MDCG 2023-5

Guidance on qualification and classification of Annex XVI products

A guide for manufacturers and notified bodies

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1 Introduction

The Regulation (EU) 2017/745 on medical devices[1], hereafter referred to as the MDR, is applicable[2] to the groups of products without an intended medical purpose that are listed in Annex XVI as from the date of application of the Commission Implementing Regulation (EU) 2022/2346[3], hereinafter referred to as the common specifications (CS).

Products without an intended medical purpose that are listed in the Annex XVI to MDR and that are included in the scope sections of the CS' annexes are covered also by the MDR. Qualification of a product without an intended medial purpose precedes its classification. Only products that qualify as devices[4] and that are covered by the CS and the MDR should then be classified according to the rules set out in Annex VIII to MDR and in Commission Implementing Regulation (EU) 2022/2347 on reclassification[5].

Classification rules set out in Annex VIII to MDR apply to those products. Also Commission Implementing Regulation (EU) 2022/2347 applies for classification purposes of certain active devices without an intended medical purpose.

The document MDCG 2021-24 on "Guidance on classification of medical devices"[6] should be read together with the present guidance document, except for the elements which are specific to devices with a medical purpose.

2 Scope

This guidance document provides elements useful for the qualification of a product as a product without an intended medical purpose listed in Annex XVI to the MDR. It also provides explanations and examples for the application of certain classification rules to products without an intended medical purpose, hereinafter also referred to as devices.

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[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices - http://data.europa.eu/eli/reg/2017/745/2020-04-24.
[2] MDR, Article 1(2).
[3] Commission Implementing Regulation (EU) 2022/2346 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 – http://data.europa.eu/eli/reg_impl/2022/2346/oj.
[4] MDR, Article 1(4).
[5] Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose - http://data.europa.eu/eli/reg_impl/2022/2347/oj.
[6] https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec1.

The examples provided do not imply that the products are a priori qualified as devices. Classification rules apply after the qualification of the product as a device has been established.

This guidance document should be used in conjunction with the MDCG 2021-24 on classification of medical devices and take into consideration Commission Implementing Regulation (EU) 2022/2347 on reclassification[7].

3 Qualification

The purpose of this chapter is to provide useful elements to support the qualification[7] of products as Annex XVI products covered by the CS. The following elements and explanations are not exhaustive.

Even if mostly related to medical devices, additional relevant elements may be found also in the Manual on borderline and classification for medical devices[8] and in MDCG 2022-5, the guidance on borderline between medical devices and medicinal products[9].

3.1 General requirements

Article 1(1) of the MDR covers only medical devices and accessories for medical devices, while Article 1(2) of the MDR establishes that the MDR applies also to the products listed in Annex XVI. While for a “medical device” and an “accessory for a medical device” there are definitions that determine the meaning of the two terms, for Annex XVI products the Regulation does not provide any definition. Therefore, to determine if a product is covered by the MDR, the descriptions of the groups of products listed in the Annex XVI must be used. The definitions of “medical device” and “accessory for a medical device” should not be used.

[7] Determination of the regulatory status of a product by deciding whether or not it is covered by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

[8] Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices - https://health.ec.europa.eu/system/files/2022-12/md_borderline_manual_12-2022_en.pdf.

[9] MDCG 2022-5 “Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices” - https://health.ec.europa.eu/system/files/2022-04/mdcg_2022-5_en_0.pdf.

The MDR is applicable to Annex XVI products as from the date of application of the CS that cover a product or a group of products. In the absence of CS for a product or a group of products the MDR does not apply to those products. Other EU legislation could be applicable. Useful information can be found in the Blue Guide on the implementation of the product rules[10].

The qualification of a product as a device should rely on information provided in the Annex XVI list and in the scope sections of the CS. More precisely, the characteristics mentioned in those provisions, such as the type of product, the technology, the functioning modalities, the target body part, organ or tissue and the intended purpose of the product should be fulfilled. Examples of products provided in the Annex XVI list and in the scope sections of the CS, should be considered as additional sources of information for the qualification, even if they are not exhaustively described.

The recital (12)[11] of the MDR states that Annex XVI products should be similar to medical devices for functioning and risk profile. This guiding principle is reflected in Article 1(2) of the MDR to take into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. Similarities with analogous medical devices can therefore also be considered as a guiding principle for the qualification of the product as a device.

3.2 Accessories

Accessories for Annex XVI products are not defined in Article 2 of the MDR. Nevertheless, such items are covered by the MDR, if they fall within the descriptions listed in the Annex XVI of the MDR and fall under the scope sections of the CS.

If the item can be used only in combination with an Annex XVI product, it could be placed on the market together with that product and considered as a piece of the product.

If the item can be used either on its own or in combination with other Annex XVI products, it could be placed on the market either on its own as an Annex XVI product, or together with the other Annex XVI products with which it is compatible. In the latter case, it could be considered as a piece of those products.

[10] COMMISSION NOTICE - The 'Blue Guide' on the implementation of EU product rules 2022 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022XC0629%2804%29&qid=1683791254087.

[11] MDR, recital (12): "Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. […].".

3.3 Dual-purpose devices

If the manufacturer claims both a medical and a non-medical intended purpose, those devices, referred to as dual-purpose devices, must fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose[12].

Certain requirements from the CS and the MDR, such as those for the acceptability of risks, may not be the same. In such cases, the most stringent requirements should be applied.

If the dual-purpose is never achieved simultaneously in one patient (e.g., the equipment can be used for the medical purpose or for the non-medical one, but never for both simultaneously), the MDR and the CS requirements could be applied separately with reference to the two intended purposes. However, certain requirements, such as those on the risk control measures, should be considered also in combination, because the measures taken for one intended purpose could generate effects on the use according to the other intended purpose. This could be the case for control measures related to the medical purpose risks, which could generate new risks related to the non-medical purpose and the other way around[13].

3.4 Multiple intended purposes

The products described in each of the 6 groups listed in the Annex XVI to the MDR are different in terms of intended purposes and characteristics. Even if a product could have some characteristics described in more than one group, it is very unlikely that it could achieve the intended purposes of more than one group. For that reason, in principle, every product should fall only in one of the 6 groups listed in the Annex XVI to the MDR. Nevertheless, if a product achieves the intended purposes of two or more groups of products and has all the characteristics described in those groups, the requirements set out in the CS for those groups should apply cumulatively.

[12] MDR, Article 1(3).

[13] For example, the limitation of the energy emission to a specific wavelength range for a laser equipment for a medical purpose (e.g., treatment of actinic keratosis) could damage the skin if the laser equipment is used for a non-medical purpose (e.g., hair removal) which requires that the energy is emitted in a different wavelength range. Conversely, the limitation of energy for laser equipment for the non-medical purpose could negatively affect the performance of the device when used for the medical purpose.

Examples:

- Lipolysis laser equipment: it emits high intensity electromagnetic radiation and removes adipose tissue. If the laser contributes to the removal of the fat tissue and does not deliver any skin treatment, the product will fall only under group 4. Conversely, if the laser contributes to the removal of the fat tissue and also delivers skin treatment, such as skin tightening, the product will fall under both groups 4 and 5;
- Equipment for radiofrequency radiation assisted liposuction: it emits high intensity electromagnetic radiation and removes adipose tissue. If the radiofrequency radiation contributes to the removal of the fat tissue and does not deliver any skin treatment, the product will fall only under group 4. Conversely, if the radiofrequency radiation also delivers skin treatment, such as skin tightening, the product will fall under both groups 4 and 5.

3.5 Practical issues of qualification

The descriptions of the groups of products listed in the Annex XVI to the MDR include terms or concepts that are not defined nor explained in detail in the Regulation itself. The following table provides guidance on how to consider those terms or concepts for qualification purposes.

Group	clarification
1	Contact lenses that are coloured or printed to achieve a non-medical purpose and that are also indicated for the purpose of correcting a sight defect, should be considered a dual-purpose device that reaches simultaneously both the medical and the non-medical purpose. The product can be considered a medical device (both features having a medical purpose) only if the colour or the print achieves a medical intended purpose.
2	The term fixation should be considered as a firmly and stable coupling of two or more body parts without any possibility for relative movements between those parts.
3	The intended purpose of the product should be facial or other dermal or mucous membrane filling. Therefore, mesotherapy products are considered as covered by the CS only if their intended purpose is or includes the filling.
3	The substance, combination of substances or items must be introduced by subcutaneous, submucous or intradermal injection or by other introduction route of administration. For the purpose of the qualification, the terms should be considered to have the following meaning. ‘Subcutaneous’ means under the skin and typically refers to the fatty tissue below the dermis; ‘submucous’ refers to the connective tissue beneath the mucosa; ‘intradermal’ means into the dermis, just below the epidermis. The administration method can be an injection or ‘other introduction’. Prefilled hyaluron pens or prefilled dermarollers are examples of other means of introduction.

Group	clarification
5	The term 'high intensity' is used to qualify the electromagnetic radiation but it is not defined in Article 2 of the MDR and its meaning is not explained. The infra-red, visible light and ultraviolet radiations[14] are referred to in Section 5 of Annex XVI to the MDR as examples of that electromagnetic radiation, therefore they should not be considered as sufficient to qualify the term high intensity. For example, radiofrequency[15] can be considered another type of electromagnetic radiation. For the purpose of deciding if the product emits high intensity electromagnetic radiation and, therefore, falls within the group 5 of Annex XVI to MDR, the electromagnetic radiation should be considered having high intensity if it is able to cause an effect[16] on the target tissue that is necessary to achieve the intended purpose of the product.

3.6 Examples of products that do not qualify as Annex XVI products

The following table provides a non-exhaustive list of examples of products that should not qualify as Annex XVI products and that are not covered by the CS. The list does not include the products that are excluded directly by the MDR and the CS[17].

Group	Product	reasons for exclusion
1	Solutions for disinfecting, cleaning and rinsing contact lenses	These products qualify as medical devices according to the last paragraph of Article 2(1) of the MDR.
	Products for keratopigmentation	Not covered by the CS. If intended for the treatment of disfiguring corneal opacities the products qualify as medical devices according to the last paragraph of Article 2(1) of the MDR.
2	Products for keratopigmentation	The product does not modify the anatomy of a body part.
3	Equipment for transferring hair follicles in the context of hair transplant surgery (follicular injection device)	The equipment is not used for facial or other dermal or mucous membrane filling purposes.

[14] The wavelength ranges of the electromagnetic radiations cited as examples are approximately the following: ultra-violet: from 100 nm to 400 nm; visible light: from 400 nm to 780 nm; infra-red: from 780 nm to 1.000.000 nm (or 1,0 mm).
[15] The part of the electromagnetic spectrum comprising approximately the frequency range from 100 kHz to 300 GHz.
[16] The possible effects can be generated by cavitation, vaporization, shock waves, dielectric breakdown, thermal effects or photochemical effects. The list is not exhaustive.
[17] Reasons for exclusions from the scope of the CS are provided directly in the implementing act, in recitals (4), (5) and (6).

Group	Product	reasons for exclusion
	Serums and creams after filler treatment	The product is not used for facial or other dermal or mucous membrane filling purposes. The product is not used by subcutaneous, submucous or intradermal injection or other introduction.
	Mesotherapy products such as those used for biorevitalization, biorejuvenation, poly-revitalizing, hydration of dermis, collagen synthesis, fibroblast stimulation, skin radiance, free radical elimination	The products are not used for facial or other dermal or mucous membrane filling purposes.
	Equipment for micro-needling	The equipment is not used for facial or other dermal or mucous membrane filling purposes.
5	Equipment emitting cold plasma	The intended purpose is achieved by an ionised gas and not by electromagnetic radiation.
	Lasers for mucous membrane rejuvenation	Mucous membrane rejuvenation is not a skin treatment.
	Products such as serums, creams or gels to be used before and/or after the hair removal treatment	Not covered by the CS.

4 Classification

4.1 General principles

The classification of products without an intended medical purpose covered by the MDR is to be done in accordance with the Rules set out in Annex VIII of the MDR. In addition, Commission Implementing Regulation (EU) 2022/2347[18], laying down rules for the reclassification of groups of certain active products without an intended medical purpose by means of derogation from the application of Annex VIII to the MDR, will be taken into account if relevant.

The classification of dual-purpose devices should consider both the medical and the non-medical purpose. In case several rules, or several sub-rules within the same rule, apply to the same device based on the device's intended purposes, the strictest rule and sub-rule resulting in the higher classification should apply[19].

[18] Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose - http://data.europa.eu/eli/reg_impl/2022/2347/oj.

The guidance MDCG 2021-24 on classification should be referred to for the general consideration on the classification rules. This guidance provides additional elements and examples which may be relevant for Annex XVI products.

This chapter presents the classification elements to be taken into account for each group of products without an intended medical purpose as listed and described in the Annex XVI of the MDR and covered by the CS. Considering that the description of each group of products contains relevant information on the product characteristics that could be useful for its classification (see also comments in point 3.1), the product descriptions from the CS are presented.

4.2 Group 1

The CS apply to contact lenses listed in Section 1 of Annex XVI to Regulation (EU) 2017/745. The CS do not apply to 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.

Class	Rule	Examples of Annex XVI products
IIa	5 All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: – class IIa if they are intended for short-term use, […]	– Short-term use coloured non-corrective contact lenses – Short-term use non-corrective contact lenses with prints
IIb	5 All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: – class IIb if they are intended for long-term use, […]	- Long-term use coloured non-corrective contact lenses - Long-term use non-corrective contact lenses with prints

4.3 Group 2

The CS apply 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. The CS do not apply to tattooing products, piercings[20] and products intended to

[19] MDR, Section 3.5 of Annex VIII.
[20] Tattooing products and piercings are already excluded from Section 2 of Annex XVI to the MDR.

be totally or partially introduced into the human body through surgically invasive means for the purpose of fixation of body parts. The CS also do not apply to active implantable devices.

Class	Rule	Examples of Annex XVI products
IIb	8 All implantable devices and long-term surgically invasive devices are classified as class IIb […]	– Subdermal and transdermal implants – Gluteal implants – Threads
III	8 All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: – […] are wholly or mainly absorbed, in which cases they are classified as class III;	– Absorbable threads
	8 – are breast implants or surgical meshes, in which cases they are classified as class III; […]	– Breast implants – Surgical meshes for breast lifting

4.4 Group 3

The CS apply 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[21], listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. The CS apply 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. The CS do not apply to active devices.

Class	Rule	Examples of Annex XVI products
IIb	8 All implantable devices and long-term surgically invasive devices are classified as class IIb […]:	– Permanent dermal fillers
III	8 All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:	– Resorbable dermal fillers

[21] Substances, combinations of substances or items for tattooing products are already excluded from Section 3 of Annex XVI to the MDR.

Class	Rule	Examples of Annex XVI products
	– have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III; […]	– Mesotherapy products for filling
	14 All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.	– Dermal fillers incorporating anaesthetics or other substance which, if used separately, can be considered to be a medicinal product

4.5 Group 4

The CS apply 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. The CS do not apply to active implantable devices.

Class	Rule	Examples of Annex XVI products
I	1 All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.	– Connecting tubes
	6 All surgically invasive devices intended for transient use are classified as class IIa unless they: – are reusable surgical instruments, in which case they are classified as class I; […]	– Cannulas (reusable)
IIa	6 All surgically invasive devices intended for transient use are classified as class IIa unless they: [...]	– Cannulas
IIb	/ Article 1(b) of Implementing Regulation (EU) 2022/2347: – equipment intended to be used to reduce, remove or destroy adipose tissue as referred to in Section 4 of Annex XVI to Regulation (EU) 2017/745, is reclassified as class IIb.	– Suction-assisted Lipoplasty (SAL) – Power-assisted Lipoplasty (PAL) – Suction pumps – Equipment for cryolipolysis

4.6 Group 5

The CS apply 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. The CS also apply to high intensity electromagnetic radiation emitting equipment intended for skin rejuvenation, removal of permanent make-up and non-medical treatment of nevi flammei, haemangioma, teleangiectasia, pigmented skin areas and scars that are not injuries within the meaning of Article 2, point (1), second indent, of Regulation (EU) 2017/745. For example, the CS apply to products intended to treat acne scars, but they do not apply to devices for other acne treatment. The CS do not apply to equipment using infrared optical radiation to warm the body or parts of the body and also not to sunbeds.

Class	Rule	Examples of Annex XVI products
IIa	/ Article 1(a) of Implementing Regulation (EU) 2022/2347: – […] unless it is intended for hair removal only in which case it is reclassified as class IIa.	– IPL/LED/Laser equipment for hair removal only
IIb	/ Article 1(a) of Implementing Regulation (EU) 2022/2347: – high intensity electromagnetic radiation emitting equipment as referred to in Section 5 of Annex XVI to Regulation (EU) 2017/745 that is intended for the use on the human body for skin treatment is reclassified as class IIb […]	– Laser equipment for hair removal, skin resurfacing, tattoo removal, hypertrophic and keloid scars, improvement of pigmentation problems (e.g., sun damage, age spots), improvement of appearance of vascular lesions – IPL equipment for hair removal, skin rejuvenation, improvement of pigmentation problems (e.g., sun damage, age spots), improvement of appearance of vascular lesions – LED equipment for skin rejuvenation, stimulation of hair growth, improvement of appearance of acne scars (e.g.: LED face masks)

4.7 Group 6

The CS apply 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. The CS do not apply to invasive devices.

Class	Rule	Examples of Annex XVI products
III	/ Article 1(c) of Implementing Regulation (EU) 2022/2347: – 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 referred to in Section 6 of Annex XVI to Regulation (EU) 2017/745 is reclassified as class III.	– Equipment for transcranial electrical stimulation to enhance cognitive performance – Equipment for transcranial magnetic or electromagnetic stimulation to enhance cognitive performance