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A BSI white paper

Medical Device Regulation (MDR) - Annex XVI

Devices without an intended medical purpose

Authors

Ester Leoni, Global Regulatory Communications Manager, Regulatory Services, BSI

Rachel Mead, Clinical Regulatory Lead, Regulatory Services, BSI

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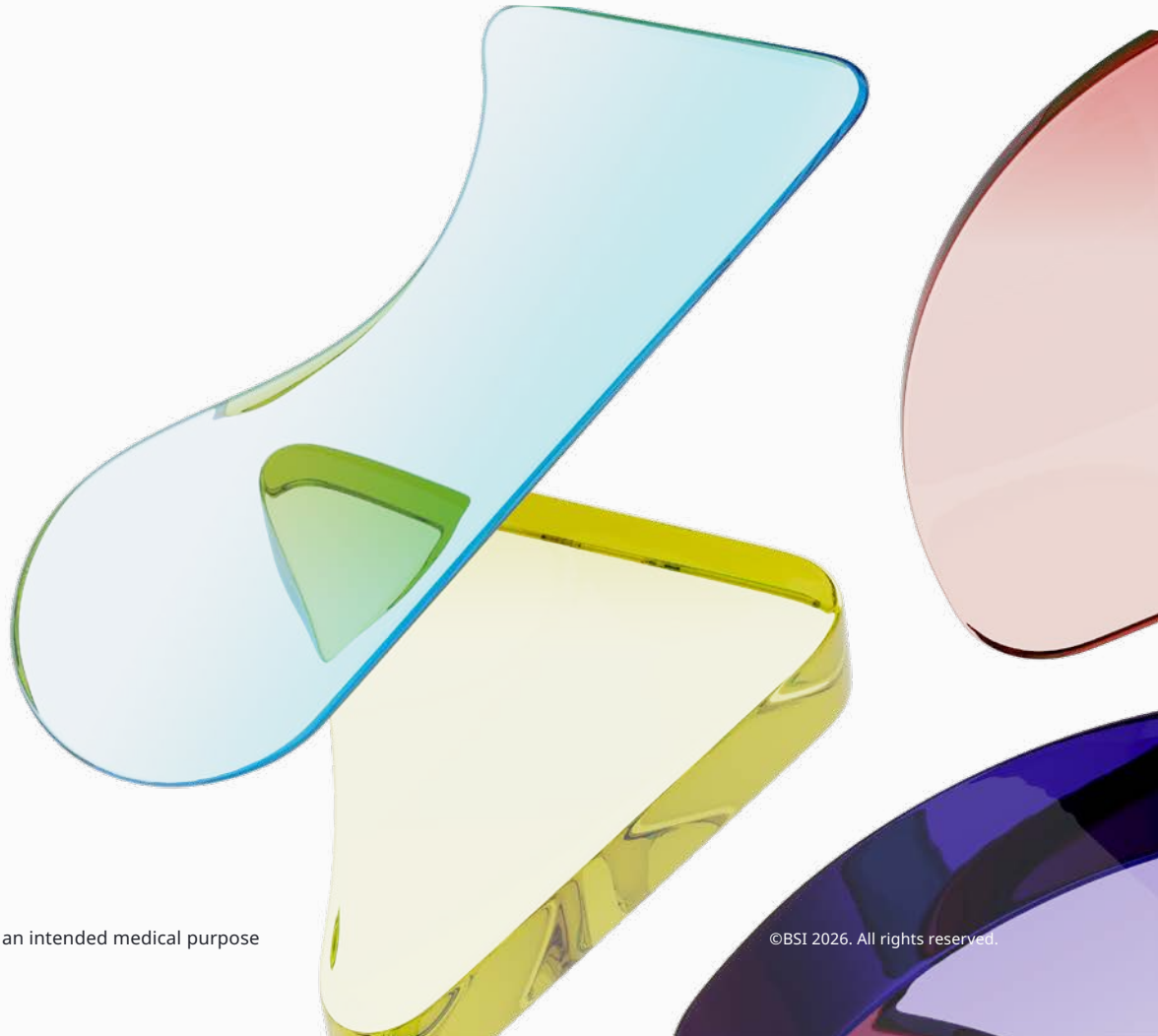

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Introduction to Annex XVI

Adopted in 2017, **the Medical Device Regulation (EU) 2017/745 (MDR)** brought increased scrutiny in several areas such as Technical Documentation, clinical evaluation and post-market clinical follow-up requirements and increased traceability of devices (UDI). Among these changes, due to increasing medical complications caused by the use of certain products for aesthetic purposes and given their similarity to medical devices in terms of functioning, risks profile and application, the MDR expanded its scope to a new group of devices defined as "products without an intended medical purpose". This group of products includes devices used for aesthetic indications and dual use products (i.e., having both medical and non-medical purpose). This group of products is today covered by MDR Annex XVI.

The list of groups of products without an intended purpose according to the MDR, includes:

- Contact lenses or other items intended to be introduced into or onto the eye.
- 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.
- 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.
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
- 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.
- Equipment intended for brain stimulation that apply electrical energy or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

For this group of products, the necessity of Common Specifications (CS) has been established in MDR Article 9.4. Indeed, according to the MDR[1], The common specifications for each of the groups of products listed in Annex XVI shall address, at least, application of risk management as set out in Annex I for the group of products in question and, where necessary, clinical evaluation regarding safety".

[1] The MDR applies only to those devices without an intended purpose listed in Annex XVI for which Common Specifications have been laid down.

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Implementing regulations

On 1 December 2022, CS for Annex XVI devices have been published by the European Commission through **Implementing Regulation (EU) 2022/2346** which entered into force on 22 December 2022. Annex XVI CS started applying 6 months after the enforcing date to allow manufacturers an acceptable amount of time to comply with the new requirements. Starting from 22 June 2023 the MDR officially started to apply to products without an intended medical purpose (Annex XVI) and manufacturers who intend to place on the market a product covered by MDR Annex XVI and by the related CS, shall comply with all applicable requirements there established.

On the same date, the European Commission adopted **Implementing Regulation (EU) 2022/2347** establishing rules for the reclassification of certain active devices now covered by MDR Annex XVI. In particular, the Regulation defines risk classes for active devices covered by points 4, 5 and 6 of Annex XVI.

Risk Class	Type of active device
IIa	Equipment that emits high-intensity electromagnetic radiation intended for use on the human body for skin treatment solely intended for hair removal.
IIb	Equipment intended for use in reducing, removing, or destroying adipose tissue. Equipment that emits high-intensity electromagnetic radiation intended for use on the human body for skin treatment not intended for hair removal.
III	Equipment intended for brain stimulation that applies electric currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Nevertheless, Implementing Regulation (EU) 2022/2346 also came with specific transitional arrangements to allow sufficient time for manufacturers to conduct clinical investigations and to for Notified Bodies to complete conformity assessment activities. The CS also establish transitional arrangements for Annex XVI products certified as medical devices under Directive 93/42/CEE (Medical Device Directive, MDD). On 21 June 2023, the EU Commission published **Implementing Regulation (EU) 2023/1194** amending the transitional provisions laid down in Implementing Regulation (EU) 2022/2346 as regards certain products without an intended medical purpose listed in MDR Annex XVI to align

the transitional provisions set out in the CS to those set out in the amended MDR by **Regulation (EU) 2023/607**.

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Clinical investigations followed by a Notified Body Conformity Assessment

To continue placing on the market a device now covered by Annex XVI through 31 December 2029, the following conditions must be met:

- The device was legally placed on the EU market before 22 June 2023 and continues to comply with the Directive requirements and national law applicable before 22 June 2023.
- There are no significant changes in the design and/or intended purpose.
- From 22 June 2024 until 22 December 2024, the sponsor received from the interested Member State the confirmation that the application for the device clinical investigation is complete and falls under the MDR scope.
- From 23 December 2024, the sponsor initiates the clinical investigation.
- From 1 January 2028 until 31 December 2029, the manufacturer and the Notified Body have signed a written formal agreement for the conformity assessment of that device.

Involvement of a Notified Body in the Conformity Assessment Procedure with no clinical investigation

To continue placing on the market a device now covered by Annex XVI through 31 December 2028, the following conditions must be met:

- The device was legally placed on the EU market before 22 June 2023 and continues to comply with the Directive requirements and national law applicable before 22 June 2023.
- There are no significant changes in the design and/or intended purpose.
- From 1 January 2027 until 31 December 2028, the manufacturer and the Notified Body have signed a written formal agreement for the conformity assessment of that device.

Annex XVI products certified as medical devices by a Notified Body under Directive 93/42/EEC (MDD)

Products covered by Annex XVI and certified by a Notified Body under Directive 93/42/CEE (MDD) must be transitioned to the MDR by the 31 December 2027 or 2028 depending on the risk class of the device. In cases where the 93/42/CEE certificate has expired after 26 May 2021 but before 20 March 2023, and for which the manufacturer has not signed an agreement with a Notified Body in advance of that certificate expiry, nor the manufacturer has received an authorization of derogation according to Art. 59(1) or an exemption according to Art. 97(1), Art. 2(3) of the Implementing Regulation (EU) 2022/2346 establishes that the placing on the market or the putting into service can take place provided the conditions set out in **Regulation (EU) 2023/607** are met. To demonstrate that a device can benefit from transitional arrangements and thus that it can continue to be placed on the market, the manufacturer should be able to provide a self-declaration stating that the conditions laid out in Art. 2 of Implementing Regulation (EU) 2022/2346 are met.

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Breaking down Common Specifications

The role of CS in Annex XVI devices conformity assessment is critical as they provide a harmonized framework guiding manufacturers, while at the same time defining safety and performance requirements their devices must meet. The CS laid down in **(EU) 2022/2346** facilitate in the conformity assessment of Annex XVI devices, covering aspects relating to Risk Management and Information for Safety. Generally, Annex XVI devices follow the conformity procedures laid down in MDR Art. 52 according to the identified risk class of the device. Annex XVI CS consists of VII Annexes. An overview follows here below:

Annex	Topic
I	General requirements for devices covered from Annex II to VII. Including risk management, information for safety, production and post-production activities, labelling and instructions for use.
Risk management specific requirements and safety information for:	
II	Contact lenses without a medical purpose. 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 are not covered by this Annex.
III	Devices intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy. Tattooing products, piercings and products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of fixation of body parts are not covered by this Annex. This Annex does not apply to active implantable devices.
IV	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 listed in Section 3 of Annex XVI. This Annex only applies 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. This Annex does not apply to active devices.
V	Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty. This Annex does not apply to active implantable devices.
VI	High intensity electromagnetic radiation 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 (including skin rejuvenation), tattoo or hair removal (including removal of permanent make-up) or other skin treatment.
VII	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.

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Qualification and classification

Qualification

Although MDR Article 2(1) provides definitions for medical devices and accessories for medical devices, no definition is provided for Annex XVI devices. To determine if a product is covered by the MDR, only the list and descriptions in Annex XVI shall be used. As per MDR Article 9.4, MDR is applicable to Annex XVI as from the date of application of the related CS. 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. All characteristics (i.e., type of product, intended purpose, technology, functioning modalities, target body part, organ, or tissue) mentioned in these provisions should be fulfilled. In case of CS absence for certain products, the MDR does not apply to those products. Similarities to analogous medical devices can be considered as additional guiding principle for qualification. According to MDR recital (12) indeed, Annex XVI products are considered similar to medical devices in terms of functioning and risk profile. Same is reported in Article 1(2) for manufacturers to take into account the state of the art and existing harmonized standards for analogous devices with medical purpose, based on similar technology.

Annex XVI accessories

Although MDR Article 2 does not include a definition for accessories for Annex XVI devices, these are to be considered covered by the MDR when they happen to fall in Annex XVI descriptions and under the scope of the related CS.

An accessory can:

- Be marketed together with an Annex XVI product and being considered as piece of that product, when to be used only in combination with that product.
- Be marketed on its own as Annex XVI product, or paired with other Annex XVI compatible products, when that accessory can be utilized on its own or in combination with other Annex XVI products.

Annex XVI dual-purpose devices

According to MDR Article 1(3), “devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose”. In case CS requirements may differ from MDR requirements, the applicable shall always be considered the most stringent requirements. It is possible to separately apply MDR and CS requirements to dual purposes which are never achieved simultaneously. However, certain requirements are to be considered also in combination considering the use effects that may occur depending on the two intended purposes interaction.

Annex XVI multiple intended purposes

Annex XVI products are differentiated in terms of characteristics and intended purpose. As guiding principle, every product should fall in only one of the six groups listed in Annex XVI. Although rare, in case a product happens to fall in two or more groups, as per intended purpose and characteristics, the CS requirements for all the groups the product results to fall into shall be applied cumulatively.

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Classification

Only products that qualify as devices and that are covered by the CS and by the MDR, should be classified according to MDR Annex VIII rules and to Regulation (EU) 2022/2347 (for certain active medical devices without an intended medical purpose). Manufacturers should also consider MDCG 2021-24 and MDCG 2023-5. Additional relevant information may also be found in the Manual of borderline and classification for medical devices and in MDCG 2022-5. When classifying dual-purpose devices, medical and non-medical purpose should both be taken into consideration. In case multiple rules or sub-rules apply, the strictest rule leading to higher classification, apply. Here below follows a table summarizing the classification criteria to be considered for Annex XVI product groups.

Annex XVI group	Device class	MDR Rule*
1	IIa, IIb	5
2	IIb, III	8
3	IIb III	8 8, 14
4	I IIa IIb	1, 6 6 See (EU) 2022/2347 Art 1(b)
5	IIa, IIb	See (EU) 2022/2347 Art 1(a)
6	III	See (EU) 2022/2347 Art 1(c)

* Unless specified otherwise.

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Borderline products and the applicability of other EU legislation

As stated in the section above, the MDR is only applicable to devices without an intended medical purpose if they are listed in Annex XVI - more specifically, to those devices for which a CS exists. Where there is uncertainty as to whether a product falls within the Annex XVI descriptions, the guidance in MDCG 2023-5 should be considered, particularly sections 3.5-3.6, which provide clarification of terms used in Annex XVI as well as examples of products that do not qualify as Annex XVI products, yet are not explicitly excluded by the MDR nor the CS.

Note that the guidance in MDCG 2023-5 explicitly excludes mesotherapy products from Annex XVI if these are not used for dermal/facial/other mucous membrane filling purposes (refer to section 3.6). Manufacturers of dermal fillers should be aware that claims relating to mesotherapy products that are not associated with dermal fillers are not admissible under Annex XVI of the MDR.

Some devices covered by Annex XVI may administer a medicinal product per the definition in Article 1 of Directive 2001/83/EC. However, the guidance presented in MDCG 2023-5 makes clear that in the case of dermal fillers incorporating anesthetics (or other substance which, if used separately, can be considered a medicinal medicinal product and that has an action ancillary to that of the devices), Rule 14 of the MDR applies.

Products that fall outside of the MDR altogether may still be subject to other EU legislation: MDCG 2023-5 refers to the Blue Guide on the implementation of EU product rules, 2022, which explains EU product rules and their application across different sectors within the single market. Other guidance documents are available also.

The Manual on Borderline and Classification under MDR and IVDR issued on September 2023, for example, in section 1.1.5 ‘Borderline between medical devices and cosmetic products’, refers to Regulation (EC) No 1223/2009 on cosmetic products, which may apply to some borderline products that are not covered by Annex XVI of the MDR.

Where a product has both a medical intended purpose and a non-medical intended purpose that falls outside of Annex XVI of the MDR, only the aspects relating to the medical intended purpose are subject to conformity assessment by the Notified Body. Therefore, its certification under the MDR and the placing of the CE mark on the device is in respect of its medical intended purpose only.

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Claiming equivalence

Conducting a clinical investigation is the most direct method to generate clinical data on general safety and performance requirements (GSPR) of a particular medical device. However, for the purpose of CE marking, clinical data can also be sourced from another medical device (with similar intended purpose and use) to which equivalence shall be demonstrated according to MDR requirements. As per Regulation (EU) 2022/2346, it is not possible to demonstrate equivalence between a medical device and an Annex XVI product in case all available clinical investigations relate only to the medical device. In such instance, clinical investigations should be conducted for products without an intended medical purpose.

Here below follows a series of cases covering demonstration of equivalence under the MDR through data based on already existing devices applicable to Annex XVI products covered by CS. For claiming equivalence purposes, manufacturers are encouraged to also consider MDCG 2020-5 and MDCG 2023-6.

Products without an intended medical purpose vs product without an intended medical purpose

- Equivalence should be demonstrated in accordance with MDR established criteria (i.e., technical, biological and clinical).
- For clinical characteristics it must be noted that some of them specifically refer to a medical purpose.

Product without an intended medical purpose vs similar medical device

- Comparison is not possible as not all clinical characteristics can be compared (i.e., severity and stage of disease).

Product without an intended medical purpose vs dual-purpose device

- Equivalence should be demonstrated comparing characteristics related to the non-medical purpose for both devices.
- Only characteristics for non-medical purpose pertaining to the dual-purpose device should be considered.
- If equivalence is demonstrated, only GSPR clinical data of the dual-purpose device applicable to the non-medical purpose should be used for the clinical evaluation of the product without an intended medical purpose.

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Clinical Evaluation Consultation Procedure

In section 5.1 of Annex IX of the MDR, described is an additional procedure that applies specifically to the conformity assessment of devices which fall into either of the following categories:

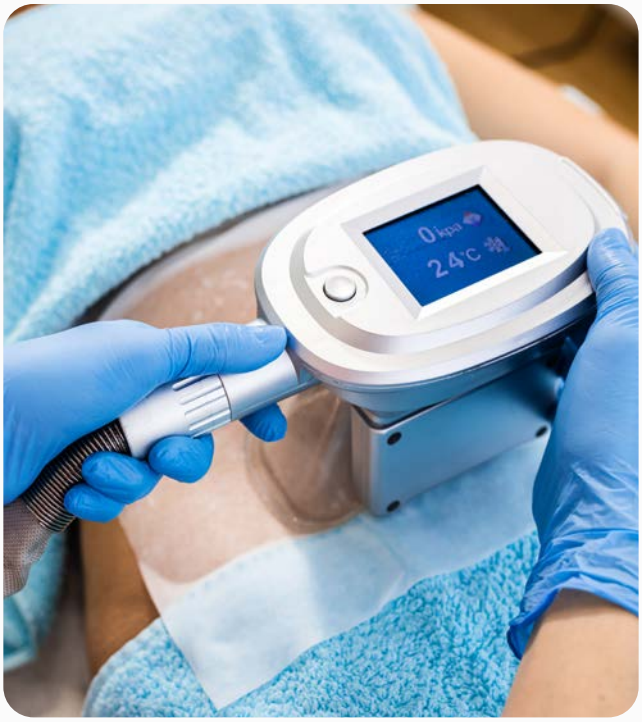
- Class III implantable devices.
- Class IIb active devices intended to administer and/or remove a medicinal product (as per Section 6.4 of Annex VIII - Rule 12).

The procedure is defined under Article 54 as the Clinical Evaluation Consultation Procedure (CECP). This article also lists its exemptions.

When assessing devices that fall into the above categories, to fulfil the requirements of the CECP, the Notified Body is required to submit to the EU Commission a Clinical Evaluation Assessment Report (CEAR)[2], presenting conclusions on the clinical evidence provided in the manufacturer's clinical evaluation report. The EU Commission then transmits the CEAR, along with the manufacturer's clinical evaluation documentation, to a relevant expert panel. The expert panel reviews the documentation and decides whether to provide a scientific opinion on the Clinical Evaluation Assessment Report prepared by the Notified Body. Where provided, the scientific opinion is duly considered by the Notified Body within the overall conformity assessment of the device.

The decision to provide a scientific opinion is based on three criteria that are listed in Section 5.1(c) of Annex IX. Although items (i) and (ii) of the list in Section 5.1(c) of Annex IX refer to clinical aspects of a device, for example 'clinical procedure' or 'benefit-risk profile', the CECP nevertheless applies in the case of devices falling under Annex XVI and within the categories listed above.

The list of exemptions in Article 54(2)(c) refers to devices for which it is confirmed that the clinical



evaluation complies with a relevant CS. However, the CS for Annex XVI devices published in Implementing Regulation (EU) 2022/2346 covers aspects relating to the application of risk management but does not cover the clinical evaluation of the device. This means that, at present, Annex XVI devices are not exempted from the CECP under Article 54(2)(c).

A device that has already been placed on the EU market and that is now regulated under MDR Annex XVI may be subject to the CECP. A device that has already been placed on the EU market under the MDD/AIMDD (i.e., legacy device), which has dual use, may be exempt from the CECP in respect of the medical intended purpose but not exempt in respect of the non-medical intended purpose; since there is a change to the intended purpose, the exemptions in Article 54(2) do not apply. Therefore, legacy medical devices that now include a non-medical intended purpose under MDR Annex XVI, will be subject to the CECP in respect to the non-medical intended purpose.

[2] After the Notified Body submits the documentation, two weeks are required for administrative processes. The Commission will then take 21 days to express on the need for a scientific opinion. If needed, 39 days will be required to provide the scientific opinion.

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Conclusion

Despite Annex XVI devices transition to new regulations and requirements may be challenging given the obligation to comply with stringent guidelines, possible changes in design, manufacturing and testing processes, the adoption of the CS comes with several benefits. The CS support Annex XVI devices compliance with the stricter MDR safety and performance requirements. They also enhance transparency and predictability in the MedTech sector through harmonization, increasing at the same time, consumer's safety, and trust in these devices. Given the complexities related to Annex XVI devices, for manufacturers, above all for SMEs (small and medium enterprises) and start-ups, it is critical to work with a Notified Body which offers world-leading expertise and experience in certifying devices that fall under Annex XVI. Importantly, it is critical to ensure timeliness in any application for certification, especially where there may be questions as to the applicability of Annex XVI (for example, in borderline cases). Also, where a manufacturer was already placing a device on the market that now falls under Annex XVI of the MDR, it is essential that their obligations as a manufacturer, and the timelines for meeting them, are fully understood.

BSI publishes a number of resources that provide guidance on the certification process and support in navigating the regulatory complexities of the MedTech Sector. To know more, **visit our website**.

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Why choose BSI?

- World-leading experience and expertise.
- Accepting Annex XVI applications since December 2022.
- Already issued 6 Annex XVI certificates to date.
- > 60 ongoing conformity assessment applications to date for dermal filling, breast augmentation, lipoplasty, body-sculpting, contact lenses, laser hair removal, dermal abrasion and facelift procedures.

Annex XVI certification process with BSI:

- Quotation & contract review.
- Quality Management System Audit.
- Microbiology Audit.
- Technical Documentation review.
- Annex XVI CS review.
- Micro/biologic/medicinal technical reviews.
- Biological/medicinal consultation (if needed).
- CECP for Class III implantable devices (if needed).
- BSI Scheme Manager submits recommendation to BSI Panel for MDR certification.
- Panel review and approval.
- Certificate issued.

BSI is accepting Annex XVI applications
Talk to us

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References and guidance

Legislation and Guidance	Focus
Medical Device Regulation (EU) 2017/745	Medical devices.
Implementing Regulation (EU) 2022/2346	Common Specifications for Annex XVI devices.
Implementing Regulation (EU) 2023/1194	Amendment to (EU) 2022/2346.
Implementing Regulation (EU) 2022/2347	Reclassification of groups of certain active products without an intended medical purpose.
Directive 2001/83/EC	Community code relating to medicinal products for human use.
European Cosmetics Regulation (EC) No 1223/2009	Cosmetic products, which may apply to some borderline products that are not covered by Annex XVI of the MDR.
Manufacturers of devices without and intended medical purpose	European Commission webpage dedicated to Annex XVI devices.
Q&A on transitional provisions for products without an intended medical purpose covered by Annex XVI of the MDR	Implementation of transitional arrangements.
MDCG 2021-24, Guidance on classification of medical devices	Classification rules according to MDR Annex VIII.
MDCG 2023-5, Guidance on qualification and classification of Annex XVI products	Qualification and classification.
MDCG 2023-6, Guidance on demonstration of equivalence for Annex XVI products	Application on equivalence criteria.
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	Support tool for case-by-case application.
MDCG 2022-5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices	Medical devices and medicinal products under the MDR.
MDCG 2020-5 Clinical Evaluation – Equivalence. A guide for manufacturers and notified bodies	Differences between the MDR and MEDDEV 2.7/1 rev. 4.
Blue Guide on the implementation of the product rules	EU product rules and their application across different sectors within the single market.

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BSI Assurance UK Ltd (0086)
Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

BSI Group America Inc.
150 Opportunity Way,
Suite 900
Reston, VA 20190
USA

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn

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