EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[1], and in particular Article 9(1) and Article 51(4) thereof,

After consulting the Committee on Medical Devices,

Whereas:

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

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

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

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

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

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

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

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

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

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

HAS ADOPTED THIS REGULATION:

Article 1

Scope

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

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

Article 2

Definitions

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

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

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

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

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

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

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

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

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

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

Article 3

General interpretation rules

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

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

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

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

Article 4

Application of classification rules to active devices

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

Article 5

Risk analysis and evaluation

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

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

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

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

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

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

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

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

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

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

Article 6

Risk control and evaluation of residual risks

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

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

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

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

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

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

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

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

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

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

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

Article 7

Label and Instruction for Use

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

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

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

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

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

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

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

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

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

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

Article 8

Clinical evaluation

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

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

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

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

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

Article 9

Performance

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

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

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

Article 10

Entry into force

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

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

Done at Brussels,

For the Commission
The President