COMMISSION IMPLEMENTING REGULATION (EU) 2022/2346

of 1 December 2022

laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

(Text with EEA relevance)

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 1(2), in conjunction with Article 9(1), thereof,

Whereas:

(1) Regulation (EU) 2017/745 lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. Regulation (EU) 2017/745 further requires the Commission to adopt for groups of products without an intended medical purpose listed in its Annex XVI, common specifications addressing, at least, application of risk management as set out in the general safety and performance requirements laid down in Annex I to that Regulation and, where necessary, clinical evaluation regarding safety.

(2) From the date of application of the common specifications, Regulation (EU) 2017/745 is to apply also to those groups of products without an intended medical purpose.

(3) In order for manufacturers to be able to demonstrate the conformity of products without an intended medical purpose with regard to application of risk management, the common specifications should cover the application of risk management as set out in the second sentence of Section 1 and in sections from 2 to 5, 8 and 9 of Annex I to Regulation (EU) 2017/745. Consequently, in accordance with Article 9(2) of Regulation (EU) 2017/745, products without an intended medical purpose that are in conformity with the common specifications are to be presumed to be in conformity with the requirements set out in those provisions.

(4) The common specifications should in principle be laid down for all groups of products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745. However, as Regulation (EU) 2017/745 regulates the placing on the market, making available on the market or putting into service in the Union, common specifications are not needed for products for which there is no information available about them being marketed in the Union. For example, there is no information on the following products being marketed in the Union: contact lenses containing tools, such as antenna or microchip, contact lenses which are active devices; active implantable products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixing a part of the body; active devices intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction; active implantable equipment intended to be used to reduce, remove or destroy adipose tissue. In addition, for some products the information available is not sufficient to allow the Commission to draw up common specifications. That is for example the case for some other items intended to be introduced into or onto the eye.

(5) Sunbeds and equipment using infrared optical radiation to warm the body or parts of the body intended for treatment of tissues or parts of the body under the skin should not be considered products for skin treatment for the purposes of Annex XVI to Regulation (EU) 2017/745. Consequently, they should not be covered by this Regulation.

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

(6) The group of products listed in point 6 of Annex XVI to Regulation (EU) 2017/745 is intended for brain stimulation where only electrical currents or magnetic or electromagnetic fields penetrate the cranium. Invasive devices intended for brain stimulation, such as electrodes or sensors that are partially or totally introduced into the human body, should not be covered by this Regulation.

(7) Regulation (EU) 2017/745 requires a product without a medical purpose listed in Annex XVI to that Regulation, when used under the conditions and for the purposes intended, to present no risks at all or present a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

(8) The groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 cover a wide variety of devices for different applications and intended uses. A common methodology for risk management should be drawn up to ensure a harmonised approach by manufacturers of different groups of devices and to facilitate a coherent implementation of the common specifications.

(9) In order to ensure appropriate risk management, it is necessary to identify specific risk factors to be analysed and minimised and to identify specific risk control measures to be implemented with respect to each group of products listed in Annex XVI to Regulation (EU) 2017/745.

(10) In order to facilitate the implementation of risk management by manufacturers of both medical devices and products without an intended medical purpose risk management for both groups of products should be based on the same harmonised principles and the requirements should be compatible. The rules on the application of risk management should therefore be in line with well-established international guidance in the field, including the international standard ISO 14971:2019 on application of risk management to medical devices.

(11) Regulation (EU) 2017/745 provides that the clinical evaluation of products without an intended medical purpose are to be based on relevant clinical data concerning performance and safety. Such data are to include information from post-market surveillance, post-market clinical follow-up, and, where applicable, specific clinical investigation. As in general it is not possible to demonstrate equivalence between a medical device and a product without an intended medical purpose, where all available results on clinical investigations relate to medical devices only, clinical investigations should be performed for products without an intended medical purpose.

(12) Where clinical investigations are performed to confirm the conformity with the relevant general safety and performance requirements, it is not possible to complete the clinical investigations and the conformity assessment within six months. For such cases transitional arrangements should be laid down.

(13) Where a notified body has to be involved in the conformity assessment procedure, it is not possible for the manufacturer to complete the conformity assessment within 6 months. For such cases transitional arrangements should be laid down.

(14) Transitional provisions should be laid down also for products covered by Annex XVI to Regulation (EU) 2017/745 for which notified bodies have issued certificates in accordance with Council Directive 93/42/EEC ([2]). Also for those products, it is not possible for the manufacturer to complete clinical investigations and the conformity assessment within 6 months.

(15) In order to ensure the product safety during the transitional period, it should be allowed to continue to place the products on the market and to make them available on the market or put them into service, provided that the products in question were already lawfully marketed in the Union before the date of application of this Regulation, that they continue to comply with the requirements of Union and national law applicable before the date of application of this Regulation and that their design and intended purpose are not significantly changed. As the purpose of putting in place the transitional arrangements is to allow the manufacturers enough time to conduct the required clinical investigations and conformity assessment procedures, the transitional arrangements should cease where manufacturers do not proceed with the clinical investigations or conformity assessment procedure, as applicable, within a reasonable timeframe.

([2]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(16) The Medical Device Coordination Group has been consulted.

(17) The application date of this Regulation should be deferred as provided for in Regulation (EU) 2017/745.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

Common specifications

1. This Regulation lays down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745.

Annex I lays down common specifications for all those groups of products without an intended medical purpose.

Annex II lays down common specifications for contact lenses as specified in Section 1 of that Annex.

Annex III lays down common specifications for products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy, with the exception of tattooing products and piercings, as specified in Section 1 of that Annex.

Annex IV lays down common specifications for substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing, as specified in Section 1 of that Annex.

Annex V lays down common specifications for equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty as specified in Section 1 of that Annex.

Annex VI lays down common specifications for high intensity electromagnetic radiation (for example, infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment as specified in Section 1 of that Annex.

Annex VII lays down common specifications for equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as specified in Section 1 of that Annex.

2. The common specifications laid down in this Regulation cover the requirements set out in the second sentence of Section 1 and in Sections 2 to 5, 8 and 9 of Annex I to Regulation (EU) 2017/745.

Article 2

Transitional provisions

1. A product for which the manufacturer intends to perform, or is performing, a clinical investigation to generate clinical data for the clinical evaluation in order to confirm the conformity with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 and the common specifications set out in this Regulation, and in the conformity assessment of which a notified body has to be involved in accordance with Article 52 of that Regulation, may be placed on the market or put into service until 22 June 2028, provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Union and national law that were applicable to it before 22 June 2023;

(b) there are no significant changes in the design and intended purpose of the product.

By way of derogation from the first subparagraph of this paragraph, from 22 June 2024 until 22 December 2024, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if the sponsor has received from the Member State concerned a notification, in accordance with Article 70(1) or (3) of Regulation (EU) 2017/745, confirming that the application for the clinical investigation of the product is complete and that the clinical investigation falls within the scope of the Regulation (EU) 2017/745.

By way of derogation from the first subparagraph, from 23 December 2024 until 22 June 2026, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if the sponsor has started the clinical investigation.

By way of derogation from the first subparagraph, from 23 June 2026 until 22 June 2028, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer.

2. A product for which the manufacturer does not intend to perform a clinical investigation, but in the conformity assessment of which a notified body has to be involved in accordance with Article 52 of that Regulation, may be placed on the market or put into service until 22 June 2025, provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Union and national law that were applicable to it before 22 June 2023;

(b) there are no significant changes in the design and intended purpose of the product.

By way of derogation from the first subparagraph, from 22 September 2023 until 22 June 2025, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer.

3. A product to which this Regulation applies and which is covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC may be placed on the market or put into service until the dates laid down in paragraph 1, first subparagraph, and paragraph 2, first subparagraph, as applicable, also after the expiry date of such certificate, provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Directive 93/42/EEC, except for the requirement to be covered by a valid certificate issued by a notified body where the certificate expires after 26 May 2021;

(b) there are no significant changes in the design and intended purpose of the product;

(c) after the expiry date of the certificate issued by a notified body in accordance with Directive 93/42/EEC, the appropriate surveillance of the compliance with the conditions referred to in points (a) and (b) of this paragraph is ensured by way of a written agreement signed by the notified body that has issued the certificate in accordance with Directive 93/42/EEC or a notified body designated in accordance with Regulation (EU) 2017/745 and the manufacturer.

Article 3

Entry into force and date of application

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

2. It shall apply from 22 June 2023. However, Article 2(3) shall apply from 22 December 2022.

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

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Scope

1. This Annex applies to all the devices covered by Annexes II to VII.

Risk Management

2. General requirements

2.1. Manufacturers shall establish and document responsibilities, operative modalities and criteria for the execution of the following steps of the risk management process:

(a) risk management planning;

(b) identification of hazards and risk analysis;

(c) risk evaluation;

(d) risk control and evaluation of residual risks;

(e) risk management review;

(f) production and post-production activities.

2.2. Top-level management of the manufacturers shall ensure that adequate resources are allocated and that competent personnel is assigned for risk management. Top-level management shall define and document a policy for establishing criteria for risk acceptability. Such policy shall take into account the generally acknowledged state of the art, known concerns related to safety expressed by interested parties and shall include the principle that risks are to be eliminated or reduced as far as possible by means of control measures without adversely affecting the overall residual risk. Top-level management shall ensure that the risk management process is executed and shall review its effectiveness and suitability at planned intervals.

2.3. The personnel responsible for performing risk management tasks shall be appropriately qualified. They shall have, where that is needed for the performance of tasks, proven and documented knowledge of and experience in using the particular device, equivalent devices without an intended medical purpose or analogous devices with a medical purpose, as well as knowledge of the technologies involved and risk management techniques. Evidence of qualification and competences of personnel, such as education, training, skills and experience, shall be documented.

An analogous device with a medical purpose shall be understood as the same device with a medical purpose or a medical device for which equivalence to the same device with a medical purpose has been demonstrated by the manufacturer in accordance with Section 3 of Annex XIV to Regulation (EU) 2017/745 of the European Parliament and of the Council ([1]).

2.4. The results of the risk management activities, including the reference to the device, the reference to the persons who carried out the activities and the dates of execution of such activities, shall be recorded. For every identified hazard, the records shall provide traceability to the results of risk analysis, risk evaluation, risk control and evaluation of residual risks.

2.5. Based on the results of the risk management process, manufacturers shall define the categories of users and consumers that are to be excluded from the use of the device or for which special conditions of use have to be applied. A consumer shall be understood as a natural person on whom a product without an intended medical purpose is intended to be used.

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

2.6. Throughout the entire lifecycle of a device, the manufacturer shall establish a system to ensure a continuous systematic update of the risk management process in relation to that device.

3. Risk management planning

3.1. Risk management planning documents shall include:

(a) references and description of the device, including its parts and components;

(b) a list of the activities to be performed in each step of the risk management process, their scope and the actions for the verification of completion and effectiveness of the risk control measures;

(c) a specification of the life cycle phases of the device covered by each activity included in the plan;

(d) a specification of responsibilities and authorities for the execution of the activities, for the approvals of the results and for the risk management review;

(e) a specification of criteria for risk acceptability based on the policy referred to in Section 2.2;

(f) a specification of criteria for the collection of relevant information from the production and from the post production phases and for the use of such information to review and update, if necessary, the risk management results.

3.2. The criteria for risk acceptability shall include the description of the criterion for the acceptability of the overall residual risk. The method for the evaluation of the overall residual risk shall be defined and documented.

3.3. In defining the criteria for risk acceptability in accordance with the principles established by the policy referred to in Section 2.2, manufacturers shall consider that all risks, including those related to surgical intervention, are to be eliminated or reduced as far as possible. 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, residual risks may be considered as being acceptable. If one or more of the conditions laid down in this Section is not met, the manufacturer shall provide a justification explaining the reasons for the acceptability of the risks.

4. Identification of hazards and risk analysis

4.1. Documents for the identification of hazards and risk analysis shall:

(a) include a description of the device, its intended use and the reasonably foreseeable misuse;

(b) list the qualitative and quantitative characteristics that could affect the safety of the device;

(c) list the known and the foreseeable hazards associated with the device, its intended use, its characteristics and its reasonably foreseeable misuse, when used in both normal and fault conditions;

(d) list the hazardous situations resulting from the consideration of the foreseeable events for each identified hazard;

(e) include the qualitative or quantitative terms and descriptions, or the categorization, for the estimation of the severity and the probability of occurrence of harms.

(f) for each hazardous situation, list the estimated severity and probability of occurrence of harms and the resulting estimation of risks.

4.2. The description of the intended use of the device shall include information on the part of the human body or type of tissue interacted with, the categories of users and consumers, the use environment and the treatment procedure.

4.3. In the risk analysis manufacturers shall take into account the specificities of various user and consumer groups. This includes considering whether the user is a healthcare professional or a lay person. In the case of a lay person distinction shall be made between a person without qualification for the use of the device and a person who uses a device in the context of his or her professional activities, and who, although not being a healthcare professional, has a proven qualification for the use of the device. It shall be presumed by the manufacturer that all those user and consumer groups have access to the device unless the device is only sold directly to healthcare professionals.

4.4. Manufacturers shall consider clinical data as one of the sources of information for the risk analysis and for the estimation of the severity and the probability of occurrence of harms.

4.5. Where due to the nature of the devices or for ethical reasons data on the probability of occurrence of harm cannot be generated, manufacturers shall estimate the risk on the basis of the nature of the harm and a worst case estimate of the probability of the harm occurring. In the technical documentation manufacturers shall provide evidence justifying the reason for not providing data on the probability of occurrence of harm.

4.6. The description of the scope for the risk analysis shall be recorded.

5. Risk evaluation

5.1. For any hazardous situation, manufacturers shall evaluate the estimated risks and determine whether the risks are acceptable in accordance with the criteria referred to in Section 3.1, point (e).

5.2. Where the risk is not acceptable, risk control shall be performed.

5.3. Where the risk is acceptable, risk control is not needed and the final estimated risk shall be considered as a residual risk.

6. Risk control and evaluation of residual risks

6.1. Documents for risk control and evaluation of residual risks shall include:

(a) a list of the implemented risk control measures and the evaluation of their effectiveness;

(b) a list of the residual risks after completed implementation of the risk control measures;

(c) the evaluation of acceptability for residual risks and for the overall residual risk, in accordance with the criteria referred to in Section 3.1, point (e);

(d) the verification of the effects of the risk control measures.

6.2. Risk control measures to be implemented by the manufacturer shall be selected from the following categories of risk control options:

(a) inherent safety ensured by design;

(b) inherent safety ensured by manufacturing;

(c) protective measures in the device or in the manufacturing process;

(d) information for safety and, where appropriate, user training.

Manufacturers shall select risk control measures in the priority order from points (a) to (d). Measures from a risk control option shall not be implemented unless the measures from the previous option cannot be implemented or, where implemented, have not resulted in the risk acceptability.

6.3. Manufacturers shall ensure that the information for safety is not limited to the instruction for use or to the label, but also available by other means. Information integrated in the device itself that the user cannot disregard and public information easily accessible to the user shall be considered. Where appropriate, user training shall be considered. The information shall be presented taking into account the degree of understanding of users and consumers as referred to in Section 9.

6.4. Risk control measures shall be taken even if the performance of the device is thereby reduced as long as the main function of the device is maintained.

6.5. When deciding on risk control measures, manufacturers shall verify whether the risk control measures generate new harm, hazards or hazardous situations and whether the estimated risks for previously identified hazardous situations are affected by those measures. The reduction of a risk shall not increase one or several other risks so that the overall residual risk could be increased.

7. Risk management review

7.1. Documents for risk management review shall include a review before the release for commercialisation of the device. The review shall ensure that:

(a) the risk management process has been carried out in accordance with the risk management planning documents referred to in Section 3.1;

(b) the overall residual risk is acceptable and the risks have been eliminated or reduced as far as possible;

(c) the system to collect and review information on the device from the production and the post-production phases is implemented.

8. Production and post-production activities

8.1. Documents for production and post production activities shall:

(a) specify the system to collect and review information on the device from the production and the post-production phases;

(b) list the sources of publicly available information on the device, on equivalent devices without an intended medical purpose or on analogous devices with a medical purpose;

(c) specify the criteria to evaluate the impact of the information collected on the results of previous risk management activities and the consequent actions on the device.

As part of the system to collect and review information on the device from the post-production phases, manufacturers shall consider clinical data from the post market surveillance, and, where applicable, clinical data from the summary of safety and clinical performance referred to in Article 32 of Regulation (EU) 2017/745 or the post-market clinical follow-up referred to in Part B of Annex XIV to that Regulation.

8.2. For the specification of the criteria to evaluate the impact of the information collected, the manufacturer shall consider:

(a) hazards or hazardous situations that have not been identified previously;

(b) hazardous situations for which the risk is no longer acceptable;

(c) whether the overall residual risk is no longer acceptable.

Any impact of the information collected affecting the effectiveness and suitability of the risk management process shall be considered as an input for the top-level management review referred to in Section 2.2.

8.3. For the specification of the consequent actions on the results of previous risk management activities, manufacturers shall consider an update of the former results of the risk management activities to:

(a) include new hazards or hazardous situations and evaluate the related risks;

(b) re-evaluate hazardous situations, residual risks and the overall residual risk no longer acceptable;

(c) establish the need for actions in relation to the devices already made available on the market.

8.4. Manufacturers shall take account of any changes in risks identification, analysis and evaluation which could arise from new data or changes in device use environment.

Information for safety

9. When providing information for safety referred to in Section 6.2, point (d), and on the risks linked to the use of the device referred to in Sections 11.2, point (c) and 12.1, point (c), manufacturers shall take into account:

(a) the different degree of understanding of users and consumers, with particular emphasis on devices intended to be used by lay persons;

(b) the work environment where the device is intended to be used, especially in case of use outside a medical or otherwise professionally controlled work environment.

10. If the device is intended by the manufacturer only for a non-medical purpose, information supplied with the device shall not bear any clinical benefit claim or statement. If the device is intended by the manufacturer for a medical and non-medical purpose, information provided for the non-medical purpose shall not bear any clinical benefit claim or statement.

11. Label

11.1. The label shall bear the words “non-medical purpose:” followed by a description of that non-medical purpose.

11.2. If feasible, manufacturers shall specify on the label:

(a) the information regarding the categories of users and consumers referred to in Section 2.5;

(b) the expected performance of the device;

(c) the risks arising from the use of the device.

12. Instructions for use

12.1. The instructions for use shall include:

(a) the information regarding the categories of users and consumers referred to in Section 2.5;

(b) a description of the expected performance of the device, in such a way so that the user and the consumer understands which non-medical effect can be expected from the use of the device;

(c) a description of the residual risks of the device, including their control measures, presented in a clear and easily understandable way so that the consumer can make an informed decision on whether to be treated with it, have it implanted or otherwise use it;

(d) the expected lifetime or the expected resorption period of the device and any necessary follow-up;

(e) reference to any harmonised standard and common specifications applied.

ANNEX II

Scope

1. This Annex applies to contact lenses listed in Section 1 of Annex XVI to Regulation (EU) 2017/745. Contact lenses containing tools, such as antenna or microchip, contact lenses which are active devices and other items intended to be introduced into or onto the eye are not covered by this Annex.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. Manufacturers shall analyse and eliminate or 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 or dislocation from the cornea, wrinkling or folding, unequal pressure on the cornea related to positioning;

(b) the selection of raw materials for lens, for surface treatments and, if relevant, for lens storage solutions in view of biological safety, biocompatibility, chemical and biological contaminants as well as permeability of oxygen and compatibility with lens storage solutions;

(c) biological safety and biocompatibility of the final product, with its packaging and storage solution, including consideration of at least the aspects of cytotoxicity, sensitization, irritation, acute systemic toxicity, subacute toxicity, implantation, sterilization residues and degradation products, extractable and leachable substances. Where the cumulative contact duration is expected to exceed 30 days, aspects of subchronic toxicity, chronic toxicity and genotoxicity shall also be considered;

(d) microbiological properties, including bioburden, microbiological contamination of the final device, residual bacterial endotoxins, sterility, contact lens disinfection and preservation;

(e) appropriateness of the primary packaging in terms of keeping the lens sterile, permanently covered by storage fluid and avoiding degradation of the product, for example 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

(a) lack of pre-use testing of suitability of lens wearing performed by ophthalmologist, optometrist, specialised optician or qualified contact lens specialist;

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

(c) lack of expertise of distributors outside the classic optician distribution chain with regard to safety or handling advice to the users;

User-related hazards/risks

(a) lack of experience with and training on the use of contact lenses of certain uses;

(b) identification of contra-indications under which contact lenses shall not be used;

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

(d) lack of hygiene, such as failure to wash and dry hands prior to users placing, using and removing lenses resulting in possible infection, severe inflammation or other diseases of the eye;

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

(f) any possible factors that could cause deterioration of eye sight such as coloration, lack of precise fitting to the eye's surface and lack of correction;

(g) identification of any non-medical conditions under which contact lenses are not be used. Conditions to be considered shall include driving, piloting or operating heavy machinery and water-based activities such as showering, bathing and swimming;

(h) increased risk of eye damage if the lenses are worn extensively (for example for long periods, consecutive multiple use);

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

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

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

(l) for multiple use contact lenses, risks linked to re-use and irregular re-use by the same consumer;

(m) lack of familiarity of consumers with emergency measures in case of any undesirable side-effects.

4. Specific risk control measures

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

(b) All materials of the lens and the inner side of its primary packaging, including its storage solution, shall be biocompatible, non-irritating and non-toxic. In addition, the substances used for colouring of or printing on the contact lenses shall not leach under the intended conditions of use.

(c) Lenses and the inner side of their primary packaging, including its storage solution shall be sterile and non-pyrogenic. If in contact with the eye, the storage liquid shall not injure the cornea, eye and the surrounding tissue.

(d) Lenses shall be designed so as not to compromise the health of the cornea, eye and surrounding tissue. Lens features such as low oxygen permeability, imprecise placing, dislocation, sharp edges, abrasion, unequal mechanical pressure distribution shall be considered.

(e) As regards lenses for multiple use, the manufacturer shall either provide effective maintenance liquids and means for cleaning and disinfecting together with the lens sufficient for the entire lifetime of the lens, or indicate the required maintenance liquids and means for cleaning and disinfecting. The manufacturer shall also either provide or indicate any other equipment or tools for the maintenance and cleaning of the lenses for multiple use.

(f) As regards lenses for multiple use, the manufacturer shall validate the maximum number of re-uses and maximum duration of use (for example in hours per day and/or number of days).

(g) Manufacturers shall consider whether eye drops need to be used to compensate for dryness. Where such eye-drops are needed, manufacturers shall define criteria to demonstrate their suitability;

(h) Manufacturers shall establish a procedure for the identification of any undesirable side-effects by the user and how to deal with them, including reporting to the manufacturer of such undesirable side-effects;

(i) The instructions for use and the label shall be designed and written in a manner so that they can be understandable by a lay person and that enables a lay person to use the device safely.

Information for safety

5. Label

5.1. The outer packaging intended to be provided to users shall contain the following indications:

(a) where devices are intended for single use, in addition to the internationally recognized symbol, in bold font of largest used size on the label the text "Do not re-use";

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

(c) the recommendation to read the instructions for use.

6. Instructions for use

6.1. The instructions for use shall contain:

(a) in bold font of largest used size in the instructions the text: "Do not re-use", in addition to the internationally recognized symbol, where devices are intended for single use;

(b) a warning "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 materials of the lens, including its surface and colouring pigments;

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

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

(g) instructions on what to do in case of displacement;

(h) hygiene measures prior to use (for example washing and drying hands), during use and after use;

(i) a warning "Do not contaminate lenses with make-up or aerosols.";

(j) a warning "Do not clean lenses with tap water.";

(k) for multiple use lenses, a detailed description of the cleaning and disinfection procedure, including the description of the necessary equipment, tools and solutions, which shall be named in detail; a description of required storage conditions;

(l) for multiple use lenses, the maximum number of re-uses and maximum duration of use(s) (for example in hours per day and/or number of days);

(m) where the use of eye drops is recommended, a description of suitable eye drops and the description on how to use them;

(n) listing of contraindications under which contact lenses are not to be used. Such a list shall 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;

(o) a warning: "Do not use whilst participating in traffic-related situations (for example driving, riding a bike), operating machinery or whilst undertaking water-related activities such as showering, bathing and swimming.";

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

(q) a statement regarding increased risk of eye damage in case of continuous wear when eye redness and irritation occur;

(r) a warning “Do not use after date of expiry.”;

(s) a clear indication of the maximum wearing time;

(t) a warning “Do not use lenses beyond maximum wearing time.”;

(u) a warning “Do not use lenses during sleeping periods”;

(v) a statement on the increased risk of eye damage if the lenses are worn extensively (for example multiple re-uses);

(w) a warning “Do not use in excessively dry or dusty environments.”;

(x) a warning “Do not re-use the primary packaging as containment for storage between uses.”, where primary packaging is not intended by the manufacturer for such use;

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

(z) a list of risks linked to ocular health associated with lens wear, as identified by risk analysis, including, if applicable, reduced availability to the cornea of water and oxygen (oxygen transmissibility);

(aa) a list of possible undesirable side-effects, their probability of occurrence and their indicators;

(bb) instructions on how to deal with complications, including emergency measures;

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

— irritation or eye pain such as stinging, burning, itching, foreign body sensation;

— 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 a qualified healthcare professional, such as an ophthalmologist, or an optometrist, authorised by national law to treat such symptoms. The continuation of these symptoms might indicate a more serious condition.”;

(dd) information on when and how to report undesirable side-effects to the manufacturer.

ANNEX III

Scope

1. This Annex applies to products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy, listed in Section 2 of Annex XVI to Regulation (EU) 2017/745. Tattooing products, piercings and products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of fixation of body parts are not covered by this Annex. This Annex does not apply to active implantable devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

   The risk analysis shall include a section on risks that are related to the specific non-medical intended purpose of introducing the device into the human body through surgically invasive means, taking into account specific characteristics of potential users and consumers of the device.

3. Specific risks

3.1. Manufacturers shall take into account the following aspects and related risks:

   (a) physical and chemical characteristics and full composition of the implant;

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

   (c) for resorbable devices, resorption and life-time in the body, indicating the half-life and the end of the resorption;

   (d) biological safety and biocompatibility of the final product, including consideration of at least the aspects of cytotoxicity, sensitisation, irritation, material mediated pyrogenicity, acute systemic toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, implantation, sterilisation residues and degradation products, extractable and leachable substances;

   (e) microbiological properties, including bioburden, microbiological contamination of the final device, residual bacterial endotoxins and sterility;

   (f) the specific anatomical location for which clinical and other data support the use of the device;

   (g) consumer specific factors (for example previous accidents, special conditions, age restrictions);

   (h) potential interactions with magnetic field, (for example heating related to magnetic resonance imaging);

   (i) use of accessories (for example delivery instruments designed to be specifically used with the device for the implantation procedure) and their compatibility with the implant;

   (j) time interval between implantations, where applicable.

3.2. Where appropriate, manufacturers shall in particular analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

   (a) microbiological contamination;

   (b) presence of manufacturing debris;

   (c) implantation procedure related aspects (including use errors);

(d) implant failure (for example rupture, unintended degradation);

(e) implant dislodgement and migration;

(f) asymmetry;

(g) implant visibility through the skin;

(h) implant deflation and wrinkling;

(i) gel bleeding and leakage;

(j) sweating and silicone migration;

(k) local inflammation and swelling;

(l) regional swelling or lymphadenopathy;

(m) capsule formation and contracture;

(n) discomfort or pain;

(o) hematoma;

(p) infection and inflammation;

(q) superficial wound;

(r) wound dehiscence;

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

(t) scarring and scar hyperpigmentation and hypertrophy;

(u) nerve injury;

(v) seroma;

(w) compartment pressure problems and compartment syndrome;

(x) limitation in cancer diagnosis;

(y) over-sized implants;

(z) vascular damage;

(aa) breast implant associated anaplastic large cell lymphoma (BIA-ALCL);

(bb) granuloma, including siliconoma where applicable;

(cc) necrosis.

4. Specific risk control measures

(a) Devices shall be sterile and non-pyrogenic. Where implants are supplied non-sterile with the intention to be sterilised before use, adequate instruction for sterilisation shall be provided.

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

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

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

(e) Manufacturers shall provide training on the implantation and safe use of the device. That training shall be accessible to users.

Information for safety

5. Label

5.1. The label shall contain:

(a) in bold font of largest used size on the label 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 are not to be used in persons who are less than 18 years old;

(c) the overall qualitative composition of the product.

6. Instructions for use

6.1. The instructions for use shall contain:

(a) on top in bold fonts of largest used size in the instructions of use 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 are not to be used in persons who are less than 18 years old;

(c) the recommendation for the user to consider any previous procedures, accidents, conditions, medications or other simultaneous treatments of the consumer that may affect the procedure (for example skin diseases, traumas and auto-immune diseases);

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

(e) a comprehensive list of contra-indications. This list shall include keloid scars;

(f) the overall qualitative and quantitative composition of the product;

(g) the recommendation for the user on a post-implantation monitoring time in order to identify any potential undesirable side-effects;

(h) an indication of the appropriate time interval between treatments, where applicable;

(i) a requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.2 before the consumer is treated with the device.

6.2. The instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a) to (e), of Annex I;

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

(c) information on when and how to report undesirable side-effects to the manufacturer, information on device removal, information on when to contact a healthcare professional;

(d) details on volume and size of the device;

(e) the statement "The users received appropriate training on how to safely use the device.", where relevant.

ANNEX IV

Scope

1. This Annex applies to substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing, listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. This Annex only applies to the means for introduction into the body, for example syringes and dermarollers, where they are prefilled with the substances, combinations of substances or other items listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. This Annex does not apply to active devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. Manufacturers shall take into account the following aspects and related risks:

(a) physical and chemical characteristics of the device;

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

(c) biological safety and biocompatibility of the final product, including consideration of at least the aspects of cytotoxicity, sensitisation, irritation, material mediated pyrogenicity, acute systemic toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, implantation, sterilisation residues and degradation products, extractable and leachable substances;

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

(e) microbiological properties, bioburden, microbiological contamination of the final device, residual bacterial endotoxins and sterility;

(f) the specific anatomical location of injection or introduction;

(g) consumer specific factors (for example previous and current treatments (medical and surgical), age restrictions, pregnancy, breast-feeding);

(h) if applicable, risks related to the use of local anaesthetic, either as part of the product or stand-alone;

(i) for non-resorbable devices, the risk associated with the removal of the device;

(j) aspects associated with the use of the device, including:

— injection technique;

— means of injection (for example rollers, catheters or needles);

— maximum quantity injected depending on location and applied technique;

— possible repeated injections;

— force required to administer the product;

— product temperature;

— transfer of the product (for example from a vial to a syringe).

3.2. Where appropriate, manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) microbiological contamination;

(b) presence of manufacturing debris;

(c) hazards associated with the procedure to inject or otherwise introduce the device (including use errors);

(d) migration of the device;

(e) device visibility through the skin;

(f) unintended local inflammation and swelling;

(g) regional swelling or lymphadenopathy;

(h) capsule formation and contracture;

(i) discomfort or pain;

(j) hematoma;

(k) infection and inflammation;

(l) superficial wound;

(m) interruption of wound healing;

(n) scarring and scar hyperpigmentation and hypertrophy;

(o) nerve injury;

(p) seroma;

(q) compartment pressure problems and compartment syndrome;

(r) granuloma, including siliconoma where applicable;

(s) edema;

(t) vascular damage;

(u) severe allergic reactions;

(v) blindness;

(w) necrosis.

4. Specific risk control measures

(a) Devices shall be sterile non-pyrogenic and intended for single use.

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

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

(d) Manufacturers shall provide training on the administration and safe use of the device. That training shall be accessible to users.

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

Information for safety

5. Label

5.1. The label shall contain:

(a) in bold fonts of largest used size on the label 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 are not to be used in persons who are less than 18 years old.

6. Instructions for use

6.1. The instructions for use shall contain:

(a) on top in bold font of largest used size in the instructions for use 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 are not to be used in persons who are less than 18 years old;

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

(d) description of treatment of the most common side-effects, such as overdosing, swelling, hardening, nodules and immune responses, with the instruction to consult a medical professional if needed;

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

(f) a list of constituents, which specifies:

— all constituents responsible for the intended action with specification of their concentration and, where applicable, their molecular weight range, their particle size and their degree of cross-linking, together with the method used for its determination;

— other constituents such as cross-linking agents, solvents, anaesthetics and preservatives, with specification of their concentration;

(g) the recommendation for the user to consider any previous procedures, accidents, conditions, medications or other simultaneous treatments of the consumer that may affect the procedure (for example skin diseases, traumas and auto-immune diseases);

(h) the recommendation for the user of a post-administration monitoring time in order to identify any potential undesirable side-effects;

(i) a requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.2 before the consumer is treated with the device.

6.2. The instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a) to (e), of Annex I;

(b) all residual risks and potential undesirable side-effects listed in a clear way and described in a language commonly understood by lay persons. 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 to the manufacturer;

(d) information on when to contact healthcare professional;

(e) any contra-indications to the procedure;

(f) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant.

In addition, a specific part of the annex shall be designed to record information on the location, the number and the volume of the injections, for each consumer. The manufacturer shall recommend the healthcare professional to fill in this specific part.

ANNEX V

Scope

1. This Annex applies to equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty, listed in Section 4 of Annex XVI to Regulation (EU) 2017/745. This Annex does not apply to active implantable devices.

Definitions

2. For the purpose of this Annex, 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 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) "lipoplasty devices" means devices intended by the manufacturer to be used for the purpose of lipoplasty.

Risk management

3. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 4 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 5 of this Annex.

4. Specific risks

4.1. Where relevant as regards the device in question, manufacturers shall 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, including the metabolisation of released tissue components, taking into account the probable different characteristics of the person undergoing treatment;

   (b) the minimum time lapse between subsequent procedures;

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

   (d) the cannula type, for example the diameter and nature of the tip of the cannula;

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

   (f) the use and subsequent metabolisation 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, for example dry or wet, and the type of anaesthetic;

   (h) whether the device is a simple liposuction device, 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 age distribution, gender and body-mass-index of the population to which the clinical data or other sources of data relate;

   (j) the way in which energy is emitted.

4.2. Where relevant as regards the device in question, manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) post-operative seroma;

(b) tissue injury, organ perforation and bleeding;

(c) post-operative ecchymosis and edema;

(d) interference with active implantable or active body-worn medical devices and with metallic passive medical devices or other metallic objects present on or inside the body;

(e) thermal injury;

(f) mechanical injuries, including those caused by unintended cavitation, and corresponding side-effects;

(g) inflammation.

4.3. For liposuction devices, in addition to the risks listed in Section 4.2, manufacturers shall analyse, eliminate or 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 anaesthetic use: consideration should be given to lidocaine-induced cardiotoxicity or lidocaine-related drug interactions for tumescent liposuction.

4.4. For lipolysis devices, in addition to those risks listed in Section 4.2, manufacturers shall in particular analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) 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 dermis, with reference to reticular dermis;

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

(h) for lipolysis devices that are surgically invasive, the hazards linked to the types and sizes of incision.

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

5. Specific risk control measures

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

5.2. Invasive parts of the devices shall be sterile and pyrogen-free before use.

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

5.4. Where applicable, manufacturers shall make sure the devices have the following functions: low energy preset, emergency stop function (for example emergency stop switch), automatic deactivation in case of over-exposure or excessive liposuction, respectively.

5.5. Liposuction devices, lipolysis devices and lipoplasty devices shall not be used in private environments by lay persons.

5.6. Manufacturers shall provide training to users on safe and effective use of the device.

Information for safety

6. Instruction for use

6.1. The instructions for use shall contain a comprehensive list of contra-indications for the consumer. It shall include the following contra-indications:

(a) coagulant disorders, being treated with anticoagulant medications;

(b) uncontrolled hypertension;

(c) diabetes mellitus;

(d) phlebitis and vasculitis;

(e) cancer or tumours;

(f) extreme obesity (body mass index above 40);

(g) pregnancy;

(h) vascular fragility;

(i) recent surgery (6 weeks);

(j) skin infections and open lesions;

(k) varicose veins in the area of treatment;

(l) medical conditions, such as heart, lung, or circulatory system disease;

(m) age less than 18;

(n) incapability to understand the consequences, implications and risks of the medical procedures (for example liposuction, lipolysis, lipoplasty) where the devices are used;

(o) elevated body temperature (pyrexia).

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.

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

6.3. The instructions for use shall contain a comprehensive list of adverse effects for the consumer. This list shall 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.

6.4. The instructions for use shall contain a comprehensive list of warnings. This list shall include the following warning:

"Liposuction, lipolysis and lipoplasty are not reliable methods for weight reduction. Consideration should be given to exercise and dietary as well as lifestyle modification, both as alternatives to liposuction and lipolysis and in order to maintain any reduction in adipose tissue which these procedures may achieve. Devices have not been validated for the treatment of clinically diagnosed obesity and therefore should not be used for such purposes.".

6.4.1. In addition to the warning referred to in Section 6.4, for liposuction devices, the instructions for use shall contain the following warning:

"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.".

6.4.2. In addition to the warnings referred to in Sections 6.4 and 6.4.1, for liposuction devices that may use a tumescent fluid, the instructions for use shall contain the following warnings:

(a) "Careful consideration shall be given to consumer 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 consumers undergoing tumescent liposuction. Consumers 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 by a medical consultation which has to be documented and during which chronic disease and drugs taken by patient need to be considered.";

(b) "Consumers shall be warned that they may experience extended post-operative analgesia (for example for 24 hours or more) which may result in reduced sensation in the areas infiltrated and therefore consumers shall be warned to protect themselves from injury.".

6.4.3. In addition to the warning referred to in Section 6.4, for lipolysis devices, the instructions for use shall contain the following warning:

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

6.5. For liposuction and lipolysis devices, the instructions for use shall contain the following warning:

"Devices intended for invasive use shall only be used in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law. The medical doctor who carries out the procedure shall be assisted by at least one medical 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 keep their knowledge of basic cardiac life support and in the checking of equipment and emergency drugs used for resuscitation purposes up-to-date. Medical doctors performing the procedure shall also be trained in advanced cardiac life support.

The medical doctor or allied health professional responsible for anaesthetic management shall ensure appropriate monitoring of the consumer both during the procedure and after it. 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.".

6.6. The instructions for use shall contain the requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.7 before the consumer is treated with the device.

6.7. The instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a), (b) and (c), of Annex I;

(b) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant;

(c) information on when and how to report undesirable side-effects to the manufacturer;

(d) a recommendation to undergo a medical consultation, including a diagnostic examination, of the areas intended for the treatment.

ANNEX VI

Scope

1. This Annex applies to high intensity electromagnetic radiation (for example infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment, listed in Section 5 of Annex XVI to Regulation (EU) 2017/745.

   For the purposes of this Annex, skin resurfacing includes skin rejuvenation.

   For the purposes of this Annex, tattoo removal includes removal of permanent make-up.

   For the purposes of this Annex, other skin treatments include non-medical treatment of nevi flammei, haemangioma, teleangiectasia, pigmented skin areas, and scars that are not injury within the meaning of Article 2, point (1), second indent, of Regulation (EU) 2017/745. For example, this Annex applies to devices intended to treat acne scars, but it does not apply to devices for other acne treatment.

   This Annex does not apply to equipment using infrared optical radiation to warm the body or parts of the body and to sunbeds.

Definitions

2. For the purpose of this Annex, the following definitions apply:

   (1) "device for professional use" means a device that is intended to be used in a healthcare environment or otherwise controlled professional environment by professionals having proven qualification in the safe and effective use of the device;

   (2) "device for home use" means a device that is intended to be used in private environments, not in a controlled professional environment, by lay persons.

Risk management

3. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 4 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 5 of this Annex.

4. Specific risks

4.1. Manufacturers shall take into account the following aspects and related risks:

   (a) various skin types and the degree of tanning of the skin;

   (b) presence of any skin abnormality (for example relief, texture or colour) or disease affecting the skin;

   (c) age of the consumers;

   (d) possibility of concurrent medical treatments or drug misuse;

   (e) use of photosensitising medicines or cosmetics;

   (f) reduced reaction to harm caused by local or systemic anaesthesia;

   (g) exposure to other light sources.

4.2. Manufacturers shall analyse, eliminate or reduce as far as possible the following risks:

   (a) burns;

   (b) formation of scars and keloids;

   (c) hypopigmentation and hyperpigmentation;

   (d) accelerated aging of skin;

(e) allergic/chemical skin reaction (for example to colour pigments of tattoos or make-up);

(f) formations of skin cancers;

(g) alteration of skin cancers, skin diseases, nevi, herpes, possible delay of disease diagnoses (for example melanoma, endocrine diseases);

(h) reactions in case of possible drug intake or use of cosmetics;

(i) possible reactions to sun or sunbed exposure;

(j) possible photosensitive dermatosis;

(k) vitiligo;

(l) erythema, mostly temporary and occasionally persistent;

(m) purpura resulting from bleeding from small blood vessels;

(n) crusting;

(o) edema;

(p) blistering;

(q) inflammation, folliculitis, skin infection;

(r) eye damage, including damage to retina and cornea;

(s) prickling or feeling of heat;

(t) dry skin and itching due to shaving or combination of shaving and light treatment;

(u) excessive pain;

(v) paradoxical hypertrichosis (increased growth of hair after treatment);

(w) overexposure;

(x) unintended release of radiation;

(y) ignition, explosion or production of fumes.

5. Specific risk control measures

5.1. Manufacturers shall apply the following safety measures as regards devices for professional use:

(a) avoidance of unauthorized access to or unintended use of the devices (for example by means of key switch or code or dual control of energy emission);

(b) display of the characteristics of the emitted optical radiation for the purpose of permanent surveillance and recording of the emission through the device in addition to the requirements of Section 16.2 of Annex I to Regulation (EU) 2017/745;

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

(d) avoidance of overexposure for each session of the treatment by particular measures;

(e) where the wavelength of the radiation emitted is less than 1 200 nm, instruments or methods to assess the skin pigmentation to ensure proper settings for the treatment;

(f) measures to avoid overexposure by repeated treatment sessions or repeated treatments;

(g) low energy preset;

(h) optimised limitation of pulse energy and pulse duration (exposure time on tissue) and a combination of these two parameters with the wavelength range;

(i) optimized limitation of treatment areas (spot sizes) also taking into account the parameters referred to in point (h);

(j) minimisation of scattered radiation;

(k) minimisation of the risk of accidental emission;

(l) emergency stop function (for example emergency stop switch);

(m) for devices for hair removal: minimisation of ultraviolet radiation (to be achieved for example by using appropriate high quality band edge filter);

(n) devices intended to deliver a permanent change of the appearance shall not be used on persons who are less than 18 years old;

(o) information for the user on the correct functioning of the device and the actual mode of operation by means of acoustic or optical means in standby mode, in operating mode and in case of loss of skin contact during the procedure;

(p) instruction of the user to protect nevi or lesions during the procedure.

5.2. Devices for home use shall not emit radiation outside the wavelength range between 400 nm and 1 200 nm. Without prejudice to Section 4, a tolerance for the emitted energy on wavelengths above 1 200 nm is permitted up to maximum 15 % of the total emitted energy.

5.3. Devices for home use may only be used for the purpose of hair removal.

5.4. Manufacturers of devices for home use shall implement the risk control measures listed in Section 5.1 unless otherwise provided in this Regulation. In addition, manufacturers of devices for home use shall:

(a) set limits for the duration of exposure and include automatic deactivation to avoid risk of overexposure;

(b) include 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, instead of applying the requirements laid down in point (c) of Section 5.1;

(c) include an integrated skin tone sensor assessing the skin patch of or near to the area to be treated and allowing emission output only if skin pigmentation is suited for treatment and if there is continuous full skin contact after skin tone analysis, instead of applying the requirements laid down in point (e) of Section 5.1.

Manufacturers of devices for home use shall also make available on the internet, videos with instructions on how to safely use the device.

5.5. Together with the device manufacturers shall provide appropriate eye protection for users, 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 accurate and safe treatment.

5.6. 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. Necessary cleaning and disinfecting instructions shall be provided.

5.7. Manufacturers shall provide training accessible to users. 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 incidents. For devices for home use, videos with instructions shall be considered as training accessible to users.

Information for safety

6. Instructions for use

6.1. The instructions for use shall contain:

(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, fluence, wavelength range [nm], pulse duration [ms], pulse profile(s);

(h) the maximum admissible treatment spot size [cm^2];

(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 not lead to overexposure;

(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 prolonged exposure to sun light or sunbeds, that might increase the risks;

(p) for devices for professional use, a requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.11 before the consumer is treated with the device.

6.2. With the exemption of devices for hair removal where excessive hair is not attributed to a medical condition, the manufacturer shall advise the users and the consumers to undergo a medical consultation including a diagnostic examination of the skin areas intended for the treatment. Manufacturers shall advise users not to treat any consumers prior to obtaining documentation from such consultation.

6.3. The instructions for use shall clearly describe requirements for cleaning and maintenance. For devices intended for professional use, the instructions for use shall include the measurement of light energy density and required safety measures, performed at least annually.

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

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

(a) the description or a listing of appropriate accessories or conditions of other products used in the procedure;

(b) the safety precautions to be taken, which include 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.

6.5. The instructions for use shall highlight the need:

(a) to avoid at all times 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.

6.6. 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.

6.7. 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. In addition, the instructions for use shall give information about further contra-indications such as photosensitive epilepsy, diabetes or pregnancy, if applicable.

6.8. For devices intended to deliver a permanent change of the appearance, the instructions for use shall indicate that they shall not be used on persons who are less than 18 years old.

6.9. For devices for professional use, the manufacturer shall ensure that all appropriate information is made available to the healthcare professional or service provider in order for them to be able to ensure that professional users are evaluating consumers. This includes consumers' suitability for treatment with devices and counselling them appropriately and adequately with respect to risks and potential outcomes of the procedure, taking into account the consumers' health history and the medications they take.

6.10. For devices for home use, the instructions for use shall contain the internet address where the videos with instructions made available in accordance with Section 5.4. can be found.

6.11. The instructions for use of devices for professional use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a), (b) and (c), of Annex I;

(b) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant;

(c) information on when and how to report undesirable side-effects to the manufacturer;

(d) a recommendation to undergo a medical consultation, including a diagnostic examination, of the skin areas intended for the treatment.

ANNEX VII

Scope

1. This Annex applies to equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as listed in Section 6 of Annex XVI to Regulation (EU) 2017/745. Such equipment includes devices for transcranial alternating current stimulation, transcranial direct current stimulation, transcranial magnetic stimulation and transcranial random noise stimulation. This Annex does not apply to invasive devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, among risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. When carrying out the risk management process, special care shall be taken as to the placement of the electrodes and the strength, waveform, duration and other parameters of the electrical current and magnetic fields.

3.2. Manufacturers shall take into account the following aspects and related risks:

(a) the incorrect placement of electrodes and coils may result in failed performance, enhanced electrical currents in tissue 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: persons who are less than 18 years old, young adults, pregnant women, psychiatric patients, persons with psychological disorders or medical conditions affecting the central nervous system, alcohol addicts, users of addictive substances and other substances that modify a person's natural perception;

(c) the presence of active implantable or body-worn medical devices and/or metallic passive medical devices or other metallic objects present on or inside the body 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.

3.3. Manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) psychological risks;

(b) neural and neuro-toxicity risks;

(c) short-term, medium-term and long-term cognitive side-effects, such as compensatory trade-offs (for example the decline or sub-serving of brain regions which are not stimulated);

(d) transient auditory threshold shift or tinnitus;

(e) long-term side-effect changes of the brain functioning;

(f) hazards linked to the long-term effects of repeated stimulation;

(g) hazards linked to the use of the device in certain environments highly stimulating or attention demanding;

(h) atypical or other idiosyncratic effects;

(i) specific hazards arising at the interface between electrodes and skin;

(j) electromagnetic interference or injury caused by interaction with active implants (for example pacemakers, implanted cardioverter-defibrillators, cochlear implants, neural implants), active devices (for example neural stimulation devices, medication infusion devices), non-active metallic implants (for example metallic dental implants) or body-worn devices (for example biosensors);

(k) hazards associated with device usage after intake of alcohol and/or soft-drugs and/or central nervous system stimulating substances/pharmaceuticals;

(l) hazards 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.

4. Specific risk control measures

4.1. When applying Section 4.2 of Annex I, unless there is specific evidence for safe use, 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 those are commonly understood as therapeutic drugs;

(e) persons who have a tumour in the central nervous system;

(f) persons who have vascular, traumatic, infectious or metabolic lesions or diseases of the brain;

(g) persons who suffer from sleep disorders, drug dependency or alcoholism;

(h) persons who are less than 18 years old;

(i) pregnant women.

4.2. Manufacturers shall apply the following safety measures where relevant:

(a) avoidance of unauthorised access to the device (for example by means of key switch or code) and unintended use of the device (for example by means of dual control of energy emission);

(b) minimisation of stray magnetic fields;

(c) minimisation of the risk of accidental emission;

(d) emergency stop function (for example emergency stop switch);

(e) automatic deactivation where maximum acceptable output is reached;

(f) automatic deactivation where maximum acceptable duration of exposure is reached;

(g) automatic deactivation in case of overexposure due to a combination of output and duration;

(h) videos with instructions on how to safely use the device made available on the internet;

(i) provision of appropriate training accessible to users on safe and effective use of the device;

(j) information for the user on the correct functioning of the device and the actual mode of operation through acoustic or optical means in standby mode, in operating mode and in case of loss of full skin contact during the procedure.

4.3. 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 (for example energy level, duration of use) or for combination of parameters. Critical values shall be set below the maximum acceptable values.

Information for safety

5. 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 effects can be expected from the use of the device (for example enhanced intelligence or improvement in mathematical ability).

6. Information on warnings, precautions and side-effects shall cover:

   (a) specific risks for persons listed in Section 4.1;

   (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.

7. Instructions for use

7.1. 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.

7.2. 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, brain area targeted, wave forms and pulse characteristics.

   Unless there is specific evidence for safe use, as provided for in Section 4.1, 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 4.1.

7.3. The instructions 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.

7.4. 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 fields 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 (for example pacemakers, implanted cardioverter-defibrillators, cochlear implants and neural implants) and active body-worn medical devices (for example 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.

7.5. Where the device is intended or expected to be applied on the consumer by a professional user, the instructions for use shall contain a requirement for the user to provide the consumer with a copy of the annex provided for in Section 7.7 before the consumer is treated with the device;

7.6. The instructions for use shall contain the internet address where the videos with instructions made available in accordance with Section 4.2, point (h) can be found.

7.7. Where the device is intended or expected to be applied on the consumer by a professional user, the instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) the information listed in Section 12.1, points (a), (b) and (c), of Annex I;

(b) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant;

(c) information on when and how to report undesirable side-effects to the manufacturer.