EUROPEAN
COMMISSION

Brussels, XXX
[…](2022) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

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

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 and for sunbeds.

(5) 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 purposes. Consequently, they should not be covered by this Regulation.

(6) As 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 devices 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 have to be 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 six months. For such cases transitional arrangements should be laid down.

(14) 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.

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

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

(17) 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 clinical investigations have to be performed in accordance with Article 61 of Regulation (EU) 2017/745, in order to confirm its 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, may be placed on the market, made available on the market and put into service until … [*OP please insert the date – 3 years after the date of application of this Regulation*], provided that the following conditions are met:

   (a) the product was already lawfully marketed in the Union before … [*OP please insert the date – date of application of this Regulation*] and continues to comply with the requirements of Union and national law that were applicable to it before … [*OP please insert the date – date of application of this Regulation*];

   (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 … [OP please insert the date – 6 months after the date of application of this Regulation] until … [OP please insert the date – 1 year after the date of application of this Regulation] the manufacturer may only place on the market or put into service the products that meet the conditions laid down in that subparagraph, if the sponsor has submitted an application for the clinical investigations of the product in accordance with Article 70(1) of Regulation (EU) 2017/745.

   By way of derogation from the first subparagraph of this paragraph, from … [OP please insert the date – 1 year and 1 day after the date of application of this Regulation] until … [OP please insert the date – 18 months after the date of application of this Regulation], the manufacturer may only place on the market or put into service the products that meet the conditions laid down in that subparagraph, if the sponsor has received from the Member State concerned a notification confirming that the application referred to in the second subparagraph of this paragraph 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 … [OP please insert the date – 18 months and 1 day after the date of application of this Regulation] until … [OP please insert the date – 3 years after the date of application of this Regulation], the manufacturer may only place on the market or put into service the products that meet the conditions laid down in that subparagraph, if the sponsor has started the clinical investigation.

2. A product for which clinical investigations do not have to be performed in accordance with Article 61 of Regulation (EU) 2017/745, 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, made available on the market and put into service until … [*OP please insert the date – 1 year after the date of application of this Regulation*], provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before … [*OP please insert the date of application of this Regulation*] and continues to comply with the requirements of Union and national law that were applicable to it before … [*OP please insert the date of application of this Regulation*];

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

By way of derogation from the first subparagraph, from … [OP please insert the date – 3 months after the date of application of this Regulation] until … [OP please insert the date – 1 year after the date of application of this Regulation], the manufacturer may only place on the market or put into service the products that meet the conditions laid down in that subparagraph, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer.

3. A product for which clinical investigations do not have to be performed in accordance with Article 61 of Regulation (EU) 2017/745, but in the conformity assessment of which a notified body has to be involved in accordance with Article 52 of that Regulation and the notified body must seek a scientific opinion in accordance with Article 52(9) of that Regulation, may be placed on the market, made available on the market and put into service until … [*OP please insert the date – 18 months after the date of application of this Regulation*], provided that the product meets the conditions laid down in paragraph 2, first subparagraph, points (a) and (b).

By way of derogation from the first subparagraph, from … [OP please insert the date – 3 months after the date of application of this Regulation] until … [OP please insert the date – 18 months after the date of application of this Regulation], the manufacturers may place on the market or put into service the products that meet the conditions laid down in that subparagraph, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer.

Article 3

Entry into force and date of application

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

It shall apply from … [*OP please insert the date – 6 months after the date of entry into force of this Regulation*].

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN