L.1111-2 and L.1111-4 of the code of public health.</p> <p>NOTE This regulation is available on web  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006685758&amp;dateTexte=&amp;categorieLien=cid">https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&amp;idArticle=LEGIARTI000006685758&amp;dateTexte=&amp;categorieLien=cid</a>  and  <a href="https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006685767&amp;cidTexte=LEGITEXT000006072665">https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006685767&amp;cidTexte=LEGITEXT000006072665</a>.</p>
6.3.4 Anaesthesia level 6.6 Aesthetic medical treatment	<p><b>French deviation</b></p> <p>Articles D.6124-91 to D.6124-103 du CSP reserve the practice of anaesthesia (general and loco-regional) to health facilities or facilities licensed for aesthetic surgery by national authorities.</p> <p>NOTE This regulation is available on web  <a href="https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198878&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726">https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198878&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726</a>,  <a href="https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198879&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726">https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198879&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726</a>,  <a href="https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198880&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726">https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198880&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726</a>, and  <a href="https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198881&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726">https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006198881&amp;cidTexte=LEGITEXT000006072665&amp;dateTexte=20050726</a></p>

Clause/subclause/section in EN 16844	Deviation
6.6, Table 1	<p><b>French deviation</b></p> <p>The implementation of adipocyte lysis techniques for aesthetic purposes following is prohibited:</p> <ul style="list-style-type: none"> <li>- Adipocyte lysis using injections of hypo-osmolar solutions;</li> <li>- Adipocyte lysis using injections of lipolytic products (phosphatidylcholine deoxycholate of sodium);</li> <li>- Adipocyte lysis using injections mesotherapeutics mixtures;</li> <li>- Adipocyte lysis using carboxytherapy;</li> <li>- Adipocyte lysis using transcutaneous laser without suction.</li> </ul> <p>Decree n° 2011-382 11th of April 2011 about prohibition on the practice of acts referred lipolitics.</p> <p>NOTE This regulation is available on web <a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023845272&amp;fastPos=1&amp;fastReqId=1110363178&amp;categorieLien=cid&amp;oldAction=rechTexte">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023845272&amp;fastPos=1&amp;fastReqId=1110363178&amp;categorieLien=cid&amp;oldAction=rechTexte</a>.</p> <p>Dermabrasion is a surgical procedure in France</p> <p>Circulaire DGS/SD 2B/DHOS/o4 n° 2005-576 23th December 2005 on authorization and functioning of aesthetic surgery facilities.</p> <p>NOTE This regulation is available on web <a href="http://www.sante.gouv.fr/fichiers/bo/2006/06-02/a0020035.htm">http://www.sante.gouv.fr/fichiers/bo/2006/06-02/a0020035.htm</a>.</p> <p>Injections of platelet rich plasma and accounting techniques in a closed system for aesthetic purposes are prohibited in France (decision 4th of November 2015, Council State).</p> <p>NOTE This regulation is available on web <a href="http://arianeinternet.conseil-etat.fr/arianeinternet/ViewRoot.asp?View=Html&amp;DMode=Html&amp;PushDirectUrl=1&amp;Item=1&amp;fond=DCE&amp;text=4+novembre+2015+plasma&amp;Page=1&amp;querytype=simple&amp;NbEltPerPages=4&amp;Pluriels=True">http://arianeinternet.conseil-etat.fr/arianeinternet/ViewRoot.asp?View=Html&amp;DMode=Html&amp;PushDirectUrl=1&amp;Item=1&amp;fond=DCE&amp;text=4+novembre+2015+plasma&amp;Page=1&amp;querytype=simple&amp;NbEltPerPages=4&amp;Pluriels=True</a>.</p>
Annex A	<p><b>German deviation</b></p> <p>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.</p> <p>Furthermore, advertising in breach of professional ethic is prohibited, see 4.7.</p>

## Bibliography

- [1] CEN/TR 15133, *Nomenclature — Collective terms and codes for groups of medical devices*
- [2] CEN/TR 15592, *Health services — Quality management systems — Guide for the use of EN ISO 9004:2000 in health services for performance improvement*
- [3] CEN/TS 15277, *Non-active surgical implants — Injectable implants*
- [4] EN 207, *Personal eye-protection equipment — Filters and eye-protectors against laser radiation (laser eye-protectors)*
- [5] EN 285, *Sterilization — Steam sterilizers — Large sterilizers*
- [6] EN 455-1, *Medical gloves for single use — Part 1: Requirements and testing for freedom from holes*
- [7] EN 455-2, *Medical gloves for single use — Part 2: Requirements and testing for physical properties*
- [8] EN 455-3, *Medical gloves for single use — Part 3: Requirements and testing for biological evaluation*
- [9] EN 455-4, *Medical gloves for single use — Part 4: Requirements and testing for shelf life determination*
- [10] EN 794-3, *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators*
- [11] EN 1040, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics — Test method and requirements (phase 1)*
- [12] EN 1041, *Information supplied by the manufacturer of medical devices*
- [13] EN 1422, *Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods*
- [14] EN 1500, *Chemical disinfectants and antiseptics — Hygienic handrub — Test method and requirements (phase 2/step 2)*
- [15] EN 1644-1, *Test methods for nonwoven compresses for medical use — Part 1: Nonwovens used in the manufacture of compresses*
- [16] EN 1644-2, *Test methods for nonwoven compresses for medical use — Part 2: Finished compresses*
- [17] EN 12464-1, *Light and lighting — Lighting of work places — Part 1: Indoor work places*
- [18] EN 12470 (all parts), *Clinical thermometers*
- [19] EN 13060, *Small steam sterilizers*
- [20] 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*

- [21] EN 14180, *Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing*
- [22] EN 15224, *Quality management systems — EN ISO 9001:2015 for healthcare*
- [23] EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*
- [24] EN 16372, *Aesthetic surgery services*
- [25] EN 60601-2-4, *Medical electrical equipment — Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4)*
- [26] EN 60601-2-22, *Medical electrical equipment — Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (IEC 60601-2-22)*
- [27] EN 60601-2-25, *Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25)*
- [28] EN 60601-2-26, *Medical electrical equipment — Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 60601-2-26)*
- [29] EN 60601-2-27, *Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601-2-27)*
- [30] EN 60601-2-30, *Medical electrical equipment — Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30)*
- [31] EN 60601-2-34, *Medical electrical equipment — Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment (IEC 60601-2-34)*
- [32] EN 60601-2-41, *Medical electrical equipment — Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41)*
- [33] EN 60601-2-46, *Medical electrical equipment — Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46)*
- [34] EN 60601-2-47, *Medical electrical equipment — Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems (IEC 60601-2-47)*
- [35] EN 60601-2-52, *Medical electrical equipment — Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52)*
- [36] EN 60601-2-57, *Medical electrical equipment — Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use (IEC 60601-2-57)*
- [37] EN 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements (IEC 60825-1)*
- [38] EN 62471, *Photobiological safety of lamps and lamp systems (IEC 62471)*



- [39] EN 62304, *Medical device software — Software life-cycle processes (IEC 62304)*
- [40] EN ISO 1942, *Dentistry — Vocabulary (ISO 1942)*
- [41] EN ISO 6009, *Hypodermic needles for single use — Colour coding for identification (ISO 6009)*
- [42] EN ISO 7396 (all parts), *Medical gas pipeline systems*
- [43] EN ISO 8362-6, *Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials (ISO 8362-6)*
- [44] EN ISO 8362-7, *Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part (ISO 8362-7)*
- [45] EN ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2015)*
- [46] EN ISO 9170-2, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2)*
- [47] EN ISO 10079 (all parts), *Medical suction equipment (ISO 10079, all parts)*
- [48] EN ISO 10781, *Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (ISO 10781)*
- [49] EN ISO 11073 (all parts), *Health informatics — Point-of-care medical device communication (ISO IEEE 11073 series)*
- [50] EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1)*
- [51] EN ISO 11810-1, *Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Part 1: Primary ignition and penetration (ISO 11810-1)*
- [52] EN ISO 11810-2, *Lasers and laser-related equipment — Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers — Part 2: Secondary ignition (ISO 11810-2)*
- [53] EN ISO 12967 (all parts), *Health informatics — Service architecture (ISO 12967, all parts)*
- [54] EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485)*
- [55] EN ISO 13606 (all parts), *Health informatics — Electronic health record communication (ISO 13606 series)*
- [56] EN ISO 14607, *Non-active surgical implants — Mammary implants — Particular requirements (ISO 14607)*
- [57] EN ISO 14630, *Non-active surgical implants — General requirements (ISO 14630)*
- [58] EN ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1)*

- [59] EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971)*
- [60] EN ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1)*
- [61] EN ISO 15225, *Medical devices — Quality management — Medical device nomenclature data structure (ISO 15225)*
- [62] EN ISO 16054, *Implants for surgery — Minimum data sets for surgical implants (ISO 16054)*
- [63] EN ISO 16061, *Instrumentation for use in association with non-active surgical implants — General requirements (ISO 16061)*
- [64] EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1)*
- [65] EN ISO 18812, *Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles (ISO 18812)*
- [66] EN ISO 19011, *Guidelines for auditing management systems (ISO 19011)*
- [67] EN ISO 21090, *Health Informatics — Harmonized data types for information interchange (ISO 21090)*
- [68] EN ISO 22600 (all parts), *Health informatics — Privilege management and access control (ISO 22600, all parts)*
- [69] EN ISO 23907, *Sharps injury protection — Requirements and test methods — Sharps containers (ISO 23907)*
- [70] EN ISO 25424, *Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424)*
- [71] EN ISO/IEC 27001, *Information technology — Security techniques — Information security management systems — Requirements (ISO/IEC 27001)*
- [72] EN ISO 27799, *Health informatics — Information security management in health using ISO/IEC 27002 (ISO 27799)*
- [73] EN ISO 80601-2-12, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12)*
- [74] EN ISO 80601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13)*
- [75] EN ISO 80601-2-55, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55)*
- [76] EN ISO 80601-2-61, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61)*
- [77] ISO 10001, *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations*

- [78] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*
- [79] ISO 10003, *Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations*
- [80] ISO 12609-1, *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications — Part 1: Specification for products*
- [81] ISO 12609-2, *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications — Part 2: Guidance for use*
- [82] ISO/TR 12773 (all parts), *Business requirements for health summary records*
- [83] ISO 17090 (all parts), *Health informatics — Public key infrastructure*
- [84] ISO 18308, *Health informatics — Requirements for an electronic health record architecture*
- [85] ISO/TS 19218-1:2011, *Medical devices — Hierarchical coding structure for adverse events — Part 1: Event-type codes*
- [86] ISO/TS 21547, *Health informatics — Security requirements for archiving of electronic health records — Principles*
- [87] ISO/TR 21548, *Health informatics — Security requirements for archiving of electronic health records — Guidelines*
- [88] ISO 26000, *Guidance on social responsibility*
- [89] ISO 31000, *Risk management — Principles and guidelines*
- [90] IEC/TR 60825-8, *Safety of laser products — Part 8: Guidelines for the safe use of laser beams on humans*
- [91] IEC/TR 62471-3, *Photobiological safety of lamps and lamp systems — Part 3: Guidelines for the safe use of intense pulsed light source equipment on humans*
- [92] GHTF/SG2/N54/R8:2006, *Medical Devices: Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*
- [93] Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19.-22. June 1946; (Official Records of the World Health Organization, no. 2, p. 100)
- [94] Surgical Safety Checklist W.H.O. 2009 edition  
<http://www.who.int/patientsafety/safesurgery/en/>
- [95] WHO GUIDELINES FOR SAFE SURGERY. 2009,  
[http://whqlibdoc.who.int/publications/2009/9789241598552\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf)
- [96] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- [97] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

- [98] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom
- [99] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- [100] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- [101] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications
- [102] Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)
- [103] Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits
- [104] Fractional photothermolysis: a new concept for cutaneous remodeling using microscopic patterns of thermal injury. Manstein D et al. *Lasers Surg Med.* 2004;34(5):426-38.
- [105] Short-term side effects of fractional photothermolysis. Fisher GH et al. *Dermatol Surg.* 2005 Sep;31(9 Pt 2):1245-9; discussion 1249.
- [106] Skin Responses to Fractional Photothermolysis. Laubach H. et al. *Lasers Surg. Med.* 2006 Feb, 38 (2) pp. 142–149
- [107] Lapidoth M., Yagima Odo M.E., Odo L.M. Novel use of erbium:YAG (2,940-nm) laser for fractional ablative photothermolysis in the treatment of photodamaged facial skin: a pilot study. *Dermatol. Surg.* 2008 Aug, 34 (8) pp. 1048–1053
- [108] Fractional laser skin therapy Marc Oliver Bodendorf et al. *JDDG*; 2009; 7: 301–308.
- [109] Update dermatologic laser therapy. Sonja Grunewald et al. *JDDG*;2010; 8: 2-13.
- [110] Fraxel. 3 Versatile Fraxel Laser Treatments With Remarkable Results and Minimal Downtime. Available at: <http://www.fraxel.com> Accessed March 21, 2014.
- [111] Reilly M.J., Cohen M., Hokugo A., Keller G. Molecular effects of fractional carbon dioxide laser resurfacing on photodamaged human skin. *Arch. Facial Plast. Surg.* 2010, 12 (5) pp. 321–325
- [112] Manuskiatti W., Fitzpatrick R.E., Goldman M.R. Long-term effectiveness and side effects of carbon dioxide laser resurfacing for resurfacing of photoaged facial skin. *J. Am. Acad. Dermatol.* 1999, 40 pp. 401–411
- [113] Metelitsa A., Alster T. Fractional Laser Skin Resurfacing treatment complications: a review. *Dermatol. Surg.* 2010, 36 pp. 299–306
- [114] West T.B., Alster T.S. Effect of pretreatment on the incidence of hyperpigmentation following cutaneous CO2 laser resurfacing. *Dermatol. Surg.* 1999 Jan, 25 (1) pp. 15–17



# British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

## About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

## Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at [bsigroup.com/standards](http://bsigroup.com/standards) or contacting our Customer Services team or Knowledge Centre.

## Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at [bsigroup.com/shop](http://bsigroup.com/shop), where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

## Copyright in BSI publications

All the content in BSI publications, including British Standards, is the property of and copyrighted by BSI or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use.

Save for the provisions below, you may not transfer, share or disseminate any portion of the standard to any other person. You may not adapt, distribute, commercially exploit, or publicly display the standard or any portion thereof in any manner whatsoever without BSI's prior written consent.

## Storing and using standards

Standards purchased in soft copy format:

- A British Standard purchased in soft copy format is licensed to a sole named user for personal or internal company use only.
- The standard may be stored on more than 1 device provided that it is accessible by the sole named user only and that only 1 copy is accessed at any one time.
- A single paper copy may be printed for personal or internal company use only.

Standards purchased in hard copy format:

- A British Standard purchased in hard copy format is for personal or internal company use only.
- It may not be further reproduced – in any format – to create an additional copy. This includes scanning of the document.

If you need more than 1 copy of the document, or if you wish to share the document on an internal network, you can save money by choosing a subscription product (see 'Subscriptions').

## Reproducing extracts

For permission to reproduce content from BSI publications contact the BSI Copyright & Licensing team.

## Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to [bsigroup.com/subscriptions](http://bsigroup.com/subscriptions).

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

**PLUS** is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit [bsigroup.com/shop](http://bsigroup.com/shop).

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email [subscriptions@bsigroup.com](mailto:subscriptions@bsigroup.com).

## Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

## Useful Contacts

### Customer Services

**Tel:** +44 345 086 9001

**Email (orders):** [orders@bsigroup.com](mailto:orders@bsigroup.com)

**Email (enquiries):** [cservices@bsigroup.com](mailto:cservices@bsigroup.com)

### Subscriptions

**Tel:** +44 345 086 9001

**Email:** [subscriptions@bsigroup.com](mailto:subscriptions@bsigroup.com)

### Knowledge Centre

**Tel:** +44 20 8996 7004

**Email:** [knowledgecentre@bsigroup.com](mailto:knowledgecentre@bsigroup.com)

### Copyright & Licensing

**Tel:** +44 20 8996 7070

**Email:** [copyright@bsigroup.com](mailto:copyright@bsigroup.com)

### BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK