Devices With No Medical Purpose

“MDR Annex XVI Devices”

Neill Bannister, *Global Head, BSI General Devices Team*

Nick Trilokekar, Ph.D., *Team Manager, BSI General Devices Team*

17th. April 2024

Contents

**Information presented within this webinar is based on current understanding of the Regulation and is subject to change.*

Regulation EU 2017/745
MDR – Annex XVI
05 Apr 2017

Devices without an intended medical purpose:

- Similar to medical devices (functioning and risk profile).
- Annex XVI - list of devices covered (6 groups)
- Article 2(71) – Introduces ’Common Specifications’
- Compliance with Common Specifications (CS)
- If device has a medical and non-medical purpose - fulfil the requirements of both!

Regulation EU 2017/745 – Annex XVI

Annex XVI Group	Examples
1. Contact lenses or other items intended to be introduced into/onto the eye	Coloured contact lenses 
2. Introduced into the body for the purpose of modifying the anatomy or fixation of body parts	Cosmetic breast implants, chin, malar, calf implants, etc. 
3. Substances intended to be used for dermal filling	Dermal Fillers 
4. Equipment intended to be used to reduce, remove or destroy adipose tissue	Laser /Cryogenic/ Ultrasound 
5. Lasers and IPL equipment, for skin resurfacing, tattoo or hair removal or other skin treatment	Hair removal, aesthetic lasers /equipment 
6. Equipment intended for brain stimulation	Transcranial stimulation (non-invasive)

Common Specifications

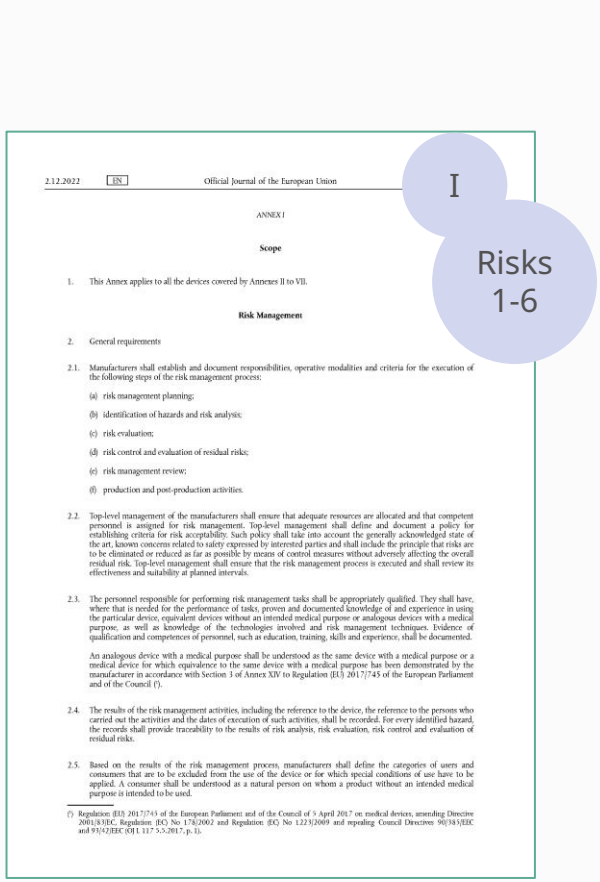
BSI could not certify Annex XVI Devices until publication of CS

Implementing Regulations

1. (EU) 2022/2346 – December 2022:
   - **Common Specifications**
2. (EU) 2022/2347 – December 2022:
   - **Reclassification of certain active products**
3. (EU) 2023/1194 – June 2023:
   - **Transitional provisions for Annex XVI devices**
4. Q&A on transitional provisions for products without an intended medical purpose covered by Annex XVI of the MDR (September 2023)

© 2024 BSI. All rights reserved.

Common Specification Publications



2.12.2022 EN Official Journal of the European Union

ANNEX I

Scope

1. This Annex applies to all the devices covered by Annexes II to VII.

Risk Management

2. General requirements

2.1. Manufacturers shall establish and document responsibilities, operative modalities and criteria for the execution of the following steps of the risk management process:

(a) risk management planning;

(b) identification of hazards and risk analysis;

(c) risk evaluation;

(d) risk control and evaluation of residual risks;

(e) risk management review;

(f) production and post-production activities.

2.2. Top-level management of the manufacturers shall ensure that adequate resources are allocated and that competent personnel is assigned for risk management. Top-level management shall define and document a policy for establishing criteria for risk acceptability. Such policy shall take into account the generally acknowledged state of the art, known concerns related to safety expressed by interested parties and shall include the principle that risks are to be eliminated or reduced as far as possible by means of control measures without adversely affecting the overall residual risk. Top-level management shall ensure that the risk management process is executed and shall review its effectiveness and suitability at planned intervals.

2.3. The personnel responsible for performing risk management tasks shall be appropriately qualified. They shall have, where that is needed for the performance of tasks, proven and documented knowledge of and experience in using the particular device, equivalent devices without an intended medical purpose or analogous devices with a medical purpose, as well as knowledge of the technologies involved and risk management techniques. Evidence of qualification and competences of personnel, such as education, training, skills and experience, shall be documented.

An analogous device with a medical purpose shall be understood as the same device with a medical purpose or a medical device for which equivalence to the same device with a medical purpose has been demonstrated by the manufacturer in accordance with Section 3 of Annex XIV to Regulation (EU) 2017/745 of the European Parliament and of the Council (1).

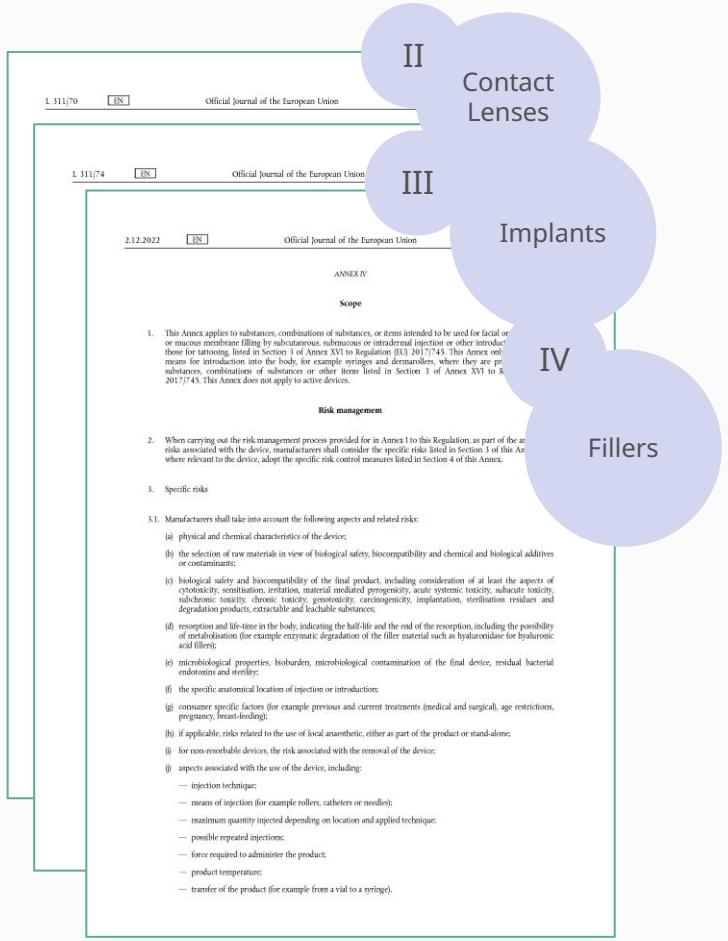
2.4. The results of the risk management activities, including the reference to the device, the reference to the persons who carried out the activities and the dates of execution of such activities, shall be recorded. For every identified hazard, the records shall provide traceability to the results of risk analysis, risk evaluation, risk control and evaluation of residual risks.

2.5. Based on the results of the risk management process, manufacturers shall define the categories of users and consumers that are to be excluded from the use of the device or for which special conditions of use have to be applied. A consumer shall be understood as a natural person on whom a product without an intended medical purpose is intended to be used.

(1) 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 (OJ L 117 5.5.2017, p. 1).

I

Risks 1-6



L 311/70 EN Official Journal of the European Union

L 311/74 EN Official Journal of the European Union

2.12.2022 EN Official Journal of the European Union

ANNEX IV

Scope

1. This Annex applies to substances, combinations of substances, or items intended to be used for facial or or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduc those for tattooing, listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. This Annex onl means for introduction into the body, for example syringes and dermarollers, where they are pr substances, combinations of substances or other items listed in Section 3 of Annex XVI to R 2017/745. This Annex does not apply to active devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the ar risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this An where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. Manufacturers shall take into account the following aspects and related risks:

(a) physical and chemical characteristics of the device;

(b) the selection of raw materials in view of biological safety, biocompatibility and chemical and biological additives or contaminants;

(c) biological safety and biocompatibility of the final product, including consideration of at least the aspects of cytotoxicity, sensitisation, irritation, material mediated pirogenicity, acute systemic toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, implantation, sterilisation residues and degradation products, extractable and leachable substances;

(d) resorption and life-time in the body, indicating the half-life and the end of the resorption, including the possibility of metabolisation (for example enzymatic degradation of the filler material such as hyaluronidase for hyaluronic acid fillers);

(e) microbiological properties, bioburden, microbiological contamination of the final device, residual bacterial endotoxins and sterility;

(f) the specific anatomical location of injection or introduction;

(g) consumer specific factors (for example previous and current treatments (medical and surgical), age restrictions, pregnancy, breast-feeding);

(h) if applicable, risks related to the use of local anaesthetic, either as part of the product or stand-alone;

(i) for non-resorbable devices, the risk associated with the removal of the device;

(j) aspects associated with the use of the device, including:

— injection technique;

— means of injection (for example rollers, catheters or needles);

— maximum quantity injected depending on location and applied technique;

— possible repeated injections;

— force required to administer the product;

— product temperature;

— transfer of the product (for example from a vial to a syringe).

II

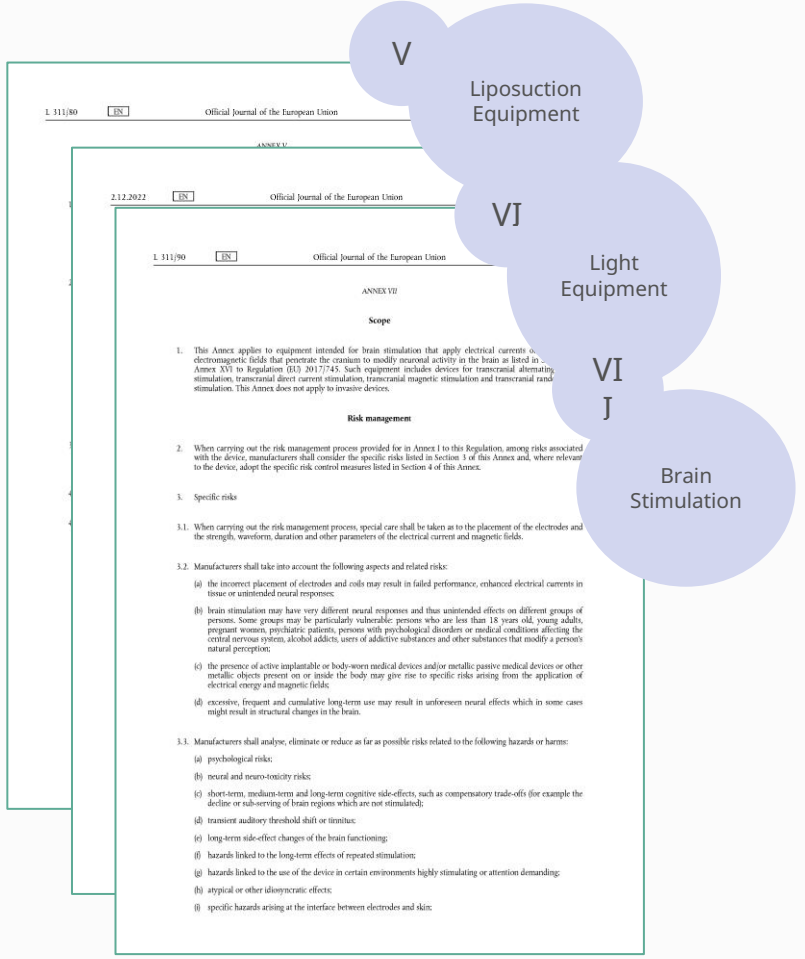
Contact Lenses

III

Implants

IV

Fillers



L 311/80 EN Official Journal of the European Union

ANNEX V

2.12.2022 EN Official Journal of the European Union

L 311/90 EN Official Journal of the European Union

ANNEX VII

Scope

1. This Annex applies to equipment intended for brain stimulation that apply electrical currents a electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as listed in Annex XVI to Regulation (EU) 2017/745. Such equipment includes devices for transcranial alternating stimulation, transcranial direct current stimulation, transcranial magnetic stimulation and transcranial rand stimulation. This Annex does not apply to invasive devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, among risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. When carrying out the risk management process, special care shall be taken as to the placement of the electrodes and the strength, waveform, duration and other parameters of the electrical current and magnetic fields.

3.2. Manufacturers shall take into account the following aspects and related risks:

(a) the incorrect placement of electrodes and coils may result in failed performance, enhanced electrical currents in tissue or unintended neural responses;

(b) brain stimulation may have very different neural responses and thus unintended effects on different groups of persons. Some groups may be particularly vulnerable: persons who are less than 18 years old, young adults, pregnant women, psychiatric patients, persons with psychological disorders or medical conditions affecting the central nervous system, alcohol addicts, users of addictive substances and other substances that modify a person's natural perception;

(c) the presence of active implantable or body-worn medical devices and/or metallic passive medical devices or other metallic objects present on or inside the body may give rise to specific risks arising from the application of electrical energy and magnetic fields;

(d) excessive, frequent and cumulative long-term use may result in unforeseen neural effects which in some cases might result in structural changes in the brain.

3.3. Manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) psychological risks;

(b) neural and neuro-toxicity risks;

(c) short-term, medium-term and long-term cognitive side-effects, such as compensatory trade-offs (for example the decline or sub-serving of brain regions which are not stimulated);

(d) transient auditory threshold shift or tinnitus;

(e) long-term side-effect changes of the brain functioning;

(f) hazards linked to the long-term effects of repeated stimulation;

(g) hazards linked to the use of the device in certain environments highly stimulating or attention demanding;

(h) atypical or other idiosyncratic effects;

(i) specific hazards arising at the interface between electrodes and skin;

V

Liposuction Equipment

VI

Light Equipment

VI J

Brain Stimulation

Transitional Provisions –Common Specifications (EU) 2022/2346

Article 2 Amendments:

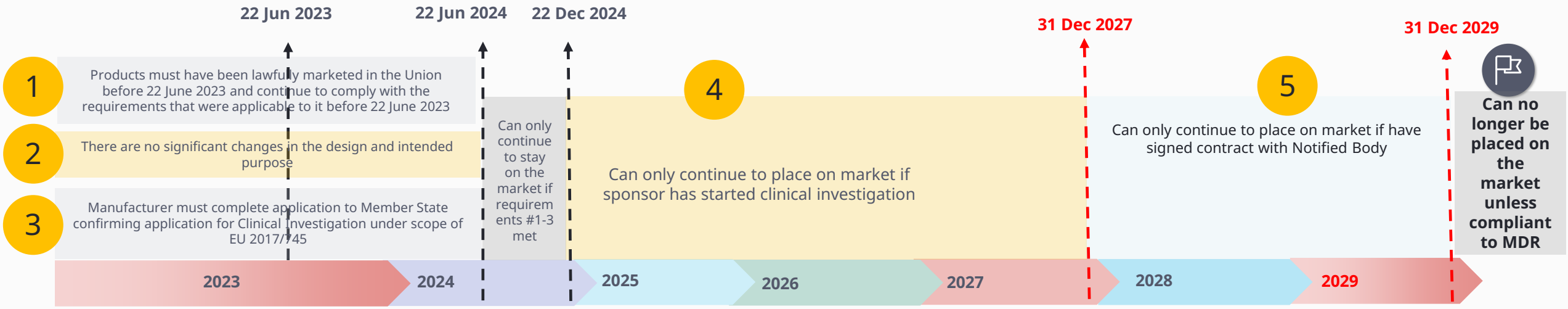
(EU) 2023/1194 of 20 June 2023:

—

Amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for products listed in Annex XVI

Transitional Provisions - Amendment (EU 2023/1194) - Reg. (EU) 2017/745 Article 2.1

Manufacturers conducting a Clinical Investigation can place on the market or put into service **until 31 Dec 2029** if:



Transitional Provisions - Amendment (EU 2023/1194) - Reg. (EU) 2017/745 Article 2.2

Manufacturer **not** conducting Clinical Investigations can continue to place on market or put into service **until 31 Dec 2028** if:

Transitional Provisions - Amendment (EU 2023/1194) - Reg. (EU) 2017/745 Article 2.3

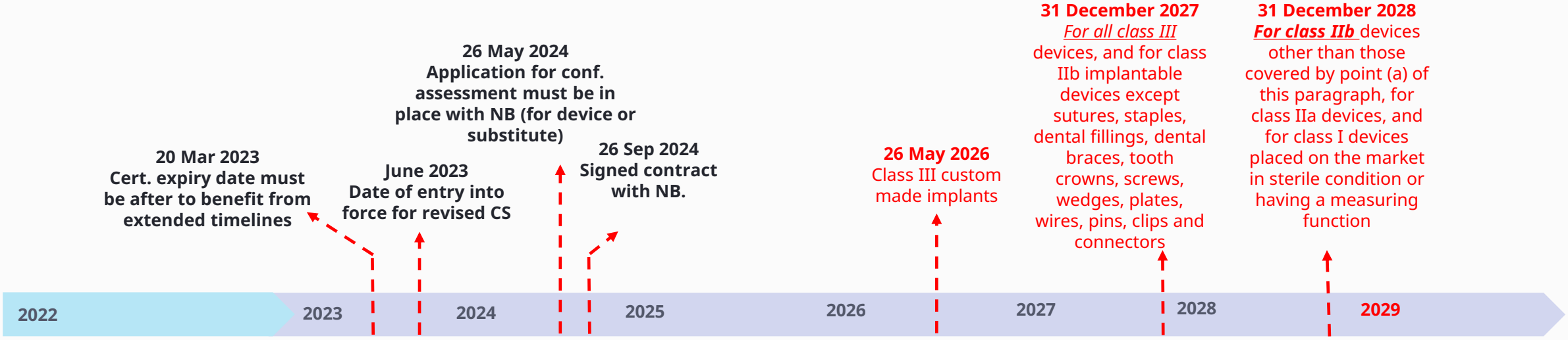
2 SCENARIOS:

1) 1) Certs from 25 May 2017 that were still valid on 26 May 2021 and have expired before 20 Mar 2023 remain valid until same dates on Para 3a of Art 120 based on risk class only if one of the following conditions is met:

(a)
before the date of expiry, the Mfr. and a NB have signed a written agreement (contract) in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

(b)
a derogation is in place under Article 59(1) or Article 97(1)

2) Products covered by certs issued from 25 May 2017 that were still valid on 26 May 2021 and have not expired as of 20 Mar 2023 (and no Derogation or MDR Contract with NB) based on risk class must follow (EU) 2023/607 transitional provisions for Medical Devices.



Guidance Documents Published

Guidance Documents

- MDCG 2023-5:

Qualification and Classification of Ann XVI Devices

- MDCG 2023-6:

Demonstration of Equivalence for Ann XVI Devices

MDCG 2023-5: Guidance on qualification and classification of Annex XVI products

Clarifications

Accessories: not defined in MDR Article 2

- If only in combination with Annex XVI product, it could be placed on the market together.
- If 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 compatible Annex XVI products.

Dual Purpose Devices:

- Must fulfil requirements applicable to devices with an intended medical purpose and without an intended medical purpose.
- Risk control measures, should be considered in combination.
- Measures taken for one intended purpose could generate effects on the use according to the other intended purpose.

Multiple intended purpose devices

- in principle, every product should fall only in one of the 6 groups listed in the Annex XVI to the MDR.
- If not, then CS of each group will apply.

MDCG 2023-5: Guidance on qualification and classification of Annex XVI products

Reclassification of Active Devices

(EU) 2022/2347 has re-classified certain Active devices without a medical purpose

- High intensity electromagnetic radiation emitting equipment for skin treatment - reclassified as Class IIb,
- unless intended for hair removal only in which case - Class IIa
- Equipment to reduce, remove or destroy adipose tissue - reclassified as Class IIb
- Brain stimulation devices apply electric currents/magnetic or electromagnetic fields that penetrate the cranium are reclassified as class III

MDCG 2023-6: Guidance on demonstration of equivalence for Annex XVI products

"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 relate to medical devices only. Therefore, clinical investigations should be performed for products without an intended medical purpose.."

Without intended medical purpose vs without intended medical purpose

- Equivalence per MDR criteria
- Used for same ~~**clinical**~~ purpose
- "in view of the expected ~~**clinical**~~ effect for a specific intended purpose"
- similar population, anatomy, age, physiology - applicable

Without an intended medical purpose vs Analogous MD

- Generally, not possible
- All clinical aspects not comparable
- 'similar severity and stage of disease' does not apply

Without an intended medical purpose vs Dual-purpose device

- Demonstrated comparing the characteristics related to the non-medical purpose for both
- Only clinical data of the dual-purpose device related to the GSPRs applicable for the non-medical purpose should be used for the clinical evaluation

Devices with No Medical Purpose

Additional Conformity Considerations - 1

Harmonised Standards

E.g. corrective contact lens standard, breast implant standard

SSCP

Per Art. 32 for Class III or Implantable Annex XVI devices

PSUR

Periodic Safety Update Report per Article 86

CECP

Clinical Evaluation Consultation Procedure - Class III implantable devices

eIFU Reg. 2021/2226

Does not cover products listed in Annex XVI of MDR

Labelling / IFU

Requirements for Ann. XVI Device groups- EU 2022/2346

Devices with No Medical Purpose

Additional Conformity Considerations - 2

CA Consultations

Needed for devices with medicinal substances or animal tissue in design/mfr.

Medicinal Substances

Device with medicinal substance ≠ device without medicinal substance

Clinical Eval. & Clinical Invest.

Should follow MDR Chapter VI and Annex XIV

“Clinical benefit “ - None

A requirement to demonstrate performance and safety of the device

MD vs Ann. XVI Equivalence

If clinical data relates to MD only, in this case clinical investigation should be performed for non-medical

Clinical Eval. Conclusion!

Is there sufficient clinical evidence for claimed device indications ?

- Need Clinical Investigation

BSI MDR Process

Application for Annex XVI Device:

- BSI Quotation & Contract Review
- Quality System Audit
- Microbiology audit
- TD review durations per Device Classification
- Ann XVI CS review
- Micro/Biologic/Medicinal Technical Reviews &
- Biologic/Medicinal Consultations if needed
- CECP (Class III Implants)

Conformity Assessment Process:

- Successful completion of :
  - QMS & Microbiology audits
  - Technical Documentation Reviews
  - Consultations (if needed)
  - CECP (if needed)

Certification Process:

- BSI Scheme Manager submits recommendation to BSI Panel for MDR certification
- Panel review and approval
- Certificate Issued

Certification of MDR Annex XVI products

BSI Experience

- BSI has certified Dermal Fillers and Breast Implants with cosmetic indications.
- Annex XVI Implant devices sent to CECP panels.
- Panels – No Opinion offered (not novel or new health or clinical risks)
- Feedback to BSI on IFU recommendations/warnings, PMCF follow up durations and state of the art comments.
- Ongoing reviews include other dermal fillers, breast implants and devices for lipoplasty, body-sculpting, contact lenses, laser hair removal, dermal abrasion, facelift procedures.

"

BSI has internal SME/Clinical/QMS expertise and capacity to accept Annex XVI Device Applications

-*Request a quote today*

For more information visit our website, here

Thank you!

BSI Group

389 Chiswick High Road

London, W4 4AL

+44 345 080 9000

bsigroup.com