1. ------IND- 2019 0525 F-- EN- ------ 20191110 --- --- PROJET

**Decree No [...] on intense pulsed light depilation processes for aesthetic purposes**

NOR:

The Prime Minister,

On the report of the Minister for the Economy and Finance and the Minister for Solidarity and Health,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

Having regard to Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market;

Having regard to Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits;

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the Consumer Code, in particular Article L412-1 thereof;

Having regard to the Labour Code, in particular Articles L6113-6 and L6351-1 thereof;

Having regard to the Public Health Code, in particular Articles L1151-2 and D1413-58 thereof;

Having regard to the Penal Code, in particular Articles 132-66 to 132-70 and R610-1 thereof;

Having regard to Decree No 2015-1083 of 27 August 2015 relating to the making available on the market of electrical equipment designed for use within certain voltage limits;

Having regard to Decree No 2018-1172 of 18 December 2018 on the conditions for registering professional and other certification and authorisations in the national registries;

Having regard to the opinion of the Supreme Council for the Paramedical Professions dated 27 June 2019;

Having regard to notification No [...];

Having heard the Council of State (social section),

Hereby decrees:

**Chapter I: general provisions and definitions**

**Article 1**

This decree applies to depilation processes for aesthetic purposes performed by professionals using intense pulsed light (IPL) depilation devices, excluding monochromatic laser-type light devices, the characteristics and conditions of use of which shall be specified by joint Order of the Ministers for Health and Consumer Affairs, following consultation with the National Agency for Food, Environmental and Occupational Health & Safety (ANSES).

**Article 2**

The following definitions shall apply:

1. professional: any doctor, any medical assistant practising under the responsibility of a doctor, or any beautician providing depilation services to consumers using this type of device;

2. operator: any person managing an establishment in which a professional as defined in (1) uses an intense pulsed light depilation device for aesthetic purposes, as defined in Article 1.

**Article 3**

Professionals within the meaning of Article 2 of this decree shall perform intense pulsed light depilation processes for aesthetic purposes only with the devices mentioned in Article 1.

**Article 4**

Any operator and any professional, within the meaning of Article 2 of this decree, using intense pulsed light devices to provide depilation services for aesthetic purposes, shall be obliged to respect the contraindications relating to this type of services and to advise consumers to seek their doctor’s advice before any such service is provided for the first time.

The contraindications shall be specified in a joint Order of the Ministers for Health and Consumer Affairs.

**Chapter II: provisions relating to the qualification of beauticians and the training of professional medical assistants practising under the authority of a doctor, who perform intense pulsed light depilation processes for aesthetic purposes**

**Article 5**

I.- To perform the depilation procedures mentioned in Article 1, all beauticians shall hold a professional qualification certificate in pulsed light depilation established by the branch of beauty & cosmetics and technical and professional education associated with the beauty and perfumery trades, registered in the specific directory mentioned in Article L6113-6 of the Labour Code.

II.- The professional qualification certificate in pulsed light depilation shall testify to the acquisition of knowledge: firstly, of the practice of intense pulsed light depilation processes for aesthetic purposes, the biological effects of the radiation emitted by intense pulsed light, the health risks associated with exposure to this radiation, the medical indications and contraindications for use, the safety rules and the declaration of adverse events in relation to the use of these devices and, secondly, the regulations in this field.

III.- Any beautician holding a professional qualification certificate in pulsed light depilation, as defined in point I, shall take a refresher course every five years and receive a training certificate from the in-service training body. They must be able to demonstrate that they have met this requirement during the course of their activity.

IV.- The operator shall publicly display the professional qualification certificate in pulsed light depilation and the valid certificate(s) of in-service training in the establishment in which the pulsed light depilation service is provided.

V.- Should a beautician cease their pulsed light depilation activity for a period of two years or more, they shall once more take a refresher course to obtain a new training certificate from the in-service training body.

VI.- A joint Order of the Ministers for Health, Consumer Affairs and Industry, issued following consultation with ANSES, shall define the characteristics of the professional qualification certificate mentioned in points I and II and specify:

* the requisite skills for performing the depilation processes referred to in Article 1, which are evaluated for issuance of the professional qualification certificate;
* the evaluation procedures and the rules concerning the composition and function of the panels awarding the professional qualification certificate.

**Article 6**

I.- In order to perform the depilation processes mentioned in Article 1, all professional medical assistants practising under the authority of a doctor shall undergo additional pulsed light depilation training at the end of which they shall be issued with a training certificate valid for five years from its date of issue.

II.- The additional pulsed light depilation training shall involve the acquisition of knowledge: firstly, of the practice of intense pulsed light depilation processes for aesthetic purposes, the biological effects of the radiation emitted by intense pulsed light, the health risks associated with exposure to this radiation, the medical indications and contraindications for use, the safety rules and the declaration of adverse events in relation to the use of these devices and, secondly, the regulations in the field.

III.- Any professional medical assistant exercising under the authority of a doctor holding a training certificate who wishes to continue their activity of intense pulsed light depilation shall be required to demonstrate that they hold a valid certificate. They shall renew the additional pulsed light depilation training every five years to obtain renewal of their training certificate before expiry of the current one.

IV.- The operator shall publicly display the training certificate of any professional medical assistant practising under the authority of a doctor in the establishment in which the pulsed light depilation service is provided.

V.- Should a professional medical assistant practising under the authority of a doctor cease this activity for a period of two years or more, they shall once more undergo a new training course in pulsed light depilation to obtain a new training certificate.

VI.- A joint Order of the Ministers for Health, Consumer Affairs and Industry, issued following consultation with ANSES, shall define the characteristics of the additional training mentioned in point I of this article for the professional medical assistants mentioned in points I and II and specify:

* the requisite skills for performing the depilation processes referred to in Article 1, which are evaluated for the delivery of this training;
* the duration of the additional training;
* the procedures for checking theoretical knowledge and for the practical test, with a view to obtaining the training certificate;
* the template for the training certificate for the additional training;
* the requirements for training bodies in terms of skills and adherence to the content, duration and standards established for the training.

VII.- The ongoing professional training bodies able to deliver the additional training for the professional medical assistants mentioned in points I and II shall be those mentioned in Article L6351-1 of the Labour Code and certified by a body recognised by France Compétences.

**Chapter III: Provisions relating to the conditions of use of intense pulsed light depilation devices**

**Article 7**

I.- The distributor or manufacturer shall demonstrate the use and maintenance of any new device installed on behalf of the persons mentioned in Article 2(1). This demonstration shall include handling the device.

The performance of this demonstration shall be recorded in a standardised document signed by both parties and held available to the officials responsible for inspections. The standardised document shall be defined by joint Order of the Ministers for Health and Consumer Affairs, following consultation with ANSES.

**Article 8**

The intense pulsed light depilation devices used shall comply with the latest safety rules in the field, as defined in the above-mentioned Decree of 27 August 2015.

**Article 9**

Operators of intense pulsed light depilation devices shall be required to provide appropriate eye protection goggles for every person exposed to the radiation of the device: consumers and the professionals performing the depilation process, which effectively filter out the wavelength(s) used.

**Article 10**

1. A monitoring sheet shall be drawn up by the operator for each device and held available for the officials responsible for inspections, in order to ensure that maintenance is traceable and in accordance with the instructions for the device.

2. Additional maintenance rules shall be specified by joint Order of the Ministers for Health and Consumer Affairs, following consultation with ANSES, concerning, in particular, the stability of the emission spectrum over time.

3. The technical characteristics of the devices shall not be modified by the user or the operator.

**Article 11**

All operators and non-salaried professionals shall be up to date with their civil liability insurance covering the depilation procedures defined in Article 1.

**Chapter IV: Provisions relating to information and warnings for users and purchasers of intense pulsed light depilation devices**

**Article 12**

All professionals and operators shall be given a user information sheet by the manufacturer or distributor. This sheet shall include:

1. the health risks caused by exposure to radiation emitted by intense pulsed light depilation devices, particularly for certain persons;

2. the contraindications for intense pulsed light depilation and mention of the advice that consumers should seek their doctor’s advice before any such service is provided for the first time;

3. the recommendations for use and the requirement of eye protection for consumers and professionals that effectively filters out the wavelength(s) used;

4. the recommendation to all professionals that they declare any adverse event arising during or after a depilation process, via the alerts portal mentioned in Article D1413-58 of the Public Health Code.

The content of the user information sheet shall be specified by joint Order of the Ministers for Health and Consumer Affairs, following consultation with ANSES.

**Article 13**

An information sheet shall be given to all consumers by the professional and at the latest before any depilation process is performed. This notice shall include:

1. the health risks caused by exposure to radiation emitted by intense pulsed light depilation devices, particularly for certain persons;

2. the contraindications for intense pulsed light depilation and mention of the advice that consumers should seek their doctor’s advice before any such service is provided for the first time;

3. the recommendations for use and the requirement of eye protection for consumers that effectively filters out the wavelength(s) used;

4. the recommendation to consumers that they declare any adverse event arising during or after a depilation process, via the alerts portal mentioned in Article 15.

The content of the information sheet shall be specified by joint Order of the Ministers for Health and Consumer Affairs, following consultation with ANSES.

**Article 14**

I. ― For any commissioning of an intense pulsed light depilation device, the operator shall visibly display a public warning notice. This warning notice shall include:

1. the health risks caused by exposure to radiation emitted by intense pulsed light depilation devices, particularly for certain persons;

2. the contraindications for intense pulsed light depilation and mention of the advice that consumers should seek their doctor’s advice before any such service is provided for the first time;

3. the recommendations for use and the requirement of eye protection for consumers that effectively filters out the wavelength(s) used;

4. the recommendation to consumers that they declare any adverse event arising during or after a depilation process, via the alerts portal mentioned in Article 15.

The content, placement and size of the warning provided for in point I shall be specified by joint Order of the Ministers for Health and Consumer Affairs, following consultation with ANSES.

**Chapter V: Provisions relating to the reporting of adverse events associated with intense pulsed light devices**

**Article 15**

Without prejudice to the provisions relating to the categories of undesirable health events that may be reported by any health professional via the alerts portal for adverse health events, the beautician or the consumer may declare any adverse event arising during or after a depilation process, via the alerts portal mentioned in Article D1413-58 of the Public Health Code. A joint Order of the Ministers for Health and Consumer Affairs shall specify how the information thus collected should be transmitted to the competent administrative authority and the content thereof for the purposes of evaluation.

**Chapter VI: Penalties**

**Article 16**

The following shall be liable to incur the fines laid down for category 5 offences:

1. using intense pulsed light depilation devices with disregard for the conditions mentioned in Article 1 of this decree;

2. for professional medical assistants practising under the authority of a doctor: using intense pulsed light depilation devices without holding a valid training certificate;

3. for beauticians: using intense pulsed light depilation devices without holding a valid professional qualification certificate in pulsed light depilation and a valid training certificate;

4. for operators: using the services of a professional medical assistant practising under the authority of a doctor who has not undertaken the additional training in pulsed light depilation and does not hold a training certificate, or a beautician who does not have a professional qualification certificate in pulsed light depilation as well as a valid training certificate;

5. for operators: modifying the technical characteristics of the devices, with disregard for the provisions mentioned in Article 10(3);

6. not informing professionals and consumers of depilation procedures carried out with intense pulsed light devices in accordance with Articles 12, 13 and 14;

7. for operators: failing to ensure traceability in the maintenance of intense pulsed light depilation devices and their operating conditions under the conditions provided for in Article 10.

Repetition of the offences laid down in this article shall be sanctioned pursuant to Articles 132-11 and 132-15 of the Penal Code.

**Article 17**

The provisions of Articles 132-66 to 132-70 of the Criminal Code on adjournment of injunction shall apply to natural persons and legal persons in the event of conviction for any of the offences provided for under this decree.

The court may impose a penalty payment of up to EUR 250 per day of delay, for a maximum period of three months.

**Chapter VII: Transitional provisions**

**Article 18**

This decree shall enter into force on the date of publication of the last of the implementation orders provided for herein, and at the latest on [DATE].

In order to meet the training conditions provided for in this decree, professional medical assistants practising under the responsibility of a doctor shall have a period of 12 months from the entry into force of the order provided for in Article 6(VI).

In order to meet the qualification conditions provided for in this decree, beauticians shall have a period of 12 months from the entry into force of the order provided for in Article 5(VI).

**Article 19**

Articles 4, 5, 6, 7, 15 and 18 may be amended by simple decree.

**Article 20**

The provisions of Article 8, Article 10(3), Article 12 and Article 16(5) shall be repealed as of the application date of the common specifications mentioned in Article 1 of the above-mentioned Regulation No 2017/745 of 5 April 2017.

**Article 21**

*The Keeper of the Seals, Minister for Justice, the Minister for Solidarity and Health and the Minister for the Economy and Finance* shall be responsible, within the scope of their respective competences, for the implementation of this decree, which shall be published in the Official Journal of the French Republic.

Done on [date]

By the Prime Minister:

The Keeper of the Seals, Minister for Justice,

The Minister for Solidarity and Health,

The Minister for the Economy and Finance,