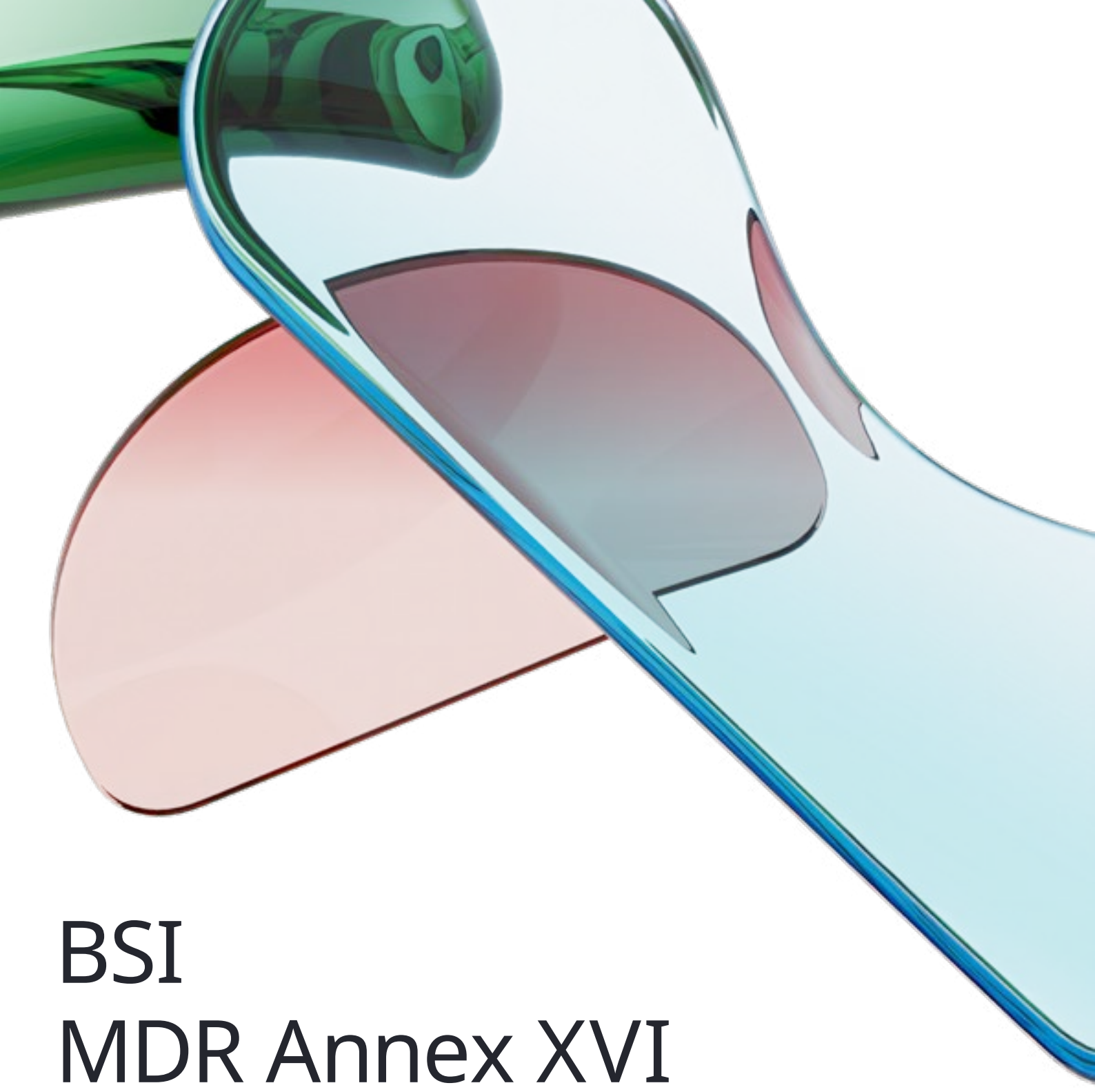

BSI MDR Annex XVI Q&A

Questions and Answers for Products without an intended medical purpose

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What type of products are covered under Annex XVI of the MDR?

There are 6 groups of products without an intended medical purpose covered by Annex XVI.

Annex XVI Group	Examples
Contact lenses or other items intended to be introduced into or onto the eye.	Coloured non-corrective contact lenses
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.	Cosmetic breast implants Calf implants Gluteal implants Absorbable threads
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.	Permanent and resorbable dermal fillers intended for facial or other dermal or mucous membrane filling.
Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.	Cannulas Suction-assisted lipoplasty Equipment for cryolipolysis
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.	IPL/LED/Laser equipment for hair removal only Laser equipment for skin resurfacing LED equipment for skin rejuvenation
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.	Equipment for transcranial electrical stimulation to enhance cognitive performance.

Are Accessories for Annex XVI products covered under MDR and the Common Specification (EU) 2022/2346?

Whilst accessories are not defined in MDR Article 2, MDCG 2023-5 confirms that accessories are covered by the MDR if they fall within the descriptions listed in the Annex XVI and under the scope of the Common Specification (EU) 2022/346. If the item can be used only in combination with an Annex XVI product, it can 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 can 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.

For example, accessories used to assist in the implantation of breast implants for aesthetic indications can be placed on the market together with the breast implant or separately.

Can a manufacturer of non-medical purpose product covered by Annex XVI of MDR get ISO 13845 certification?

A manufacturer of non-medical purpose product can achieve ISO 13485 certification for the products listed in Annex XVI. For products not listed in Annex XVI, as long as the manufacturer can demonstrate that the product qualifies as a 'medical device' in at least one jurisdiction in the world as per the applicable medical device legislations in that jurisdiction, an application of ISO 13485 can be made.

What are the transition provisions for products without an intended medical purpose covered by Annex XVI of the MDR?

The MDR establishes a fixed period of 6 months to allow the implementation of the new applicable requirements laid down in the Common Specification. This period started on 22 December 2022 and ended on 22 June 2023. However, the Common Specification included dedicated transitional provisions to cover the following specific cases:

- When a Notified Body needs to be involved in the conformity assessment procedure
- When the manufacturer considers carrying out a clinical investigation followed by conformity assessment involving a Notified Body
- When the Annex XVI product is covered by an MDD certificate that is expired and is no longer valid pursuant to Article 120(2) of the MDR

Products that need Notified Body certification and the manufacturer intends to carry out a clinical investigation for, will have until 31 December 2029 provided specific conditions are met.

Products that need Notified Body certification and the manufacturer decides not to perform a clinical investigation for, will have until 31 December 2028 provided specific conditions are met.

Annex XVI products that are covered by a valid MDD certificate pursuant to Article 120(2) of the MDR, the transitional provisions established in paragraphs 3, 3a, 3b, 3c, 3d and 3e of Article 120 of the MDR apply. Further information on Article 120 transition provisions can be found in our MDR Transition FAQs and MDR Transition Guidance.

How long would it currently take to engage with BSI for conformity assessment activities for Annex XVI products and how does the length of conformity assessment compare to other devices under MDR?

BSI is a full scope Notified Body and can accept and certify all types of medical devices under the MDR including Annex XVI products. There are no restrictions, and we are accepting applications for all device types including Annex XVI products. Please get in touch with us using General Enquiry | BSI (bsigroup.com) to discuss your Annex XVI certification path.

BSI is the 1st Notified Body to publish capacity and lead times for MDR application and conformity assessments. Current capacity and lead-times can be found on the BSI website.

The length of the conformity assessment process for Annex XVI products is comparable to other similar devices under the MDR.

For dual products (with both medical and non-medical purpose), do they need to be treated separately with their own technical documentation and CE certificate?

There is no need to have two separate sets of Technical Documentation, one for the medical purposes and another for the non-medical purposes respectively, for dual products with both medical and non-medical purposes. However, the technical documentation will need to clearly demonstrate how all elements of the MDR and the Common Specification (EU) 2022/2346 have been met. The Clinical Evaluation Report can be combined or separate, however, should clearly demonstrate the evidence used to demonstrate safety and performance for both the medical and non-medical indications. The requirement for dual purpose devices is to cumulatively meet the requirements of both the MDR and Common Specification.

Are manufacturers of products without a medical purpose expected to follow harmonized standards for MDR?

Where there is a harmonised standard, these can be used as a way of demonstrating compliance to GSPRs. The manufacturers must also follow the Common Specification published for the Annex XVI products. Any standards currently published for a device with medical indications may also be used as a basis for the analogous product without the medical indications (e.g., corrective contact lens standard, mammary implants standard).

What happens if a manufacturer decides that a device does not require a clinical investigation and it is recognised during the conformity assessment process by the NB that the current clinical evidence is not sufficient and additional clinical data/ evidence is required which may require a clinical investigation?

The legal manufacturer needs to determine if there is sufficient clinical evidence for demonstrating the safety and performance of the product for the claimed indications. The Notified Body (NB) reviews and verifies if the data is sufficient to demonstrate safety and performance.

The following guidance is available for manufacturers:

- MDCG 2023-6 Guidance on demonstration of equivalence for Annex XVI products - A guide for manufacturers and notified bodies
- MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices. Background note on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation
- MDCG 2020-5 Guidance on clinical evaluation – Equivalence

Manufacturers may also utilise the process of structured dialogue with the NB to understand in more detail, to the extent possible, requirements related to clinical evidence and clinical evaluation for the products. It is recommended that the manufacturers lodge their applications for Annex XVI products as soon as possible to ensure that there is sufficient transition time left for undertaking a clinical investigation if required.

If a manufacturer has both medical and non-medical indications for a device, is it possible to utilise the clinical data from the medical indication to support the non-medical indications.

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 of clinical investigations or the available clinical evidence relates to the medical device only (for the medical indications). Further guidance is provided in MDCG 2023-6.

Can I provide an electronic IFU (eIFU) for Annex XVI products?

No. Products covered by Annex XVI are excluded from the scope of Regulation (EU) 2021/2226 regarding eIFUs.

Do Annex XVI products qualify for the Clinical Evaluation Consultation Procedure (CECP) as per Article 54 dependent on their classification?

Yes. As per Article 1.2 of MDR, the regulation applies in its entirety, including the requirements related to CECP for devices covered by Annex XVI, based on their classification.

Are Annex XVI products such as dermal fillers (which are class III implantable) exempt from CECP if they are compliant with the published CS (EU) 2022/2346, according to Article 54.2.c of MDR?

Article 54.2.c of MDR provides an exemption from the CECP process only if the clinical evaluation of the subject device complies with a Common Specification that describes the principles of clinical evaluation of that kind of device. The Common Specification (EU) 2022/2346, does not describe the principles of clinical evaluation for Annex XVI products. Hence, compliance with (EU) 2022/2346 does not automatically exempt an Annex XVI product from the CECP process.

Are Annex XVI products such as dermal fillers, breast implants (which are class III implantable) exempt from CECP as per Article 54.2.b of MDR if the same devices were previously placed on the market under the MDD for medical indications?

Article 54.2.b of MDR provides an exemption from CECP if the subject device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose. Since products with non-medical indications were not covered by the scope of MDD, this exemption does not apply to Annex XVI products under the MDR, even if those devices were previously marketed under the MDD for certain medical indications.

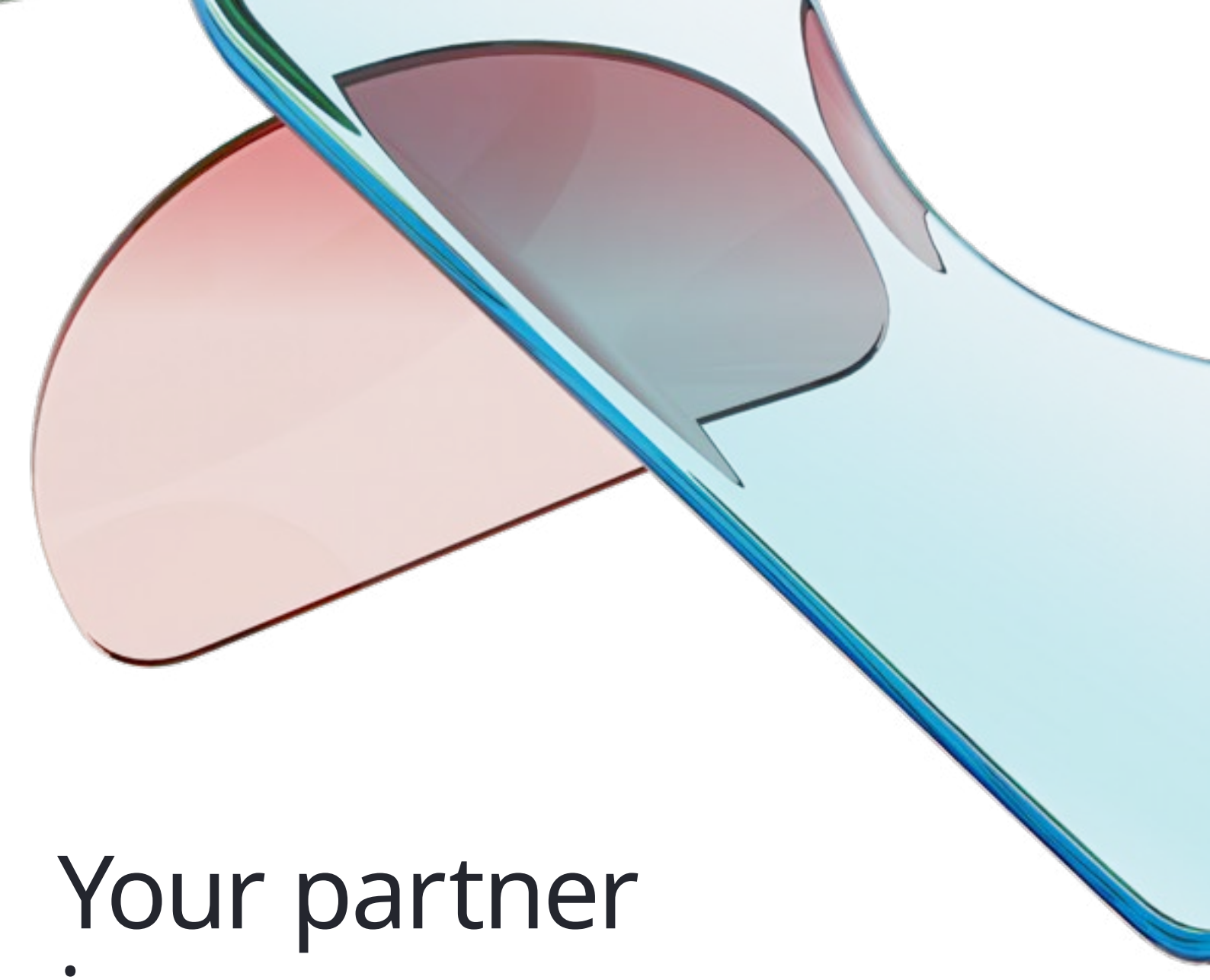
BSI has significant experience of the CECP process for high-risk devices including Class III implantable Annex XVI devices.

Hyaluronic acid in a prefilled syringe (injected intradermally) is intended only for skin hydration and skin quality improvement but does NOT have indication “filling wrinkles/augment tissue”. Will it qualify as Annex XVI product under MDR?

Only devices that fall within the scope of Annex XVI and for which the Common Specification (EU) 2022/2346 applies, can be certified under the MDR. Per MDCG 2023-5, only devices that have an indication for facial or dermal or mucous membrane filling can be certified under MDR.

Does the MDR allow the future addition of new product types to Annex XVI?

As per MDR Article 1.5, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list in Annex XVI, by adding new groups of products in order to protect the health and safety of users or other persons or other aspects of public health.



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