LEX ebook of Annex XVI devices

Devices in scope of Annex XVI devices are:

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. 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.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (e.g. 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.
6. 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.

Type	Reference	Description
Regulation	(EU) 2017/745 - Annex XVI	Medical Devices Regulation - *List of groups of products without an intended medical purpose*
Regulation	Commission Implementing Regulation (EU) 2022/2346	Common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
Regulation	Commission Implementing Regulation (EU) 2022/2347	Reclassification of groups of certain active products without an intended medical purpose
Regulation	(EU) 2023/607	Transitional provisions for certain medical devices and in vitro diagnostic medical devices
Regulation	Commission Implementing Regulation (EU) 2023/1194	Transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
Guidance	Q&A ON TRANSITIONAL PROVISIONS FOR PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE COVERED BY ANNEX XVI OF THE MDR	
Guidance	MDCG 2023-5	Guidance on qualification and classification of Annex XVI products - A guide for manufacturers and notified bodies
Guidance	MDCG2023-6	Guidance on demonstration of equivalence for Annex XVI products - A guide for manufacturers and notified bodies
Template	Self-declaration	
Template	NB confirmation letter	

Transitional provisions under MDR

MDR is applicable to devices without medical purposes (Annex XVI devices) **on 22 June 2023** when the common specifications under (EU) 2022/2346 became applicable. Any class I self-certified devices in scope of Annex XVI needs to comply with the MDR after **22 June 2023**, any new devices in scope of Annex XVI, marketed after 22 June 2023, needs to meet the MDR requirements.

However, transitional provisions exist for:

1. Annex XVI devices lawfully marketed in EU before 22 June 2023 (i.e., without MDD certificate)
2. Annex XVI devices already CE marked under MDD before 22 June 2023 and for which:
   - the MDD certificate was still valid after 20 March 2023
   - the MDD certificate was no longer valid before 20 March 2023 but a derogation has been granted per Article 59(1), or a permission of sales has been obtained for non-compliant devices per article 97(1), or an agreement with NB has been signed under MDR, before that date.

Note: Any devices in scope a MDD certificate that expired prior 20 March 2023 without derogation per Article 59(1) or permission per Article 97(1) or MDR agreement with a NB, are not eligible to the transition period.

Per (EU) 2023/607, legacy Annex XVI devices with a valid MDD certificate (devices (2) above) on 20 March 2023, can continue to be marketed in EU until:

- **31 December 2027** for all class III devices and class IIb implantable device (except WET devices)
- **31 December 2028** for classes Im,s, IIa, IIb non-implantable devices and IIb WET.

The transitional provisions are applicable as long as:

- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
- legacy devices are not significanlty modified in terms of design and intended purpose,
- legacy devices continue to comply with MDD directives
- requirements from article 120 of the MDR (i.e., post-market surveillance, vigilance and registration of economic operators) are met.
- no later than 26 May 2024, the manufacturer has put in place a QMS per Article 10(9)
- no later than 26 May 2024, the manufacturer has lodged a formal application with the NB
- no later than 26 September 2024, the NB and manufacturer have a signed agreement under MDR

Per (EU) 2023/1194, legacy devices lawfully placed on the market before 22 June 2023 (i.e., devices (1) above) can benefit from the transitional provisions from the Common Specifications (CS) under (EU) 2022/2346 and continue to be marketed in EU until:

- **31 December 2028** when a NB is involved in the conformity assessment procedure, no clinical investigation is deemed required for the compliance to the MDR and considering the following deadlines are met:
  - An agreement has been signed between the manufacturer and NB from **01 January 2027 to 31 December 2028** for the conformity assessment of the Annex XVI devices.
- **31 December 2029** when a NB is involved in the conformity assessment procedure, a clinical investigation (CI) is required for the compliance to MDR and considering the following deadlines are met:
  - An CI application must be submitted to and confirmed by the Member State concerned by the CI **from 22 June 2024 to 22 December 2024**
  - The Sponsor of the CI has initiated the CI from **23 December 2024 to 31 December 2027**
  - An agreement has been signed between the manufacturer and NB from **1 January 2028 to 31 December 2029** for the conformity assessment of the Annex XVI devices.

Those transitional provisions are applicable as long as:

- the devices are not significanlty modified in terms of design and intended purpose,
- the devices continue to comply with the applicable requirements of the EU or national law that were applicable before 22 June 2023.

Note: for dual purpose devices (i.e., devices with medical and non-medical purposes), MDR transitional provisions from (EU) 2023/607 and CS transitional provisions from (EU) 2023/1194 need to be fulfilled.

Finally, manufacturers need to demonstrate that the devices benefit from the transitional provisions via the signature of a self-declaration that needs to be updated as soon as new conditions are met. When a written agreement has been signed with the NB, a confirmation letter can be issued by the NB. The templates currently available are exclusively for compliance to (EU) 2023/607 and need to be customized if (EU) 2023/1194 is applicable.

Common Specifications

The common specifications (CS) are the key requirements to be met for the conformity assessment of devices without medical purposes. The requirements applicable to the 6 categories of devices are described in annexes of the CS. The format of annexes is the same and describes:

- the risk management activities
- the information for safety including the requirements applicable to labels and instructions for use

Conformity Assessment

Products that meet the definitions of medical device, accessory for medical devices or products listed in Annex XVI are all referred to as devices in the MDR. Hence, with some exceptions, requirements applicable to medical devices are also applicable to Annex XVI devices. For instance:

- The device classifications and conformity assessment routes are the same for devices with or without medical purposes.
- General Safety and Performance Requirements (GPSR) n°9 clarifies the interpretation of GSPRs 1 and 8 for devices without medical purpose.

As a general advice, manufacturers should similarly consider MDR requirements for a medical device or an Annex XVI device, except when specified.

However, some devices are for medical and non-medical purposes and are named dual-purpose devices. Those devices must fulfil cumulatively the requirements applicable to devices with and without medical purposes (e.g., clinical evaluation for both populations).

Classification

Annex XVI devices should be classified using the recommendations from MDCG 2021-24 in conjunction to MDCG 2023-5 specific to devices without medical purposes. The guidance clarifies the status of devices and gives some examples of borderline products. For instance, the status of accessories to Annex XVI devices are considered as Annex XVI devices under the MDR.

Though the classification of Annex XVI devices follows the rules of Annex VIII of the MDR, (EU) 2022/2347 has introduced a reclassification of groups of certain active products without an intended medical purpose. As a result, the following has been modified:

- 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, unless it is intended for hair removal only in which case it is reclassified as class IIa;
- 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;
- 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) 2017/745is reclassified as class III.

Risk Management

As the risk management process per current EN ISO 14971 is based on the consideration of benefits for the patients, the standard cannot be applied to devices without medical purpose. As a result, the Annex I of the common specifications under (EU) 2022/2346, which is applicable to all categories of devices, describes the risk management method to be carried out, including the risk management planning, identification of hazards and risk analysis, risk evaluation, risk control and evaluation of residual risks, risk managemment review and production and post-production activities.

In addition, from Annex II to Annex VII, the risks recognized for each device category, are described to be properly addressed via the risk management process. The risks may be related to the design and manufacturing, distribution chain, user-related hazards, microbiology, biocompatibility, patient-related risk, etc. Specific risk control measures to be considered are also described. The Annexes provide deep and useful information that should be considered as the minimum risk and risk mitigation measures to be discussed in the risk management file.

Information for Safety

In addition to the GSPR 23 of the MDR, specific labelling requirements recognized for each category of devices, are described in the annexes of common specifications under (EU) 2022/2346. The requirements are under the form of safety information that are required to be discussed in the labels or instructions for use. Information for users, special warnings or recommendations, contra-indications, lifetime requirements, recognized residual risks, recognized patients side-effects, etc. are identified for each device category.

Clinical Activities

Devices without medical purpose also need to comply with article 61 of the MDR related to the clinical evaluation. The same requirements are applicable to devices with or without medical purpose except the consideration of clinical benefits. Without medical purpose, the devices do not have any clinical benefit. As a result, the requirements applicable to clinical benefits will be understood as a requirement to demonstrate the performance of the device. In addition, the equivalence cannot be demonstrated between Annex XVI devices and devices with a medical purpose whereas equivalence can be justified using devices with dual purposes.