EUROPEAN
COMMISSION

Brussels, XXX
[…](2018) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on Common Specifications and application of classification rules to devices without an intended medical purpose subject to Regulation 2017/745[…]

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on common specifications and application of classification rules to devices without an intended medical purpose subject to Regulation 2017/745 […]

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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[1], and in particular Article 9(1) and Article 51(4) thereof,

After consulting the Committee on Medical Devices,

Whereas:

(1) Regulation (EU) 2017/745 sets out provisions applicable to devices without an intended medical purpose as listed in Annex XVI.

(2) Contrary to medical devices, which, as defined in Article 2(1) of Regulation (EU) 2017/745, have an intended medical purpose, devices listed in Annex XVI are intended only for an aesthetic or other non-medical purpose. Hence, in order to ensure a proper mitigation of the risks pertaining to the use of these products, it is necessary to establish a set of specific requirements they need to satisfy in addition to the applicable ones laid down in Regulation (EU) 2017/745.

(3) Manufacturers of devices without an intended medical purpose are for the first time subject to the relevant provisions of the medical devices legislation. Therefore, it is important to ensure a consistent and effective application of these provisions by manufacturers and notified bodies. In order to achieve this, the provisions established in the Regulation (EU) 2017/745, and in particular, the general principles set out in Annex I to that Regulation, should be complemented with respect to their applicability to the individual group of devices, especially with reference to the risk management and, if required, to the clinical evaluation.

(4) Manufacturers of devices without an intended medical purpose must apply the risk management process established in Annex I of Regulation (EU) 2017/745 in

[1] OJ L 117, 5.5.2017, p.1.

conjunction with the provisions set out in this Regulation. As part of this process, it is necessary to identify specific risks to be analysed and minimised and specific risk control measures to be implemented with respect to individual groups of devices.

(5) In order for manufacturers to be able to demonstrate compliance of devices without a medical intended purpose with applicable provisions of Regulation (EU) 2017/745, requirements of this Implementing Regulation need to be satisfied.

(6) Classification rules for active devices set out in Section 6 and Section 7.9 of Annex VIII to Regulation (EU) 2017/745 should apply also to devices without any intended medical purpose so as to allow a classification consistent with the same level of safety of analogous devices with medical purpose.

(7) When assessing residual risks, manufacturer should take into account that information for safety is often discarded by professional users and even more frequently by lay persons. Manufacturers should therefore make the information readily available by other means, either publicly available or obtainable retrospectively.

(8) The measures provided for in this Regulation are in accordance with the opinion of the […] Committee, [for acts adopted after consultation of a committee under the examination procedure]

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Implementing Regulation applies to the devices covered by Annex XVI of the Regulation (EU) 2017/745.

Annexes from I to VI of this Regulation lay down product-specific requirements with reference to groups of products without an intended medical purpose listed in Annex XVI of the Regulation (EU) 2017/745. The provisions of the Annexes to this Implementing Regulation apply to devices referred to in the *first subparagraph* only with regard their intended non-medical use.

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

(1) "liposuction" means the surgical removal of localised subcutaneous fat deposits by aspiration;

(2) "liposuction devices" means devices intended by the manufacturer to be used for the purpose of liposuction;

(3) "lipolysis" means the localised [*in situ*] destruction of fat deposit;

(4) "lipolysis devices" means devices intended by the manufacturer to be used for the purpose of lipolysis;

(5) "lipoplasty" means the modification of body contours by removal of excess fat;

(6) "devices for professional use" means devices which are intended to be used in the context of a medical or an otherwise controlled professional environment by persons having proven qualification in the safe and effective use of the device;

(7) "devices for home use" means devices which are intended to be used in private environments, meaning not in a controlled professional environment, also by lay persons;

(8) "non-medical professional" means an individual using the device in the context of his/her professional activities, and who although not being a healthcare professional has proven professional qualification;

(9) "analogous device" of a device referred to in *first paragraph of Article 1* means the same device with intended medical purpose.

Article 3

General interpretation rules

(1) Whenever the provisions of the Regulation (EU) 2017/745 refer to patient-related aspects they shall be interpreted as a referring to the groups of consumers for which the device is intended by the manufacturer.

(2) Whenever the provisions of the Regulation (EU) 2017/745 refer to the user of the device they shall be interpreted as referring to healthcare professionals and lay persons, including non-medical professionals, intended to use devices referred to in *first paragraph of Article 1* of this Regulation.

(3) When executing the obligations laid down in the Regulation (EU) 2017/745, with particular reference to the general safety and performance requirements and clinical evaluation, as well as the obligations laid down in this Implementing Regulation, manufacturers shall take account of the experience gained from the concerned devices and analogous devices.

They shall also take account of experience gained from other devices utilising the same or similar technologies.

Article 4

Application of classification rules to active devices

(1) Active devices without an intended medical purpose are classified in accordance with Section 6 and Section 7.9 of Annex VIII to Regulation (EU) 2017/745 although definitions 2.4 and 2.5 of that Annex cannot be applied to them.

Article 5

Risk analysis and evaluation

(1) The personnel of the manufacturer responsible for performing risk management tasks shall be appropriately qualified. This shall include, where appropriate, proven

knowledge and experience with the particular device, analogues or similar devices and their use, the technologies involved or risk management techniques.

(2) Manufacturers shall assess and describe in their technical documentation and their instruction for use the probability of occurrence and the severity of harms by using, where applicable, qualitative and quantitative terms.

(3) The harms, their severity and their probability of occurrence have to be determined by the manufacturer and, if not possible, estimated, for use by physicians, by healthcare professionals other than physicians and by lay persons, including non-medical professionals to the extent these groups have or might have access to the device. It is presumed that all these groups have access to the device unless the device is only sold directly to those users who have proven professional qualification.

(4) Where, by the nature of the devices or for ethical reasons, no data on the probability of occurrence of harm may be generated, manufacturers shall evaluate the risk on the basis of the nature of the harm and a worst case estimate of the probability of the harm occurring.

(5) Manufacturers shall substantiate in the technical documentation the reasons for not providing data on the probability of occurrence of harm.

(6) Provisions shall be made to take account of any changes in risks which could arise from new data or changes in device use environment.

(7) Manufacturers shall not discard any potential risks as being negligible from the outset without prior analysis and documentation.

(8) In their risk analysis, manufacturers shall take into account the specificities of various user and consumer groups.

As a result of the risk management process, manufacturers shall specify the categories of consumers and users that are to be excluded from the application of the device or for which special conditions have to be applied.

Article 6

Risk control and evaluation of residual risks

(1) When reducing risks in accordance with Annex I Points (4) (b) and 5(b) of Regulation (EU) 2017/745, manufacturers shall take into account to which degree users and consumers commonly understand the risks linked to the use of the device in order to effectively reduce risks.

(2) Where appropriate, information for safety provided to the user and that he/she cannot avoid to read may be qualified as reducing risks. In particular, in case information is integrated into the control menu of the user interface of the device, or if appropriate training of users is envisaged.

(3) Risk control measures adopted in accordance with Chapters I and II of Annex I to Regulation (EU) 2017/745 shall be put in place even if the performance of the device is thereby reduced whilst maintaining the main function of the device.

(4) When deciding on risk control measures in accordance with Annex I Point 4 of Regulation (EU) 2017/745, manufacturers shall verify whether the risk control measures generate new harms, hazards or hazardous situations and whether the estimated risks for previously identified hazardous situations are affected by these measures.

(5) A risk shall not be reduced as far as possible if such optimized reduction of this risk would increase one or several other risks so that the overall residual risk is increased.

(6) A risk does not need to be reduced as far as possible if the optimized reduction of this risk would increase one or several other risks so that the overall residual risk is still the same.

(7) All the residual risks have to be combined to constitute the overall residual risk.

The overall residual risk includes all identified risks occurring during use within the intended purpose and during reasonably foreseeable misuse.

(8) Annex I Point 9 of Regulation (EU) 2017/745 has to be applied in a view of the intended purpose[, the utility of the intended purpose], the modalities of use, and the availability of similar devices based on similar technology and alternative technologies or methods with lower residual risk.

(9) Devices shall be designed and manufactured in such a way as to limit the residual risks due to exposure to the device, as far as technically possible.

(10) If the [undesirable] side-effects [are of transient nature and] do not require medical or surgical intervention to prevent life-threatening illness or permanent impairment of a body function or permanent damage to a body structure and if residual risks are less or at least of the same level as risks related to the use of similar medical devices, the residual risks are acceptable.

Article 7

Label and Instruction for Use

(1) Devices listed in Annex XVI of the Regulation (EU) 2017/745 which are intended by the manufacturer for both a medical and a non-medical purpose shall be labelled “for medical and non-medical use”.

(2) Devices listed in Annex XVI of the Regulation (EU) 2017/745 which are intended by the manufacturer for only a non-medical purpose shall be labelled “for non-medical use”.

(3) When informing users and consumers in accordance with Annex I, Point 4 (c) and last sentence, Point 23, Point 23.4(g) in particular, of Regulation (EU) 2017/745, manufacturers shall take into account to which degree users and consumers commonly understand the risks linked to the use of the device.

(4) Manufacturers shall highlight in the instructions for use and, if possible, on the label the user groups for which risks are particularly high and also specify the categories of consumers referred to in *Article 5(9) second subparagraph*.

(5) Particular attention shall be given to devices which are likely to be used by lay persons or outside a medical or otherwise professionally controlled work environment.

The manufacturer shall in the instruction for use present the risks, including the residual risks [and any undesirable side-effects] in a transparent and easy understandable way so that the consumer can take an informed decision on whether to use the device [or not].

(6) Manufacturers shall highlight in the instructions for use that the use of the products may cause psychological harm if this is the case.

(7) The instructions for use shall describe the intended non-medical purpose and the particular risks and precautions to be taken which are linked thereto.

(8) The instructions for use and, if possible, the label, shall indicate the performance that the consumer can expect from the use of the device as well as the risks arising from its use. The intended performance shall be described in such a way that the consumer understands which non-medical benefits can be expected from the use of the device.

(9) Where applicable, the instructions for use shall contain an annex, easy to hand-over to the consumer, which lists, in a language commonly understood by laypersons, all the information to be provided to the consumer. The instructions for use shall contain the recommendation to hand this annex out to the consumer .

Article 8

Clinical evaluation

(1) Clinical evaluation regarding the safety and performance of the device shall be based on clinical data providing a sufficient level of clinical evidence. The evaluation of the acceptability of residual risks shall be based on such data.

(2) The clinical evaluation shall be performed as a systematic life cycle process , paying particular attention to the long-term effects of the use of the device.

(3) Clinical data demonstrating the conformity with the legal requirements for devices with an intended medical purpose can only be referred to in order to demonstrate the fulfilment of legal requirements for devices without an intended medical purpose if those devices also comply with Point 9 of Annex I to the Regulation (EU) 2017/745 as well as applicable provisions of this Implementing Regulation.

(4) [Where required] in order to demonstrate compliance with the applicable legal requirements regarding safety and performance, clinical investigations shall be consistently performed for devices without an intended medical purpose.

Clinical investigations shall be processed according to the same rules as clinical investigations regarding devices with an intended medical purpose.

Article 9

Performance

(1) Manufacturers shall substantiate in the technical documentation that devices achieve the intended performance as described in the information supplied with the devices.

(2) Where applicable, the manufacturer shall, in the summary of safety and clinical performance, present the risks, including the residual risks in a transparent and easy understandable way so that the consumer can take an informed decision on whether to use the device [or not].

(3) Performance statements shall be formulated in terms that are consistent with the expectations of consumers. In order to substantiate that this is the case, the expectations of intended consumers shall be investigated.

Article 10

Entry into force

This Regulation shall enter into force on the […] day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President

EUROPEAN
COMMISSION

Brussels, XXX
[…](2018) XXX draft

ANNEXES 1 to 6

ANNEXES

to the

Commission implementing Regulation

on Common Specifications and application of classification rules to devices without an intended medical purpose subject to Regulation 2017/745

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

ANNEX I

1. Scope

This Annex applies to non-active non-corrective contact lenses falling under No. 1 of Annex XVI to Regulation (EU) 2017/745, which do not contain antenna or other active tools.

2. Risk management

When applying the risk management process established in Annex I of Regulation (EU) 2017/745 and specified in Article 5 and 6 of this Regulation, manufacturers shall in particular analyse and minimise the specific risks listed in section 2.1 of this Annex. In addition, manufactures shall implement the specific risk control measures listed in section 2.2 of this Annex

2.1. Specific risks

Manufacturers shall in particular analyse and reduce as far as possible the risks linked to the following aspects:

Design and manufacturing

(a) the shape of the device, in particular in view of avoiding irritation by edges or sharps, disconnection/dislocation from the cornea, wrinkling or folding, ["suction cup" effect,] equality of pressure on the cornea related to positioning;

(b) the selection of raw materials for lens and surface in view of biocompatibility and chemical and biological contaminants;

(c) biocompatibility of the final product, with its packaging and storage solution, including, but not limited to aspects of cytotoxicity, acute systemic toxicity, sub-chronic toxicity, cornea reactivity, genotoxicity, sensitization, irritation, inflammation, allergic reactions, sterilization residues and degradation products;

(d) microbiological contamination of the final device;

(e) appropriateness of the primary packaging in terms of keeping the lens sterile, permanently covered by storage fluid and avoiding degradation of the product, e.g. by leaching of container or cover materials, by intrusion of microbial contaminations;

(f) the effect of long-term storage and the conditions of storage on the stability and properties of the lens;

Distribution chain, informing the user

(g) typical lack of pre-use testing of suitability of lens wearing performed by ophthalmologist or specialized optician;

(h) lack of expertise of distributors outside the classic optician distribution chain with regard to both the selection of appropriate lenses and their use and the storage and safe transport of contact lenses;

(i) given that distribution of these devices is usually outside the classic optician distribution chain, the possible lack of any safety or handling advice to the users from a typical non-corrective contact lens distributors;

User related hazards/risks

(j) lack of experience and training of certain users with use of any type of contact lens;

(k) identification of contraindications under which contact lenses shall not be used;

(l) possible reduced availability to the cornea of tear film and oxygen;

(m) typical lack of hygiene of users during placing, using and removal resulting in severe inflammation or other diseases of the eye;

(n) possible vision hindrance and reduced transmission of light;

(o) deterioration of eye sight due to coloration, lack of precise fitting to the eye's surface and lack of correction;

(p) identification of [non-medical] conditions such as driving, piloting or the operating of heavy machines under which contact lenses shall not be used;

(q) increased risk of eye damage if the lenses are worn extensively (e.g. for long periods, consecutive multiple use);

(r) increased risk of eye damage if still worn when eye redness and irritation occur;

(s) the effect of duration of use on any of the risks mentioned above;

(t) possible misuse of the primary packaging as containment for storage between several uses;

(u) for multiple use contact lenses, risks linked to re-use and irregular re-use by the same consumer; lack of familiarity of consumers with emergency measures in case of adverse events.

2.2. Specific risk control measures - Safety requirements

2.2.1 The vision field shall not be reduced by the lens, including in case of reasonably foreseeable dislocation or imprecise placing. The lens shall permit transmission at least of sufficient light for adequate visibility under any situation of use.

2.2.2 The colour agents used for staining in the contact lenses shall not leach under the intended conditions of use.

2.2.3 All materials of the lens, the inner side of their primary packaging including its storage solution shall be fully biocompatible, non-irritating, non-toxic.

2.2.4 Lenses, the inner side of their primary packaging including its storage solution shall be sterile, pyrogen-free. If in contact with the eye the storage liquid shall not injur the cornea, eye and the surrounding tissue .

2.2.5 Given that lenses are not usually fitted by an optician, they shall be designed so as not to compromise the health of the cornea, eye and surrounding tissue (e.g. by too low permeability, dislocation, sharp edges, abrasion, unequal mechanical pressure distribution).

2.2.6 If the lens is for multiple use, the manufacturer must either provide effective maintenance liquids and means for cleaning and disinfecting

together with the lens covering the entire lifetime or specify the required maintenance liquids and means for cleaning and disinfecting. The manufacturer must verify any further accessories or parts thereof [in all Member States] where the lenses are made available on the market.

2.2.7 If the lens is for multiple use, the maximum number of re-uses and maximum duration of use(s) shall be validated by the manufacturer.

2.2.8 Manufacturers shall take into account the need of using eye drops to compensate for dryness. Such eye-drops and their criteria for suitability shall be identified and described to the user/consumer;

2.2.9 Identification of adverse events by the consumer and how to deal with them, including reporting to the manufacturer of such adverse events;

2.2.10 The instruction for use and label shall be designed and written in a way as to be understandable by a lay user and allowing the lay user safe use of the devices.

2.2.11 Presence of substances referred to in Section 10.4.1 of Annex I to Regulation (EU) 2017/745 shall be evaluated independently of their concentration.

3. Performance

No additional criteria than those mentioned in Regulation (EU) 2017/745 and in Article 9 of this Regulation are required.

4. Clinical evaluation

The clinical evaluation shall in particular cover the aspects in sections 2.1 and 2.2 of this Annex as well as performance aspects.

The duration of the clinical investigation and their follow-up should cover enough time to identify long-term complications.

5. Label and Instructions for use

5.1. Label

The label shall contain the following indications on the outer packaging intended to be provided to the consumers:

(a) indication of categories of users excluded, as well as any contraindications.

(b) if devices are intended for single use, in addition to the internationally recognized symbol, in bold fonts at least of the average font size the text “Only for single use”;

(c) indication of the dimensions of the lens (outer diameter of the lens and base curve radius);

(d) the recommendation to read the instruction for use for proper use;

(e) date of expiry.

5.2. Instructions for use

The instruction for use shall contain in a language commonly understood by lay persons and the text should be easy read with normal or corrected vision in an illumination of (215 ± 15) lx:

(a) if devices are intended for single use, in addition to the internationally recognized symbol, in bold fonts of highest used size the text: “Only for single use.”;

(b) the warning that used lenses shall not be used by other persons;

(c) the indication of the dimensions of the lens (outer diameter of the lens and base curve radius);

(d) the indication of the raw materials for lens and surface;

(e) the indication of water content and oxygen permeability;

(f) an indication about the possible effect of incorrect storage conditions on the product quality and maximum storage time;

(g) an illustrated instructions on how to safely place and remove the lens;

(h) instructions on what to do in case of dislocation;

(i) hygiene measures before, during and after use;

(j) a warning “Do not contaminate lenses with make-up or aerosols.”;

(k) for multiple-use lenses, the cleaning, disinfecting and storage procedure and conditions shall be described in full including the necessary equipment and solutions – which shall be named in detail;

(l) listing of contraindications under which contact lenses shall not be used. Such a list shall at least include: dry eyes (inadequate tear fluid), use of eye medication, allergies, inflammation or redness in or around the eye, poor health affecting the eye such as cold and flu, previous medical intervention which may adversely affect the use of the device, any other systemic illness affecting the eye;

(m) a warning: “Do not use whilst participating in traffic-related situation (e.g. driving, biking), operating machines or whilst being in or under water.”;

(n) a warning: “Avoid activities where possible vision hindrance and reduced transmission of light create a risk.”;

(o) increased risk of eye damage if still worn when eye redness and irritation occur;

(p) a warning “Not to use after date of expiry.”;

(q) a clear indication of the maximum recommended wearing time.

(r) a warning “Not to use lenses beyond maximum recommended wearing time.”

(s) a warning on the increased risk of eye damage if the lenses are worn extensively (e.g. during sleeping periods, consecutive multiple use);

(t) a warning “Not to use in excessively dry or dusty environments.”;

(u) a warning: “Do not re-use the primary packaging as containment for storage between uses.”;

(v) a warning: “Do not re-use the storage solution.”;

(w) a list of risks linked to the reduced availability to the cornea of water and oxygen;

(x) a list of possible adverse events, their probability of occurrence and their indicators;

(y) instruction on how to deal with adverse events, including emergency measures;

(z) an instruction “Remove the lens immediately in case of:

– irritation or eye pain such as stinging, burning, itching;

– reduced comfort when compared with previous wearing of an identical lens;

– unusual secretions or excessive tear-flow,

– redness of the eye,

– severe or persistent dryness,

– reduced or blurred vision linked to the use of the lens.

If any of these symptoms continue after removal of the lens, contact an ophthalmologist. The continuity of these symptoms might indicate a more serious condition.”;

(aa) information on how to report undesirable side effects [in the Member States where the device is placed on the market].

ANNEX II

1. Scope

This Annex applies to devices intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy falling under No. 2 of Annex XVI to Regulation (EU) 2017/745. Items to be introduced into or onto the eyes falling under No. 1 of Annex XVI Regulation (EU) 2017/745 and substances, combination of substances or items falling under No. 3 of Annex XVI Regulation (EU) 2017/745 are not covered by this Annex.

2. Risk management

When applying the risk management process established in Annex I of Regulation (EU) 2017/745 and specified in Article 5 and 6 of this Regulation, manufacturers shall in particular analyse and minimise the specific risks listed in section 2.1 of this Annex. In addition, manufactures shall implement the specific risk control measures listed in section 2.2 of this Annex

2.1. Specific risks

For each specific product covered by this Annex, the risk analysis shall include a section on risks that are relevant only to the specific non-medical intended purpose of introducing this device into the human body through surgically invasive means, taking into account specific characteristics of potential users and consumers of the particular product.

2.1.1 When undertaking the risk management, manufacturers shall in particular take into account the following aspects and the related risks:

(a) physical and chemical characteristics and full composition of the implant;
(b) the selection of raw materials in view of biocompatibility and chemical and biological contaminants;
(c) for resorbable devices, resorption and life-time in the body, indicating the half-life and the end of the resorption;
(d) biocompatibility of the final product, including, but not limited to, aspects of cytotoxicity, acute systemic toxicity, sub-chronic toxicity, intradermal reactivity, genotoxicity, skin sensitization, intradermal and subcutaneous implantation;
(e) the selection of raw materials in view of biocompatibility and chemical and biological additives or contaminants;
(f) microbiological contamination of the final device;
(g) the specific anatomical location for which clinical and other data support the use of the device;

(h) patient specific factors (e.g. previous accidents, special conditions, age restrictions).

(i) Potential interactions with magnetic field, e.g. MRI-related heating.

2.1.2 Where appropriate, manufacturers shall in particular analyse and reduce as far as possible the following risks:

(a) microbiological contamination;

(b) presence of manufacturing debris;

(c) implantation procedure risks (including use errors);

(d) implant failure (e.g. rupture, unintended degradation);

(e) implant dislodgement and migration;

(f) asymmetry;

(g) implant visibility through the skin;

(h) implant deflation/wrinkling;

(i) severe gel bleeding/leakage;

(j) sweating and/or silicone migration;

(k) local inflammation/swelling;

(l) regional swelling (axillary lymph nodes);

(m) capsule formation and contracture;

(n) discomfort/ constant severe excessive pain;

(o) hematoma;

(p) infection/inflammation;

(q) superficial wound;

(r) wound dehiscence;

(s) extrusion of implant/interruption of wound healing;

(t) scarring /scar hyperpigmentation and hypertrophy;

(u) nerve injury;

(v) seroma;

(w) compartment pressure problems/compartment syndrome;

(x) limitation in cancer diagnosis;

(y) over-sized implants.

2.2. Specific risk control measures

2.2.1 The devices shall be sterile and free from pyrogens. Where metallic implants are supplied non-sterile with the intention to be sterilised before use, adequate instruction for sterilisation shall be provided.

2.2.2 The safe use of the device shall be supported by clinical and other data considering the anatomical location.

2.2.3 Long-term data shall be collected to evaluate the presence of non-degradable substances originating from the devices.

2.2.4 Manufacturers shall provide training accessible to users.

2.2.5 Presence of substances referred to in Section 10.4.1 (a) and (b) of Annex I to Regulation (EU) 2017/745 shall be evaluated independently of their concentration.

3. Performance

No additional criteria than those mentioned in Regulation (EU) 2017/745 and in Article 9 of this Regulation are required.

4. Clinical investigation and evaluation

4.1. The clinical evaluation shall in particular cover the aspects identified in sections 2.1 and 2.2 of this Annex as well as performance aspects.

4.2. The duration of clinical investigations and their follow-up shall cover sufficient time to assess the duration of the intended performance and to identify long-term complications.

4.3. Clinical investigations shall include all specific anatomical locations for which the device may be used according to its intended purpose.

4.4. In the clinical evaluation, the manufacturer shall include an evaluation of the surgical procedure to introduce the device into the human body.

4.5. As part of the clinical evaluation, changes in the quality of life of implant recipients shall be included, as determined using a recognised instrument to measure this.

5. Label and Instructions for use

5.1. The label shall contain:

(a) in bold fonts at least of the average font size the text “Only to be implanted in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law.”

(b) a clear indication that devices shall not be implanted in minors.

(c) the full composition of the product.

5.2. The instructions for use shall contain:

(a) on top in bold fonts of highest used size the text: “Only to be implanted in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law.”

(b) a clear indication that devices shall not be implanted in minors.

(c) the instruction for the user to consider any previous procedures, accidents, conditions or medications of the consumer that may affect the procedure.

(d) the instruction for the user to consider any specific risks that may be applicable to activities of the consumer (e.g. profession, sports or other activities regularly performed by the consumer).

(e) a comprehensive list of contra-indications. This list shall at least contain keloid scars.

(f) the full composition of the product.

(g) the recommendation for the user to consider any previous procedures, conditions or medication of the consumer that may affect the procedure (e.g. skin diseases, traumas),

(h) the recommendation for the user of a post-administration monitoring time in order to identify potential adverse events.

5.3. The annex referred to in Article 7(8) shall contain:

(a) Information mandatorily to be provided to consumers in accordance with the Regulation (EU) 2017/745 or horizontal provisions of this IR;

(b) all residual risks and potential side-effects listed, including those commonly related to surgery such as bleeding, potential drug interactions and the risks associated with anaesthesia, in a transparent way;

(c) information on how to report undesirable side effects, information on device removal, information on when to contact healthcare professional;

(d) the volume and size of the device.

ANNEX III

1. Scope

1.1. This Annex applies to devices falling under No. 3 of Annex XVI to Regulation (EU) 2017/745. However, it does not apply to the means for introduction in the body such as syringes, dermarollers or other similar means unless these are prefilled with the substances, combinations of substances or other items falling under No. 3 of Annex XVI to Regulation (EU) 2017/745.

2. Risk management

When applying the risk management process established in Annex I of Regulation (EU) 2017/745 and specified in Article 5 and 6 of this Regulation, manufacturers shall in particular analyse and minimise the specific risks listed in section 2.1 of this Annex. In addition, manufactures shall implement the specific risk control measures listed in section 2.2 of this Annex

2.1. Specific risks

When undertaking the risk management, manufacturers shall in particular take into account the following aspects and the related risks:

(a) physical and chemical characteristics of the device;

(b) the selection of raw materials in view of biocompatibility and chemical and biological additives or contaminants;

(c) biocompatibility of the final product, including, but not limited to, aspects of cytotoxicity, local and systemic toxicity (acute, sub-chronic and chronic), intradermal reactivity, genotoxicity, sensitization, intradermal and subcutaneous implantation;

(d) resorption and life-time in the body, indicating the half-life and the end of the resorption, including the possibility of metabolisation (e.g. enzymatic degradation of the filler material such as hyaluronidase for hyaluronic acid fillers);

(e) microbiological contamination of the final device;

(f) the specific anatomical location;

(g) patient specific factors (e.g. previous and current treatments (medical and surgical), age restrictions, pregnancy, breast-feeding);

(h) aspects associated to the use of the device, including but not limited to the injection technique, means used for injection like rollers, catheters or needles, maximum quantity injected depending on location and applied technique and storage or transfer of the product during or following procedures

2.2. Specific risk control measures

2.2.1 The devices shall be sterile and free from pyrogens.

2.2.2 The safe use of the device shall be supported by clinical and other data considering the anatomical location.

2.2.3 Long-term data shall be collected to evaluate the presence of non-degradable substances originating from the devices.

2.2.4 Manufacturers shall provide training to users.

2.2.5 Presence of substances referred to in Section 10.4.1 (a) and (b) of Annex I to Regulation (EU) 2017/745 shall be evaluated independently of their concentration.

3. Performance

No additional criteria than those mentioned in Regulation (EU) 2017/745 and in Article 9 of this Regulation are required.

4. Clinical evaluation

4.1. The clinical evaluation shall in particular cover the aspects listed sections 2.1 and 2.2 of this Annex as well as performance aspects.

4.2. Clinical investigations shall include all specific anatomical locations for which the device may be used according to its intended purpose.

4.3. The duration of the clinical investigations and of the post-market clinical follow-up should cover enough time to assess the duration of the aesthetic effect and to identify long-term complications.

5. Label and instruction for use

5.1. Label

The label shall contain:

a) the text “Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law”.

b) a clear indication that devices shall not be used in minors.

5.2. Instructions for use

5.2.1 The instruction for use shall contain:

a) on top in bold fonts of highest used size the text: “Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.”

b) a clear indication that devices shall not be used in minors.

c) precise and detailed technical information for a good administering practice.

d) accurate and detailed description for treatment of most common side-effects, like overdosing, swelling, hardening and immune responses.

e) clear instructions for users as to how and when new injections can be placed at previously injected locations.

f) a list of ingredients, which specifies all:

- ingredients responsible for the intended action with specification of their molecular weight range, their degree of cross linkage and their concentration,
- other added ingredients such as cross linking agents, solvents, anesthesia, preservatives.

g) the recommendation for the user to consider any previous procedures, conditions or medication of the consumer that may affect the procedure (e.g. skin diseases, traumas).

h) the recommendation for the user of a post-administration monitoring time in order to identify potential adverse events.

5.2.2 The annex referred to in Article 7(8) shall contain:

a) Information mandatorily to be provided to consumers in accordance with Regulation (EU) 2017/745 or horizontal provisions of this Regulation,

b) all residual risks and potential undesirable side-effects listed in a transparent way and described in a language comprehensive for lay people. This includes a clear declaration on the presence of any substances referred to in Section 10.4.1 of Annex I to Regulation (EU) 2017/745, heavy metals or other contaminants,

c) information on when and how to report undesirable side effects;

d) information on when to contact healthcare professional;

e) any contraindications to the procedure.

In addition, a specific part of the annex shall be reserved for information on the location, the number and the volume of the injections as well as the resorption period of the product. The manufacturer shall recommend the healthcare professional to filled in this specific part.

ANNEX IV

1. Scope

This Annex applies to all devices falling under No. 4 of Annex XVI of Regulation (EU) 2017/745.

2. Risk management

When applying the risk management process established in Annex I of Regulation (EU) 2017/745 and specified in Article 5 and 6 of this Regulation, manufacturers shall in particular analyse and minimise the specific risks listed in section 2.1 of this Annex. In addition, manufactures shall implement the specific risk control measures listed in section 2.2 of this Annex

2.1. Specific risks

2.1.1 When undertaking the risk management, manufacturers shall in particular take into account the following aspects and related risks

(a) the volume of adipose tissue which may be removed, or in the case of lipolysis, destroyed and the expected metabolic effect taking into account the probable different characteristics of the person undergoing under treatment;

(b) the minimum time lapse between subsequent procedures;

(c) the anatomical location of the use of the device;

(d) the cannula type i.e. the diameter and nature of the tip of the cannula;

(e) the amount of suction which will be applied;

(f) the use of infiltrative fluid with a justification for the choice of fluid and its composition;

(g) the type of liposuction which the device is intended to provide, e.g. dry, wet, the type of anesthetic;

(h) whether the device is a simple liposuction, i.e. blunt cannula suction or whether it incorporates any other mechanism of action[, for example the use of laser energy or ultrasound];

(i) the body-mass-index of the population to which the clinical data or other sources relate;

(j) the way in which energy is emitted, i.e. externally or internally.

2.1.2 Manufacturers shall in particular analyse and reduce as far as possible the following risks:

(a) post-operative seroma;

(b) tissue injury organ perforation and bleeding;

(c) post-operative ecchymosis and oedema;

(d) indirect risks, such as the risk caused by the interference with active implantable or active body-worn medical devices and of metallic passive medical devices or other metallic objects present on or inside the body.

2.1.3 For liposuction devices, in addition to those risks listed in 2.2.2 of this Annex, manufacturers shall in particular analyse and reduce as far as possible the following risks:

(a) haemorrhage;

(b) perforation of abdominal viscera, thorax or peritoneum;

(c) pulmonary embolism;

(d) bacterial infections such as necrotizing fasciitis, gas gangrene, and sepsis;

(e) hypovolemic shock;

(f) thrombophlebitis;

(g) seizures;

(h) risks related to local anesthetic use, particular consideration should be given to lidocaine-induced cardiotoxicity or lidocaine-related drug interactions for tumescent liposuction.

2.1.4 For lipolysis devices, in addition to those risks listed in 2.2.2 of this Annex, manufacturers shall in particular analyse and reduce as far as possible the following risks:

(a) thermal injury, including burns to incision sites and overlying tissue;

(b) other harmful effects of the internal or external local discharge of energy;

(c) over-exposure;

(d) neurovascular and local tissue injury, including reduction in cutaneous sensory nerve function;

(e) remodelling of collagen that may lead to neoformations;

(f) reorganisation of the reticular dermis;

(g) body deformity or similar poor aesthetic outcome causing the need for medical intervention;

(h) for internal lipolysis, the risks linked to the types and sizes of incision.

When complying with requirements under this section, manufacturers shall in particular take account of the nature of the tissue and its hydration status.

2.2. Specific risk control measures

2.2.1 All materials coming into contact with the body shall be fully biocompatible, non-irritating, and non-toxic when used in accordance with the instructions for use.

2.2.2 Invasive parts shall be sterile and pyrogen-free.

2.2.3 Manufacturers shall provide training to users.

2.2.4 Lipolysis devices shall contain controls for the application time, the waveform, the energy applied and the temperature reached on or in the body. They shall contain simultaneous visual and audible automatic alarms for cases where a critical value is reached for one parameter (e.g. temperature, energy level, duration of use) or for a combination of parameters.

2.2.5 Where applicable, manufacturers must further provide the following: low energy preset, emergency stop switch, automatic deactivation in case of over-exposure or excessive liposuction, respectively.

3. Performance

When demonstrating the performance of their device, manufacturers shall provide evidence that adipose tissue is effectively reduced, removed or destroyed to the extent claimed in the technical documentation, the instructions for use and in publicity material "claimed performance".

4. Clinical evaluation

The clinical evaluation shall in particular cover the aspects listed in Section 2.1 and 2.2 of this Annex as well as performance aspects.

5. Label and instructions for use

5.1. The instructions for use and, if possible, the label, shall indicate the performances that the consumer can expect from the use of the device as well as the risks arising from its use. The intended performances shall be described in such a way that the consumer understands which non-medical performance can be expected from the use of the device.

5.2. The instructions for use shall contain a comprehensive list of contra-indications for the user. Taking into account that each medical consultation is unique and therefore this list does not supersede the clinical judgement of a healthcare professional, this list shall at least contain the following contra-indications:

(a) coagulant disorders, on anticoagulant medications;

(b) uncontrolled hypertension;

(c) diabetes mellitus;

(d) phlebitis and/or vasculitis;

(e) cancer or tumors;

(f) excessive obesity;

(g) pregnancy;

(h) vascular fragility;

(i) recent surgery (6 weeks);

(j) skin infections/ open lesions;

(k) varicose veins (in the area of treatment);

(l) age less than 18;

(m) incapability to understand the consequences, implications and risks of the use of the device in conjunction with necessary medical procedures.

In addition to the contra-indications listed in the first subparagraph, for lipolysis devices employing radiofrequency electric currents or electromagnetic fields the list shall contain the following:

(a) any metallic passive medical device or other metallic object present on or inside the body;

(b) any active implantable or active body-worn medical device.

5.3. The instructions for use shall list the body parts on which the device cannot be used.

5.4. The instructions for use shall contain a comprehensive list of adverse effects for the user. This list shall at least include the following adverse effects:

(a) hyper- or hypovolaemia;

(b) bradycardia;

(c) venous thromboembolism;

(d) fat embolism;

(e) infection;

(f) fluid accumulation;

(g) skin erythema or panniculitis;

(h) contour irregularities.

5.5. The instructions for use shall contain a comprehensive list of warnings. This list shall at least include the following:

"Neither liposuction nor lipolysis is a reliable method for long-term weight reduction. Consideration should be given to exercise and dietary as well as lifestyle modification, both as an alternative to liposuction and lipolysis and in order to maintain any reduction

in adipose tissue which these procedures achieves. Devices have not been validated for the treatment of clinically diagnosed obesity and therefore should not be used for such purposes."

In addition to the warnings referred to in the first paragraph, for liposuction devices, the instruction for use shall contain the following

(a) "this device shall be used with extreme caution on consumers with chronic medical conditions, such as diabetes, heart, lung, or circulatory system disease or obesity.";

(b) "the volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and the consumer's safety. The capacity of providing adequate, timely fluid management is essential for the consumer's safety."

In addition to the warnings above, for liposuction devices that include the use of tumescent fluid, the instructions for use shall contain:

(a) "Careful consideration shall be given to patient suitability with respect to medication which has the potential to cause bradycardia or hypotension as this has been reported as the cause of death in a number of patients undergoing tumescent liposuction. Patients taking drugs such as beta-adrenergic antagonists, non-dihydropyridine calcium-channel blockers, cardiac glycosides, and centrally acting alpha-adrenergic agonists shall be subject to very careful consideration as deaths have been reported due to bradycardia and hypotension. The procedure has to be preceded the medical consultation which has to be documented and considers chronic disease and drugs taken by patient."

(b) "Patients shall be warned that they may have extended post-operative analgesia (i.e. for 24 hours or more) which may result in reduced sensation in the areas infiltrated and therefore patients should be warned to protect themselves from injury."

In addition to the warnings referred to in the first paragraph, for lipolysis devices, the instructions for use shall contain:

"Liver or cardiovascular dysfunction, such that the transient release of glycerol or free fatty acid may be associated with increased risk."

5.6. For liposuction and invasive lipolysis devices, the instructions for use shall contain the following recommendations:

"Devices intended for invasive use shall only be used by appropriately trained healthcare practitioners and in a medical environment. Liposuction and invasive lipolysis shall only be performed by appropriately trained medical doctors who are qualified or accredited in accordance with national law. The doctor who carries out the

procedure shall be assisted by at least one doctor or allied health professional who is qualified or accredited in accordance with national law.

All staff involved in the procedure shall be trained and shall maintain currency in Basic Cardiac Life Support and in the checking of equipment and emergency drugs used for resuscitation purposes. Doctors performing the procedure shall also be trained in Advanced Cardiac Life Support.

The doctor or allied health professional responsible for anesthetic management shall ensure that appropriate monitoring of the patient is undertaken, both during and post-procedure. With respect to tumescent liposuction, appropriate post-procedure monitoring shall be in place as lidocaine levels have been found to rise for up to 16 hours post-delivery."

5.7. For lipolysis devices, the instructions for use shall in addition contain at least the following recommendations:

"Devices intended for non-invasive lipolysis shall only be used by persons who have received the appropriate training in using the device safely. Appropriate training implies, besides studying, having observed at least 20 procedures and having performed at least 30 procedures under close supervision by a routine user of the device."

ANNEX V

1. Scope

1.1. This Annex applies to devices falling under No. 5 of Annex XVI to Regulation (EU) 2017/745 which use high intensity electromagnetic radiation in the wavelength range of 180 nm to 20000 nm for one or more of the following non-medical purposes:

(c) skin resurfacing (including skin rejuvenation),

(d) tattoo removal (including the removal of permanent make-up),

(e) hair removal,

(f) or other skin treatment.

1.2. Other skin treatments in the meaning of the last indent include, but are not limited to treatment of nevi flammei, haemangioma, teleangiectasia, spider veins, pigmented skin areas, and scars that do not yet fall under the definition of "injury" in the meaning of the 2nd indent of Article 2(1) of Regulation (EU) 2017/745. Accordingly, devices intended to treat acne scars are included, whilst devices for other acne treatment are excluded.

Sunbeds used for tanning of the skin or products using infrared optical radiation to warm the body or parts of the body are not covered by these common specifications.

2. Risk management

When applying the risk management process established in Annex I of Regulation (EU) 2017/745 and specified in Article 5 and 6 of this Regulation, manufacturers shall in particular analyse and minimise the specific risks listed in section 2.1 of this Annex. In addition, manufactures shall implement the specific risk control measures listed in section 2.2 of this Annex.

2.1. Specific risks

2.1.1. When undertaking the risk management, manufacturers shall take exposure to other light sources into account.

2.1.2. When undertaking the risk management, manufacturers shall in particular take into account the following aspects and the related risks:

(g) the various skin types[1] and the degree of tanning of the skin;

(h) the age of the consumers;

(i) the possibility of concurrent medical treatments or drug misuse;

[1] e.g. according to the Fitzpatrick scale: http://www.mdpi.com/1422-0067/14/6/12222/htm

(j) the reduced reaction to harm caused by local or systemic anesthesia.

2.1.3. Manufacturers of devices using high intensity optical[/photon electromagnetic] radiation shall in particular analyse and reduce as far as possible the following risks:

(a) burns;
(b) formation of scars / keloids;
(c) hypo- / hyperpigmentation;
(d) accelerated aging of skin;
(e) allergic / chemical skin reaction (e.g. to colour pigments of tattoos or make-up);
(f) alterations of melanoma, nevi, herpes, possible delay of disease diagnoses (e.g. melanoma, endocrine diseases);
(g) reactions in case of possible drug intake;
(h) reactions to sun or possible sunbed exposure;
(i) erythema, mostly temporary and/or occasionally persistent;
(j) purpura resulting from bleeding from small blood vessels;
(k) crusting;
(l) oedema;
(m) blistering;
(n) inflammation, folliculitis, skin infection;
(o) eye damage, including retina and cornea;
(p) prickling or feeling of heat;
(q) dry skin and itching due to shaving or combination of shaving and light treatment;
(r) excessive pain;
(s) paradoxical hypertrichosis (increased growth of hair after treatment);
(t) unintended release of radiation;
(u) in the case of lasers: ignition, explosion or production of fumes.

2.2. Specific risk control measures

2.2.1. Manufacturers shall apply the following safety concepts to devices for professional use:

(a) avoidance of unauthorized [unintended] access to the devices (e.g. by means of key switch or code or dual control of energy emission);
(b) information for the user on the correct functioning of the device and the concrete[actual] operation mode by means of acoustic and / or optical means in standby mode, in operating mode and in case of loss of full skin contact during the procedure;

(c) display of the characteristics of the emitted optical radiation for the purpose of permanent surveillance and recording (documentation) of the emission through the device in addition to what is stipulated in Section 16.2 of Chapter II of Annex I to Regulation (EU) 2017/745;

(d) continuous contact controls and an interlock system ensuring that the device works only in case of full skin contact with the emitting area of the device;

(e) automatic deactivation in case of overexposure, [i.e. the manufacturer must minimize the risk of overexposure by particular measures];

(f) skin tone sensor with the sensor area being at least as large as the output/application window and allowing emission output only if skin pigmentation is suited for treatment [and there is continuous full skin contact after skin tone analysis];

(g) exposure controls detecting overexposure by repeated treatments;

(h) low energy preset;

(i) optimized limitation of pulse energy (max. 12 J/cm2 for IPL (intense pulsed light); max. 19 J/cm2 for lasers);

(j) optimized limitation of pulse duration;

(k) optimized limitation of treatment areas (spot sizes);

(l) minimization of scattered radiation;

(m) minimization of the risk of accidental emission;

(n) emergency stop switch;

(o) for devices intended to remove hair: no emission of UV radiation, to be achieved e.g. by using appropriate high quality band edge filter, which cuts off wavelengths below 500nm;

(p) devices intended to deliver a permanent change of the appearance shall not be used on minors.

2.2.2. Devices for home use are only permitted for the purpose of hair removal.

2.2.3. Manufacturers of devices for home use shall implement the risk control measures listed under 2.2.1 of this Annex for devices for professional use and in addition the following risk control measures:

(a) automatic emergency stop where maximum acceptable duration of exposure is reached.

2.2.4. Manufacturers shall provide, together with the device, appropriate eye protection for users, the consumers and any other person likely to be exposed to the radiation due to reflection, misuse or mishandling of the emitting device. The eye protection for the user

has to ensure that the eyes are protected from intense pulsed light or laser light whilst not impairing the accurate and safe treatment. The eye protection for consumers shall be opaque.

If the eye protection is intended to be used several times, it must be ensured that the protection level is not negatively impacted by necessary cleaning or disinfecting procedures during the whole lifetime of the device. Accordingly, the necessary cleaning and disinfecting instructions shall be provided.

2.2.5. Manufacturers shall provide training accessible to user. Such training shall cover the conditions for safe and effective use of the device, the management of any associated incidents, and the identification and subsequent processing of reportable ones.

3. Performance

3.1. When demonstrating the performance of their device, manufacturers shall in particular provide evidence that:

- the claimed output of energy is achieved by the device;
- the application of the device achieves the intended performance claim.

3.2. The description of performance shall include an indication of the area of the skin which is intended to be treated.

4. Clinical evaluation

The clinical evaluation shall in particular cover the aspects listed sections 2.1 and 2.2 of this Annex as well as performance aspects.

5. Label and instruction for use

5.1. The instructions for use shall provide information on:

(a) the minimum radiation intensity, duration and frequency of use necessary to trigger the desired effect;

(b) the maximum and the recommended radiation intensity, duration and frequency of use;

(c) the minimum interval between several applications at the same location,

(d) the risks arising from excessive use;

(e) the radiation intensity, duration and frequency which triggers a sharp increase of risks, if any;

(f) the radiation intensity, duration and frequency beyond which there is no more additional performance,

(g) the pulse energy [J/cm2], pulse density [J/kg], wavelength range [nm], pulse duration [ms], pulse profile(s);

(h) the maximum admissible treatment spot size [cm2];

(i) description of the minimum homogeneity of the treatment spot;

(j) description of requirements for the spatial distribution of the treatments spots, taking into account that overlapping treated areas shall be avoided;

(k) safety features of the device;

(l) the expected lifetime of the device;

(m) the expected stability of performance;

(n) cosmetics and drugs interacting or expected to interact with the treatment and their description;

(o) other sources of radiation, such as sunbeds, that might increase the risks.

5.2. [With the exemption of devices for hair removal,] the manufacturer shall clearly convey the necessity that the users and the consumers need to undergo a medical consultation including a diagnostic examination of the skin areas intended for the treatment. Manufacturers shall recommend users not to treat any consumers prior to obtaining documentation from this consultation[, especially when any doubt can subsist regarding the consumer's ability to receive such treatment].

5.3. The instructions for use shall clearly describe requirements for cleaning and maintenance. For devices intended for professional use, these shall include the periodical least annual, measurement of light energy density and required controlled measures.

For devices for professional use, the manufacturer shall also instruct on how to ensure constant performance and recommend an at least annual electrical safety tests and maintenance.

5.4. The instructions for use shall clearly describe the operating environment and the conditions in which the devices can be operated safely. For professional use devices, these includes also:

a) the description/listing of appropriate accessories or conditions of other products used in the procedure,

b) the safety precautions to be taken which include, but are not limited to the use of non-reflective instruments (no mirrors shall be used), the use of absorbing or diffusing surfaces of tools as well as the avoidance of inflammable products and substances and, where applicable, the need to provide adequate room ventilation,

c) an adequate warning notice outside the procedure room.

5.5. The instructions for use shall highlight the need:

(a) to avoid under any circumstances exposure of eyes to emitted light;

(b) for users, consumers and any other person likely to be exposed to the radiation due to reflection, misuse or mishandling of the emitting device to wear appropriate eye protection during treatments with intense pulsed light or laser devices, especially when these devices are to be used close to the face.

5.6. The instructions for use shall clearly indicate for which consumers, on which parts of the skin, on which types of skin and for which conditions of skin the device shall not be used.

5.7. The instructions for use shall clearly indicate that the device is not to be used on skin parts which have an increased likelihood of skin cancer, open wounds or rashes, or swollen, red, irritated, infected, or inflamed areas or skin eruptions.

5.8. For devices intended to deliver a permanent change of the appearance the instructions for use shall indicate that they shall not be used on minors.

5.9. The manufacturer should ensure that all appropriate information is made available to the healthcare professional or service provider to enable them to ensure that professional users are evaluating customers. This includes, but is not limited to customers' suitability for treatment with devices falling under these common specifications and counselling them appropriately and adequately with respect to risks and potential outcomes of the procedure, taking into account the customer's health history and concomitant medications.

5.10. The annex referred to in Article 7(8) shall also highlight the recommendation to undergo a medical consultation including [a diagnostic] examination of the skin areas intended for the treatment.

ANNEX VI

1. Scope

This Annex applies to all non-invasive devices falling under No. 6 of Annex XVI to Regulation (EU) 2017/745. This includes, but is not limited to, devices for transcranial alternating current stimulation, transcranial direct current stimulation, transcranial magnetic stimulation and transcranial Random Noise Stimulation.

2. Risk management

When applying the risk management process established in Annex I of Regulation (EU) 2017/745 and specified in Article 5 and 6 of this Regulation, manufacturers shall in particular analyse and minimise the specific risks listed in section 2.1 of this Annex. In addition, manufactures shall implement the specific risk control measures listed in section 2.2 of this Annex.

2.1 Specific risks

2.1.1 When undertaking the risk management, special care shall be applied as to the placement of the electrodes and the strength, waveform, duration and other parameters of the electrical current and magnetic fields.

2.1.2 When undertaking the risk management, manufacturers shall in particular take into account the following aspects and the related risks:

(a) the incorrect placement of electrodes and coils can result in failed performance or unintended neural responses,

(b) brain stimulation may have very different neural responses and thus unintended effects on different groups of persons. Some groups may be particularly vulnerable: minors, young adults, pregnant women, psychiatric patients, persons with psychological disorders or medical conditions affecting the central nervous system, alcohol addicts, users of illicit substances and other substances that modify a person's natural perception,

(c) the presence of active implantable or body-worn medical devices and/or of metallic passive medical devices or other metallic objects present on or inside the body metallic implants may give rise to specific risks arising from the application of electrical energy and magnetic fields,

(d) excessive, frequent and cumulative long-term use may result in unforeseen neural effects which in some cases might result in structural changes in the brain.

2.1.3 Manufacturers shall in particular analyse and reduce as far as possible the following risks:

a) psychological risks;
b) neural and neuro-toxicity risks;
c) short-term, medium-term and long-term cognitive side-effects, therein in particular compensatory trade-offs, meaning e.g. the decline or sub-serving of brain regions which are not stimulated;
d) side-effect changes of the brain functioning that last for several months or longer,
e) risks linked to the long term effects of repeated stimulation;
f) risks linked to certain highly stimulating or attention demanding environments;
g) atypical or other idiosyncratic effects;
h) specific risks arising at the interface between electrodes and skin;
i) indirect risks, such as the risk of electromagnetic interference or injury caused by interaction with active implants (e.g. pacemakers, implanted cardioverter-defibrillators, cochlear implants and neural implants), active devices (e.g. neural stimulation devices and medication infusion devices), non-active metallic implants or body-worn medical devices;
j) risks associated with device usage after intake of alcohol and/or soft-drugs and/or central nervous system stimulating substances/pharmaceuticals; risks associated with possible potentiating effects of combined use (usage of few/several devices in the same time targeting same person or different person) and reasonable foreseeable misuse.

2.2 Specific risk control measures

2.2.1 When applying the provision referred to in Article 5(8), unless there is specific evidence for safe use, in particular the following categories of consumers shall be excluded:

a) persons with a history of epilepsy;
b) persons undergoing pharmaceutical treatment for conditions related to the central nervous system;
c) persons undergoing therapeutic treatment which change the excitability of the central nervous system;
d) users of illicit substances or other substances that modify a person's natural perception regardless of whether these are commonly understood as therapeutic drugs;
e) persons who have a tumor in the central nervous system;
f) persons who have vascular, traumatic, infectious or metabolic lesions of the brain;

g) persons who suffer from clinically established sleep deprivation, drug dependency or alcoholism;
h) persons who are less than 18 years old;
i) pregnant women.

2.2.2 Manufacturers shall apply the following safety concepts wherever relevant:

a) avoidance of unauthorized [unintended] access (e.g. by means of key switch or code or dual control of energy emission);
b) information for the user on the correct functioning of the device and the concrete [actual] operation mode by means of acoustic and / or optical means in standby mode, in operating mode and in case of loss of full skin contact during the procedure;
c) minimization of stray magnetic fields;
d) minimization of the risk of accidental emission;
e) emergency stop switch;
f) automatic deactivation where maximum acceptable output is reached;
g) automatic deactivation where maximum acceptable duration of exposure is reached;
h) automatic deactivation in case of overexposure due to a combination of output and duration;
i) instructional videos on how to safely use the device made available on the internet wherever possible;
j) provide appropriate training to users covering conditions for safe and effective use of the device.

2.2.3 Devices shall contain controls for the application time, the waveform and, the energy applied. They shall contain automatic alarms for cases where a critical value is reached for one parameter (e.g. energy level, duration of use) or for combination of parameters.

3. Performance

3.1 When demonstrating the performance of their device, manufacturers shall provide evidence that:

a) the claimed output of energy (electrical energy or magnetic field) is achieved by the device;
b) the application of the device achieves the intended performance claim.

3.2 The description of performance shall include an indication of the targeted areas of the brain. This description shall also include a list of effects which are aimed to be reached by application of the device, the localization of these effects and the subject group for whom the stimulation is intended.

3.3 Demonstration of performance for devices claiming to increase skills or other human capabilities shall include tests comparing the skills or capabilities before and after stimulation.

4. Clinical evaluation

The clinical evaluation shall in particular cover the aspects listed in sections 2.2.1 and 2.2.2 of this Annex as well as performance aspects. Both in the initial clinical evaluation and in the Post-Market Clinical Follow up (PMCF), manufacturers shall pay particular attention to the long-term effects of repeated stimulation.

5. Label and Instructions for use

5.1 The instructions for use and, if possible, the label, shall indicate the performances that the consumer can expect from the use of the device as well as the risks arising from its use. The intended performances shall be described in such a way that the consumer understands which non-medical benefits can be expected from the use of the device, [e.g. enhanced intelligence or improvement in mathematical ability].

5.2 The instructions for use shall indicate clearly how electrodes and magnetic coils are to be placed on the head. If the exact placement cannot be indicated, the instructions for use shall be specific enough to allow correct placement. The risks arising from a wrong placement of electrodes and coils shall be explained as well as potential negative effects on performance.

5.3 The instructions for use shall provide information on:

a) the duration, intensity and frequency of stimulation and all risks arising from use, including from excessive use;
b) the energy delivered, area of brain targeted, wave forms and pulse characteristics.

5.4 Unless there is specific evidence for safe use, as mentioned in section 2.2.3 the instructions for use shall clearly indicate that the device is not to be used on or by the categories of consumers listed in Section 2.2.1 of this Annex.

The instruction for use shall also clearly indicate that the device is not to be used in case of open wounds or rashes, or swollen, red, irritated, infected, or inflamed areas or skin eruptions where components of the device will come into contact with these areas.

5.5 The instructions for use shall list all possible direct and indirect risks to the consumer undergoing brain stimulation and to the user by interaction of the electric currents, magnetic or electromagnetic fields generated by the brain stimulation device with metallic passive implanted medical devices and other metallic objects present on or inside the body as well as with active implantable medical devices (e.g. pacemakers, implanted cardioverter-defibrillators, cochlear implants and neural implants) and active body-worn medical devices (e.g. neural stimulation devices and medication infusion devices) . This shall include information on conduction of electric current, reinforcement of internal electric fields, heating or displacement of metallic implants such as electrodes, stents, clips, pins, plates, screws, braces, or other metallic objects such as shrapnel or jewellery.

5.6 Information on warnings, precautions and known side-effects shall at least cover:

a) specific risks for persons listed in Section 2.2.1;
b) risks for persons with active implantable or active body-worn medical devices;
c) risks for persons with metallic passive medical devices or other metallic objects present on or inside the body;
d) information about how to deal with over-exposure to energy;
e) information on how to deal with psychological disturbances;
f) [information on how to deal with other side-effects prevalent at a rate of 1/100 or above.]

5.7 The instructions for use shall display the internet address where the manufacturer has published his instructional videos in accordance with Section 2.2.5 (i).

5.8 If the device is intended or expected to be applied on the consumer by a professional user, the instructions for use shall contain the annex referred to in Article 7(8).