Navigating MDR Annex XVI for Non-Medical Products

“Devices with no medical purpose”: Dermal Fillers

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14th May 2024

Our Speakers today

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Contents

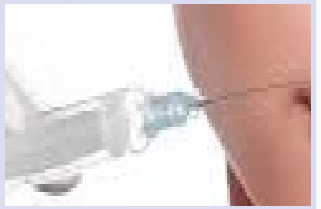
**Information presented within this webinar is based on current understanding of the Regulation and is subject to change.*

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, calf implants, etc.
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.	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

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)

Transitional Provisions – Annex XVI Devices

(EU) 2023/1194 of 20 June 2023, Article 2 Amendments:

Amending Implementing Reg. (EU) 2022/2346 as regards the transitional provisions for Annex XVI products

Article 2.1:

Conducting Clinical Investigation

- Lawfully marketed before 22 Jun 2023 and continue to comply with requirements.
- No significant change in design or intended purpose.
- Application to CA for Clinical. Investigation under scope of MDR (22 Jun 2024).
- Stay on market if started clinical investigation (22 Dec 2024)
- Stay on market if contract with NB (31 Dec 2027)
- Compliant to MDR by 31 Dec 2029

Article 2.2:

Not Conducting Clinical Investigation

Continue to place on market until 31 Dec 2026 if:

- Lawfully marketed before 22 Jun 2023 and continue to comply with requirements.
- No significant change in design or intended purpose.
- Stay on market after 31 Dec 2026 if signed MDR contract with NB.
- Compliant to MDR by 31 Dec 2028.

Article 2.3:

Two Scenarios

1. Valid from 25 May 2017- 26 May 2021 & expired before 20 Mar 2023.

- Class III, Class IIb implant (except WET) – 31 Dec 2027
- Class IIb (other), Class IIa, Class Is/Im - 31 Dec 2028

Conditions:

Before expiry, written contract w NB, Or Derogation under Art. 59(1) or Art. 97(1)

2. Not Expired as of 20 Mar 2023: Dates above

- MDR Application w NB 26 May 2024
- Contract w NB signed 26 Sep 2024

What are Dermal Fillers?

- **MDR Annex XVI- Group 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.

- **Also known as:**
  - Injectable implants,
  - Soft tissue fillers,
  - Wrinkle fillers

Uses: Facial volumizing, Smoothen wrinkles/fine lines/folds

Directives: Medical purpose - treatment of facial Lipoatrophy in HIV patients on antiretroviral therapies.

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

- Permanent Dermal Fillers (Class IIb)
- Resorbable Dermal Fillers (Class III)
- Mesotherapy products for filling (only)

Products that don't qualify: (Non-fillers)

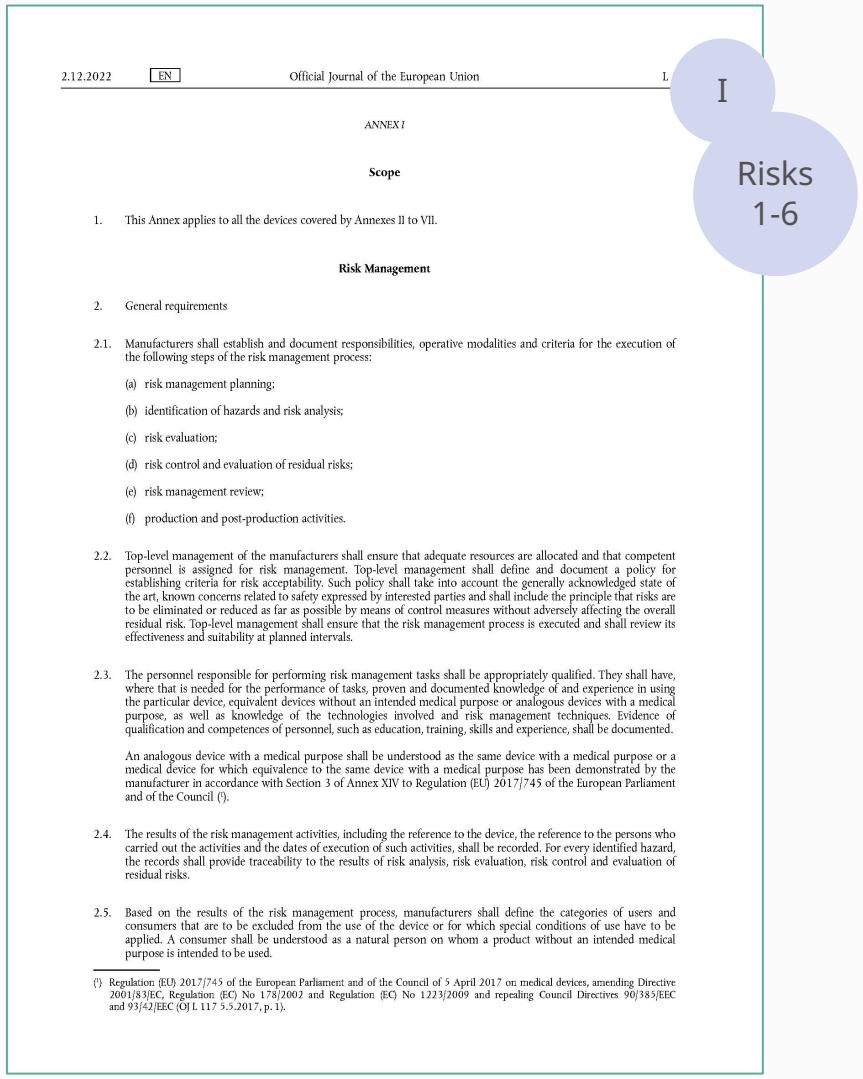
- Mesotherapy products such as those used for biorevitalization, biorejuvenation, poly-revitalizing, hydration of dermis, collagen synthesis, fibroblast stimulation, skin radiance, free radical elimination
- Serums or creams after filler treatment

Dermal Fillers and Accessories

European Medical Device Nomenclature (EMDN)

Device Codes	Device Types (examples)	Features
P900402 – Resorbable Filling and Reconstruction devices	Dermal Filler – Hyaluronic acid (HA)	• Variants differ in HA concentration, crosslink density, molecular wt. etc. • Animal or Recombinant source • With or Without Lidocaine
	Dermal Filler – Calcium hydroxyapatite (CaHA)	Particles suspended in gel carrier
	Dermal Filler – Poly-L-lactic acid	Particles suspended in gel carrier
	Dermal Filler - Collagen	Allergic reactions (Bovine)
P900403 – Non-Resorbable Filling and Reconstruction Devices	Dermal Filler - Polymethylmethacrylate (PMMA)	Particles suspended in gel carrier
Accessories: A01010101 HYPODERMIC NEEDLES FOR SYRINGE	• Hypodermic Needle • Cannula	Available in different sizes (22G to 30G) based on viscosity of injection formulation & desired depth.

Common Specification Publications



2.12.2022 EN Official Journal of the European Union L

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).

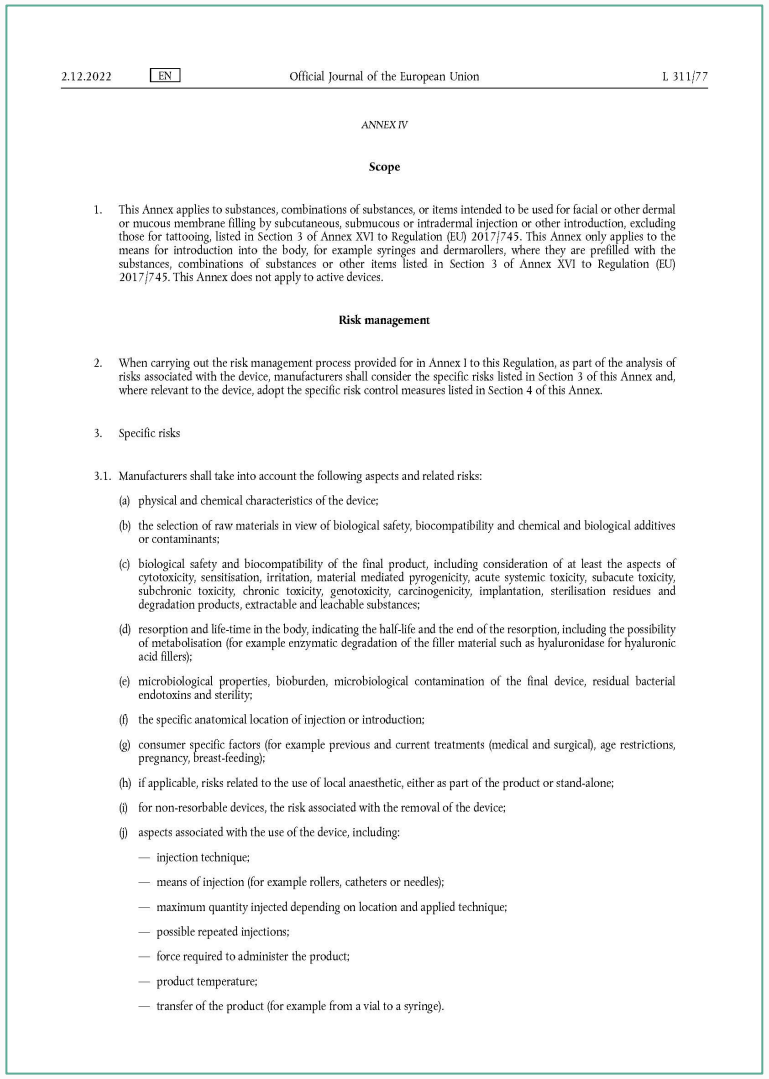
2.4. The results of the risk management activities, including the reference to the device, the reference to the persons who carried out the activities and the dates of execution of such activities, shall be recorded. For every identified hazard, the records shall provide traceability to the results of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



2.12.2022 EN Official Journal of the European Union L 311/77

ANNEX IV

Scope

1. This Annex applies 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, listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. 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 to Regulation (EU) 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 analysis of 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. 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 pyrogenicity, 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).

Fillers

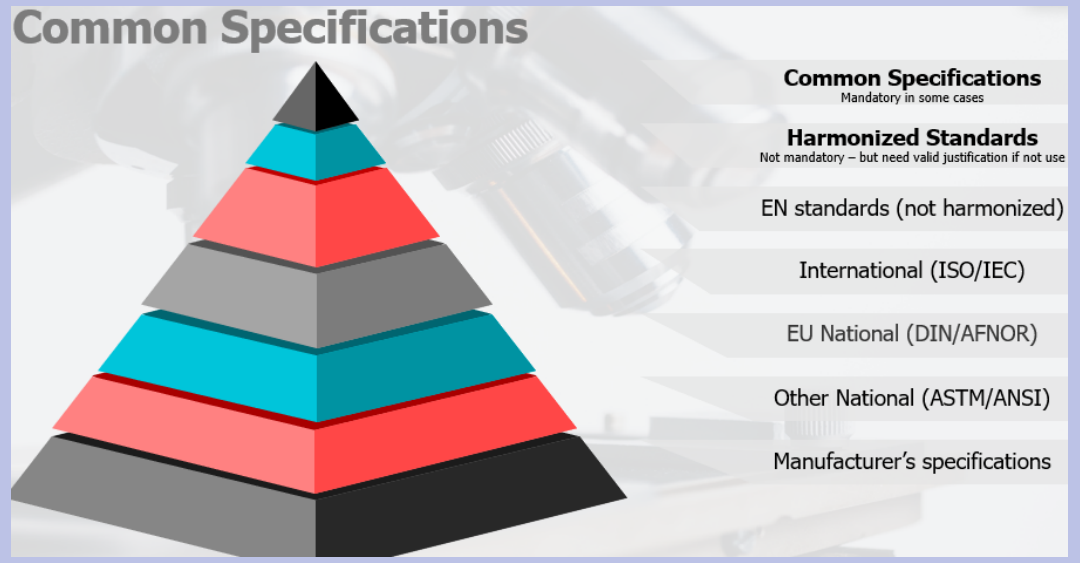
IV

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2346 of 1 December 2022

Annex IV: Dermal Fillers (Mandatory)

Risk Management:

“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.**”**



Section 3: Specific Risks Highlights

- Physical/Chemical/Biological Risks – Biocompatibility
- Resorption & Life-time: half-life and end of resorption
- Microbiological properties, bioburden, endotoxins
- Anatomical location of use
- Risk of removal (non-resorbable)
- Consumer factors (age, pregnancy, breast-feeding, disease)

Section 3: Specific User Risks Highlights

- Injection technique
- Devices (needles, catheters, rollers etc.)
- Max quantity to be injected/location
- Possible repeat injections/frequency?
- Force to administer product
- Product temperature
- Transfer (e.g. vial to syringe)

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2346 of 1 December 2022

Annex IV: Dermal Fillers

Risk Management:

"Where appropriate, manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms"

- microbiological contamination, manufacturing debris, procedure to inject or otherwise introduce the device, migration of the device, device visibility through the skin, unintended local inflammation and swelling, regional swelling, capsule formation and contracture, discomfort or pain, hematoma, infection and inflammation, superficial wound, scarring, nerve injury, seroma, edema, granuloma, vascular damage, allergic reaction, blindness, necrosis

Section 5: Labelling Requirements

Label shall contain in bold fonts of largest used size

- "Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law"."
- "devices are not to be used in persons who are less than 18 years old"

Section 6: IFU Requirements- Highlights

- Above statements
- Precise instruction for administration practise
- Description of treatment for most common side effects (provided)
- How and when for new injections at previous sites
- A list of filler constituents including additives (details provided)
- Recommendation for post-procedure monitoring period
- Requirement for user to provide patient leaflet
- Patient leaflet: all residual risks and potential undesirable side-effects listed in a clear way and described in a language commonly understood by lay persons.
- Information on how to report side effects to manufacturer.

Other Resources

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

To: Medical device manufacturers

27 September 2022

Dear Recipient,

Facial swelling in those with a history of hyaluronic acid-based dermal fillers after COVID-19 vaccination.

The MHRA is writing to all manufacturers who market hyaluronic acid-based dermal fillers (CE or UKCA marked) in the UK to ensure that their internal risk management processes and external patient safety information are appropriate to manage potential risks of dermal filler and vaccine interactions.

FDA

Search Menu

N THIS SECTION: Aesthetic (Cosmetic) Devices

Aesthetic (Cosmetic) Devices

Dermal Fillers (Soft Tissue Fillers)

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En español

Dermal fillers, also known as injectable implants, soft tissue fillers, lip and facial fillers, or wrinkle fillers are medical device implants approved by the FDA for use in helping to create a smoother and/or fuller appearance in the face, including nasolabial folds (the lines extending from the sides of the nose to the edges of the mouth), cheeks, chin, lips, and back of the hands.

Since some dermal fillers are naturally absorbed over time, patients may need to repeat the procedure after some time to maintain the desired effect. Successful results will depend on the underlying tissue structure and the volume and type of filler used. The time that the effect lasts depends on the filler material and the area where it is injected.

On this page:

- Approved Uses of Dermal Fillers

ansm
Agence nationale de sécurité du médicament et des produits de santé

Topical Report
Injectable products to fill wrinkles

1 –Contextual elements

Injectable wrinkle fillers are mostly used to treat facial wrinkles by injecting a gel into the skin (dermis). They respond to the definition of a long-term, invasive, surgical device since they are introduced invasively into the skin using a syringe and are intended to remain in place for at least thirty days. They also follow the same regulations as implants in terms of classification.

They have been developed as a result of the extended use of devices used to fill volumes of the body. These devices are qualified by their ability to change the patient's anatomy and are used for reconstructive purposes in the treatment, for instance, of facial lipoatrophy, debilitating scars or morphological asymmetry.

The market for these devices is constantly developing, accounting for a sales volume of over 3 000 000 syringes in France between 2003 and 2008, i.e. 600 000 syringes by year. Approximately 100 products are currently placed on the market by 35 manufacturers in France.

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Dermal fillers in the Netherlands
a market surveillance study

RIVM Letter report 2017-0023
P. Keizers et al.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Things to consider before undergoing procedures involving dermal fillers

Fact sheet

Published: 22 August 2019

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Non-surgical enhancements using cosmetic injections, such as dermal fillers, are becoming increasingly popular in Australia. Dermal fillers are materials injected under the skin to reduce the appearance of facial

FDA Executive Summary General Issues Panel Meeting on Dermal Fillers

Prepared for the Meeting of the General and Plastic Surgery Devices Advisory Panel

March 23, 2021

Medicinal Aspects

Ancillary substances

Rule 14

Consultation Process

Documentation

Timelines and costs

Biological aspects

Ancillary Medicinal Substances

Rule 14

- Principal action must be physical
- Can be supported by ancillary medicinal substance
- E.g. lidocaine
- Additional requirements

From Annex VIII

7. SPECIAL RULES

7.1. Rule 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.

Ancillary Substances

- MDCG 2022-5 for definition
  - Does it meet the definition of a medicine (pharmacological, immunological and metabolic) action
  - Does it have a supportive (ancillary) action.
- Both must be yes to be part of Rule 14
- Justification should be provided for all borderline ingredients
- If not ancillary no claims of benefits pertaining to that substance may be made in labelling etc.

- Some borderline examples:
  - Ascorbic acid,
  - Cyanocobalamine
  - Thiamine nitrate
  - Retinol acetate
  - Pyridoxine hydrochloride
  - Nicotinamide

MDR Rule 14 Devices – Conformity Assessment Process

5.2. Procedure in the case of devices incorporating a medicinal substance

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma and that has an action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(b) Before issuing an EU technical documentation assessment certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately, may be considered to be a medicinal product falling exclusively within the scope of the Annex to Regulation (EC) No 726/2004, the notified body shall seek the opinion of the EMA.

MDR 2017/745 Annex IX, Chapter II, Section 5.2

Documentation Requirements

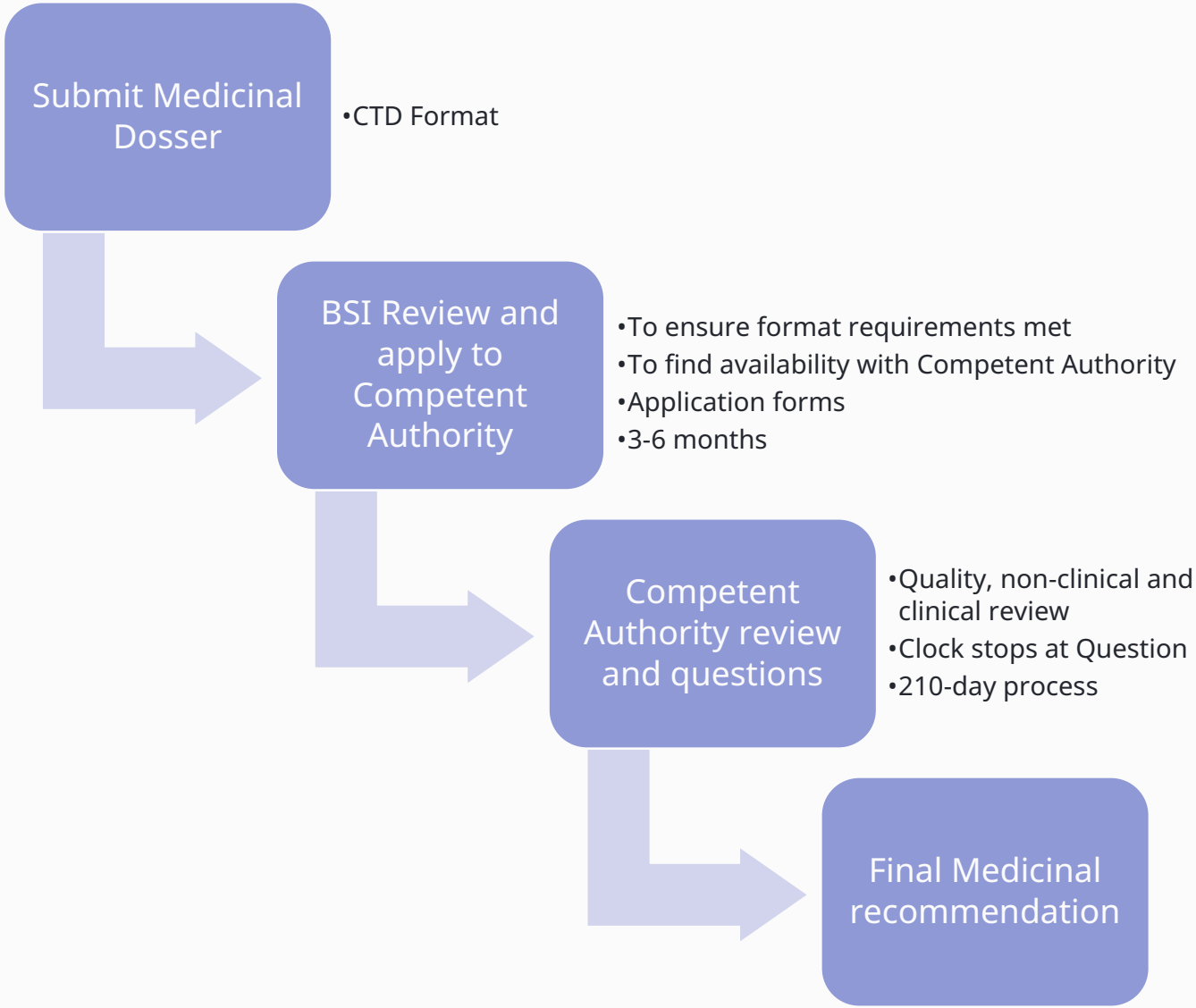
Different Dossier requirements to the Technical File (CTD)

- Overview
- Drug Substance information (ASMF, CEP, full data)
- Incorporation of substance into the device
- Pre-clinical and clinical data (usefulness)

Medicinal Dossier guidance

For devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR)

Process and timelines



Available CAs as per HMA Website*

Medicines Agency	Fees
FAGG – AFMPS, Belgium	Initial : €41,970 Changes: €18,350
SUKL, Czechia	Initial : 70,000 CZK = €2,900 Changes: 15,000 CZK = €615
ANSM, France	Currently have no fees
BfArM, Germany	Initial : €5,000 – 50,000 Changes: €1,250 – 12,500
DKMA, Denmark	Initial : 72,000 DDK = €9,800 Changes: 72000 DDK
OGEYI, Hungary	Initial : €2,000
MEB, The Netherlands	Initial : €21,090 – 37,640 Changes: €2,350 - €14,250 MDR Reconsultation: €14,250
NAMMDR, Romania	Initial : €535 – 2,600 Changes: €250 - 665
AEMPS, Spain	Initial : €1,540
MPA, Sweden	Initial : 150,000 SEK - €14,500
EMA	Initial : €44,000 – 89,000 Changes: €3,300 – 44,400

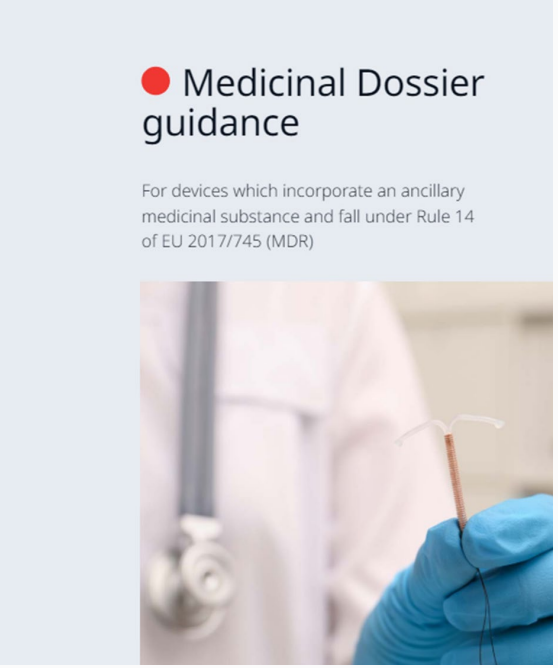
Note: HMA Site also lists HPRA, Ireland, INFRAMED, Portugal, EOF. Greece, URPL, Poland, Malta, however these agencies have not responded to BSI requests for application availability

*https://www.hma.eu/about-hma/combination-products.html

Guidance

- BSI Medicinal dossier guidance

  https://www.bsigroup.com/siteassets/pdf/en/insights-and-media/insights/brochures/bsi-md-mdr-medicinal-dossier-guidance-en-gb.pdf
- Medical Device Regulation (EU) 2017/745
- MDCG 2022-5
- Each Competent Authority has format guides



Materials of Biological Origin

e.g. Hyaluronic acid

- Animal derived- Class III Rule 18- GSPR 13.2

Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

- Assessments for devices utilising non-viable animal tissue or cells or their derivatives will require a review against the requirements of EN ISO 22442 parts 1-3 and, where applicable, Regulation (EU) 722/2012

Materials of Biological Origin

e.g. Hyaluronic acid

- Bacterial Fermentation- GSPR 13.3

13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Devices with No Medical Purpose: Dermal Fillers

Additional Conformity Considerations - 1

Harmonised Standards

N/A for dermal fillers, Standards exist for needles, syringes, luers, etc.

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

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 2023-6: 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

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 MDR certified Dermal Fillers with cosmetic indications.

- Annex XVI Dermal Filler - CECP panel review.
  - No opinion offered
  - Not novel, clinical risks are known.
  - Contents already in clinical use in the same anatomical locations.
  - Consider risks of injecting in vascular, nasal and glabellar regions (blindness/stroke).

"

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

- *Request a quote today*

OR CONTACT

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Thank you!

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