MDR Clinical Requirements on spinal implants

2026-04-21

Presenter: Marion Soubelet Principal Technical Specialist, Clinical Evaluation Specialist, Scheme Manager, Ortho & Dental, BSI

Q&A: Dan Hoehn, Technical Team Manager, Ortho & Dental, BSI

Introduction of the Speakers

Marion Soubelet

BSI O&D team's Spine Subject Matter Expert

Represents BSI in the Spine Registries Meeting

Q&A

Dan Hoehn

Technical Team Manager - BSI O&D

Agenda

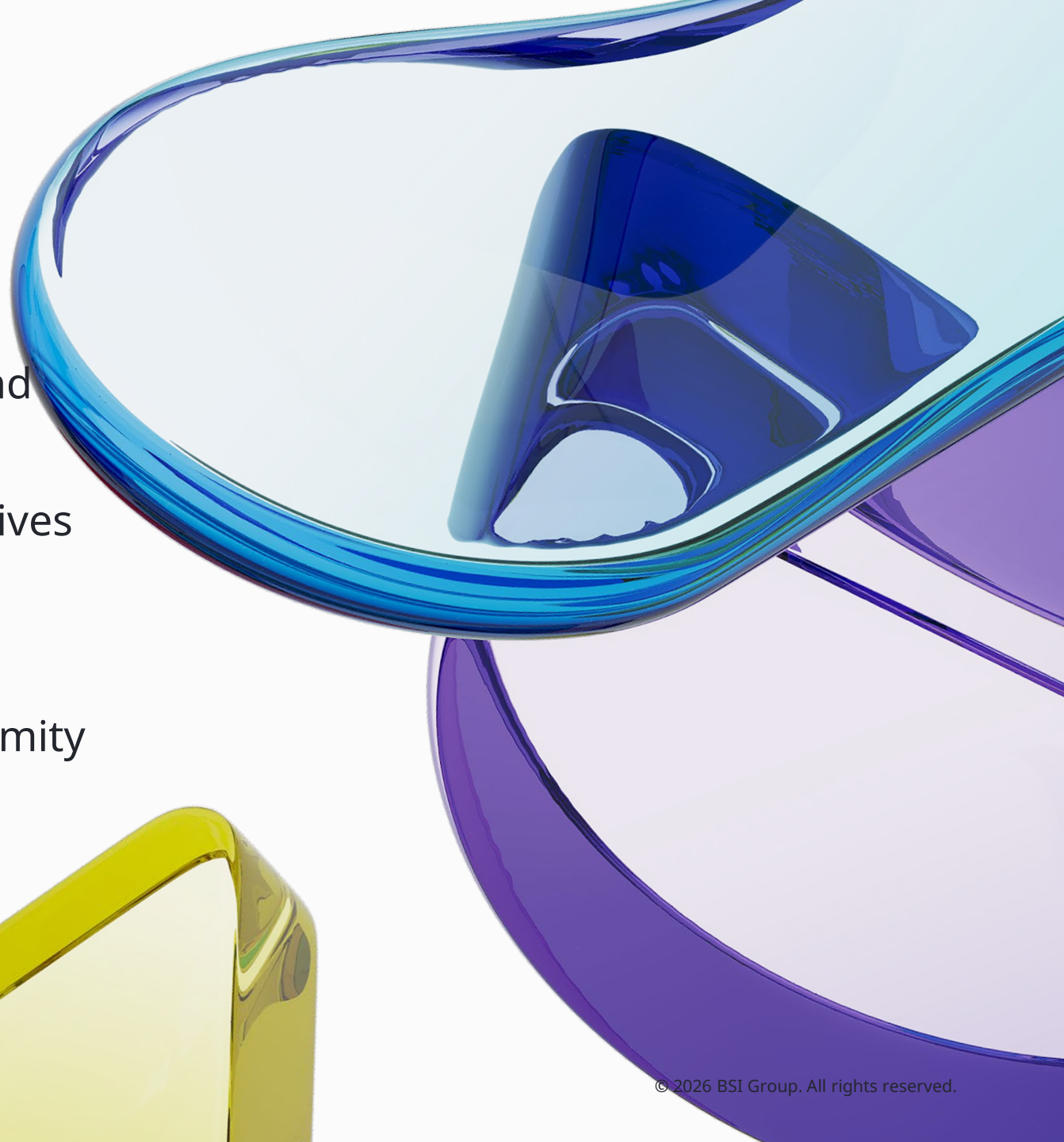
I. Introduction

II. Impact of EU MDR on spinal devices and Clinical Requirements

III. Clinical Safety and Performance objectives

IV. Source of clinical data (PMCF studies, registries, literature, PMS etc)

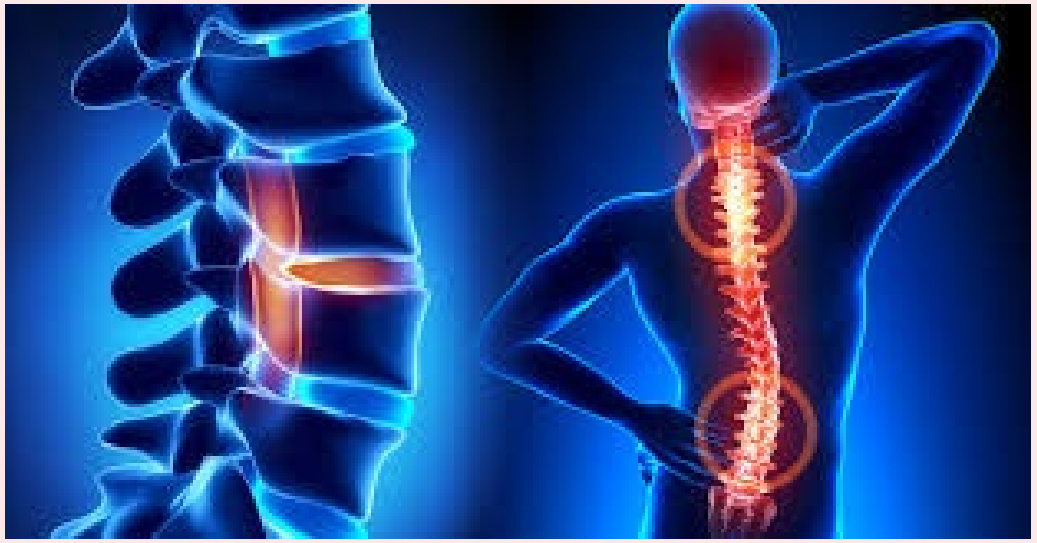
V. Frequent issues in Submission/ Conformity assessments



Poll 1: Which of the following best describes your current professional role?

1. Research & Development (R&D) of Medical Device Manufacturers
2. Regulatory Affairs Professional, Regulatory Agency or Government Body (including Notified Body)
3. Clinical Professional (e.g., clinician, other healthcare provider)
4. Research Professional (Academia or Consulting Firm)
5. Other

INTRODUCTION



Main Spinal Device

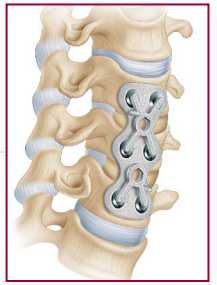
Spinal Fusion

- Interbody Fusion Devices (IBF)
- Vertebral Replacement Devices (VBR)
- Spinal and Pedicle Fixation Systems (rods, screws, plates, hooks, connectors)

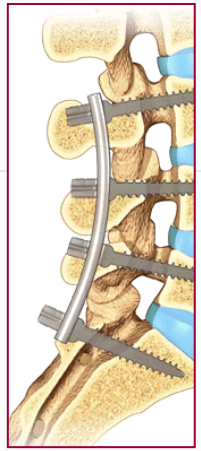
Spinal Motion Preservation

- Lumbar and Cervical Disc prosthesis
- Dynamic Spinal and Pedicle Fixation System
- Posterior interspinous spacers

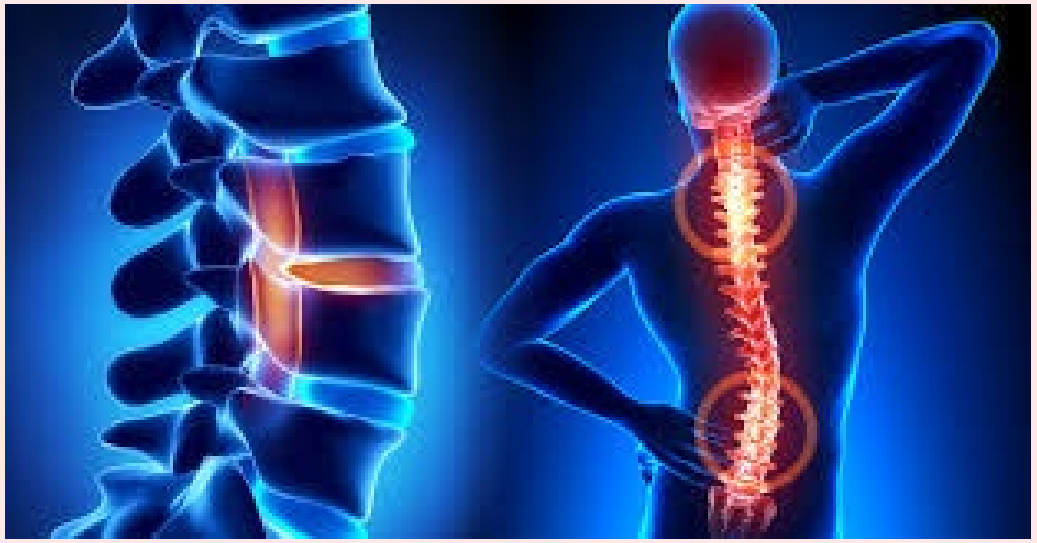
Cervical



Thoraco-lumbar



Impact of EU MDR on spinal devices and Clinical Requirements



Poll 2: What is the classification of total cervical disc replacement?

1. Class IIB WET under MDR
2. Class IIB non WET under MDR
3. Class III under MDR
4. Class IIB under MDD
5. Class III under MDD

Classification of spinal devices in EU MDR 2017/745

Per Annex VIII of MDR 2017/745, rule 8

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

— are intended to be placed in the teeth, in which case they are classified as class IIa;

— are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;

— have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

— are intended to administer medicinal products, in which case they are classified as class III;

— are active implantable devices or their accessories, in which cases they are classified as class III;

— are breast implants or surgical meshes, in which cases they are classified as class III;

— are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or

— are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

Per MDCG 2021-24: Guidance on classification of medical devices

III	- are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments	• Spinal disc replacement implants • Spinal implants: hooks that fix the rod on the spinal column • Stems that are implantable in contact with the spinal column • Device placed in the disc space • Interbody fusion devices

Most part of the spinal devices have been up classified as class III under MDR 2017/745 when compared to MDD 93/42 as class IIB.

Clinical requirements

Key Chapters and Annexes of MDR 2017/745:

- Chapter VI: Clinical Evaluations and Clinical Investigations
- Chapter VII: Post-market Surveillance, Vigilance and Market Surveillance
- Annex II: Technical Documentation (particularly Section 6.1)
- Annex III: Technical Documentation on Post-market Surveillance
- Annex XIV: Clinical Evaluation and Post-market Clinical Follow Up
- Annex XV: Clinical Investigations

Experts involved in the clinical evaluation assessment

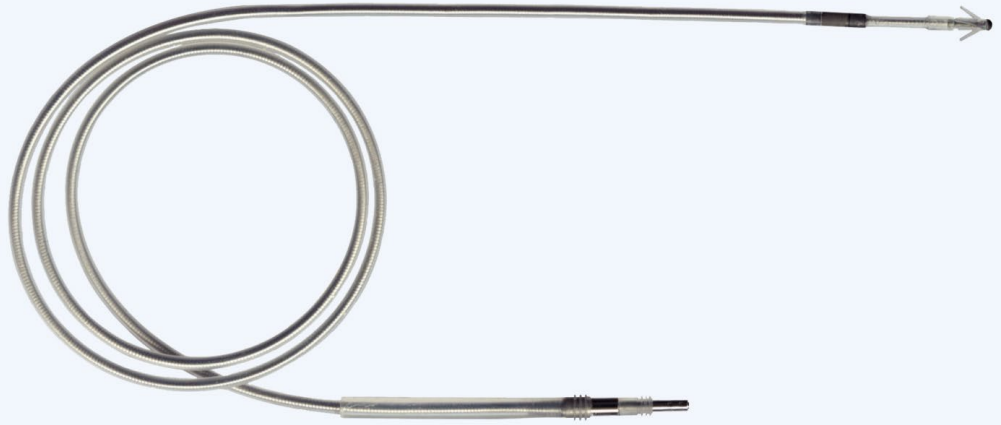
A clinician is employed to evaluate the clinical data held on the device and the manufacturer's benefit-risk assessment

A medicinal expert (pharmacist) is employed to evaluate the impact of any medicinal substances

A biostatistician may be also be employed to evaluate the output of clinical investigations

Biocompatibility experts are employed to assess exposure to and degradation of materials in the human body

Medical Device 'X'



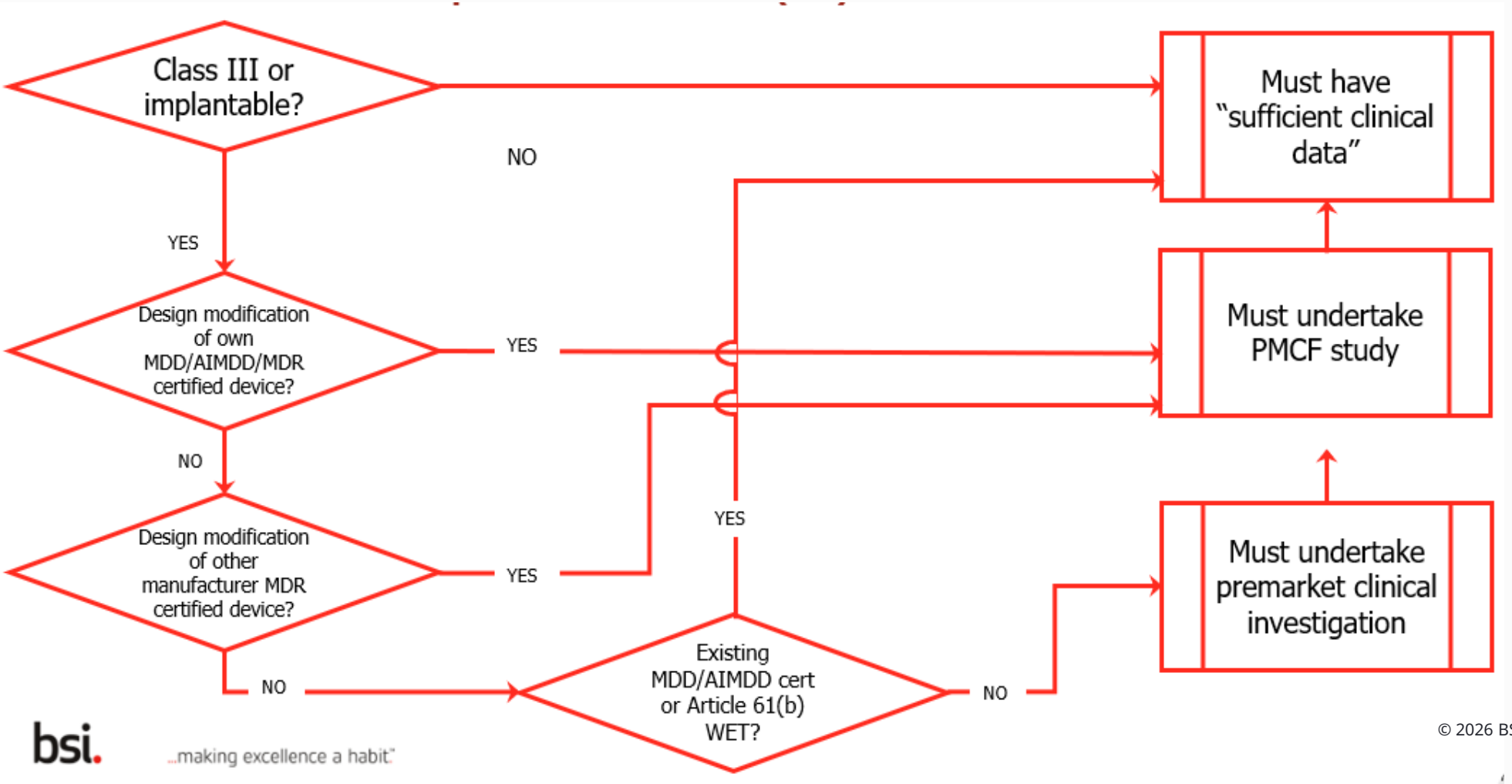
The technical expert is employed to evaluate the design/development processes, compliance with technical standards and review pre-clinical data

The clinical evaluation specialist evaluates the clinical evaluation documentation for conformity to the regulations and to relevant standards

Novel devices may require additional clinical expertise specific to the device and field of application

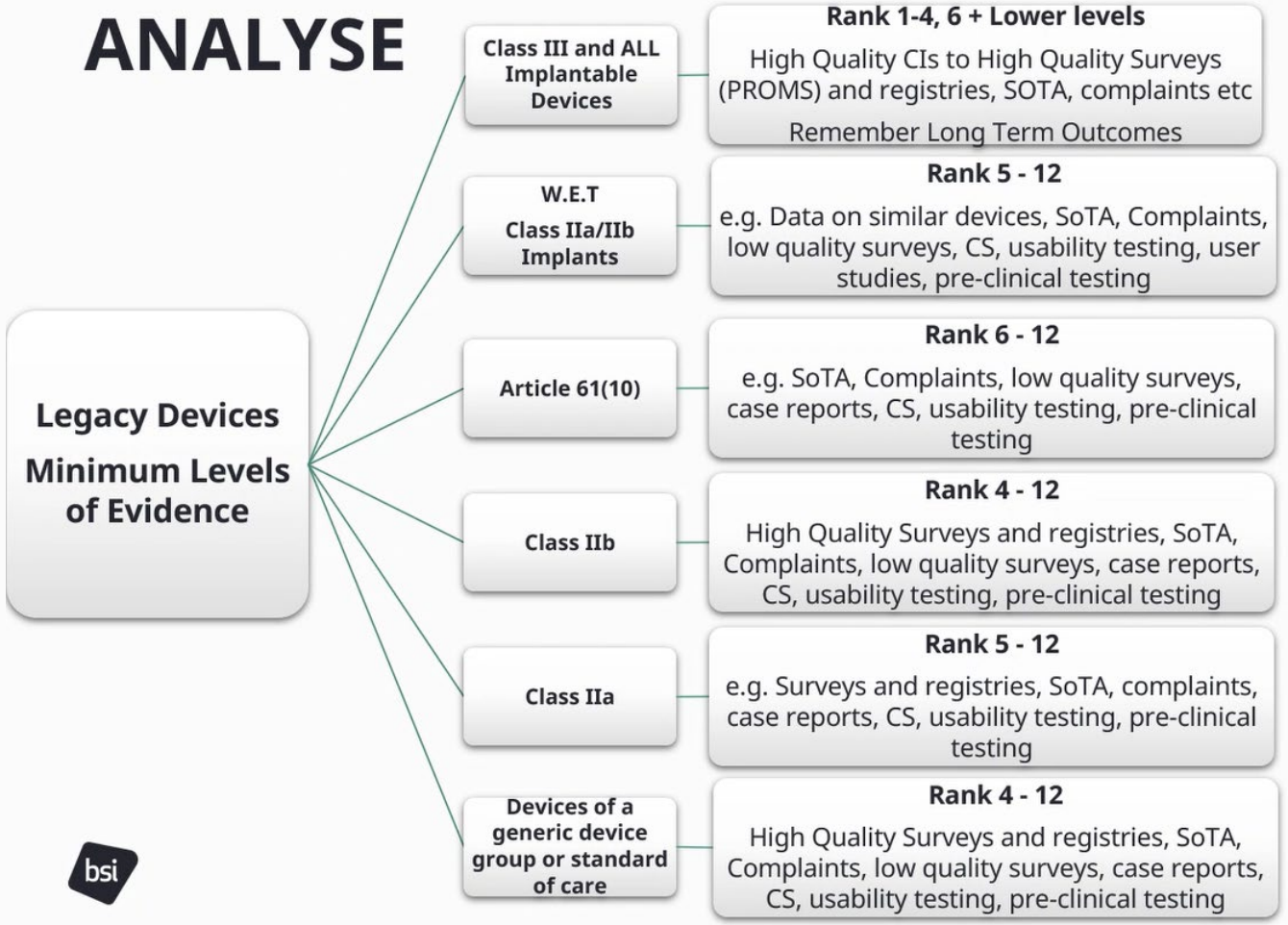
Animal tissue experts assess impact of the use of animal by-products either in the device or used in the manufacturing process

MDR Clinical evidence requirements



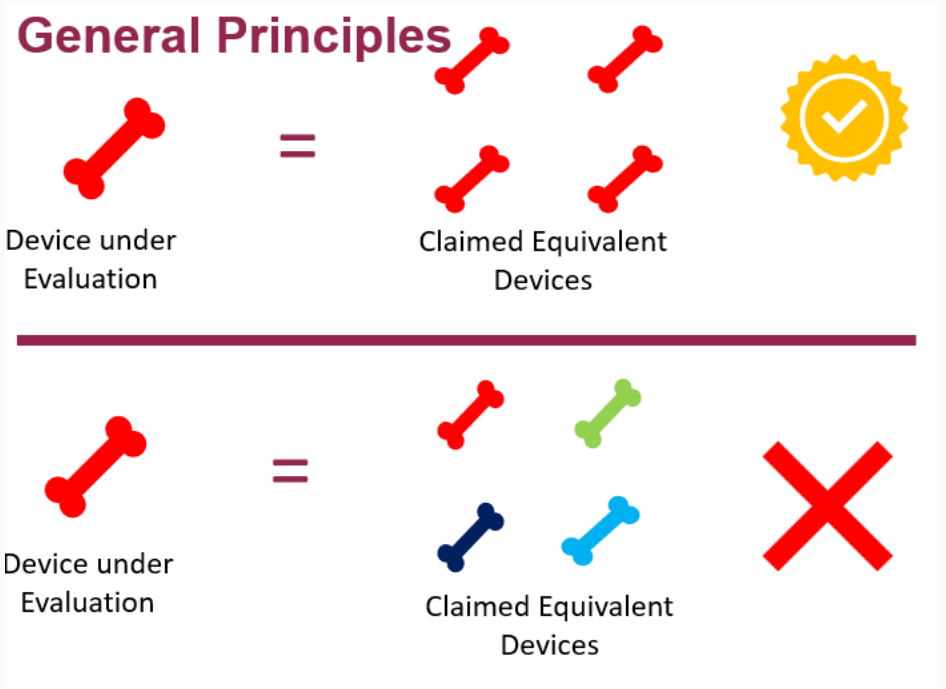
bsi. ...making excellence a habit.

Level of clinical data from MDCG 2020-6 (Legacy devices)



Equivalence and the MDR: Annex XIV Part A

- Provision is made under the MDR for claiming equivalence but relies on demonstrating sufficient knowledge of the claimed equivalent device
- It is not acceptable to use different parts of different devices to claim equivalence. (Sometimes referred to as the Frankenstein Approach)
- Any differences (biological, technical, clinical) require justification and evidence that they do not significantly impact clinical performance and/or safety. Use the table provided in MDCG 2020-5 to demonstrate equivalence.



Exemptions from clinical investigations: Article 61(4)

Article 61(4) allows for exemptions for clinical investigations of class III and implantable devices where:

— the device has been designed by modifications of a device already marketed by the same manufacturer,

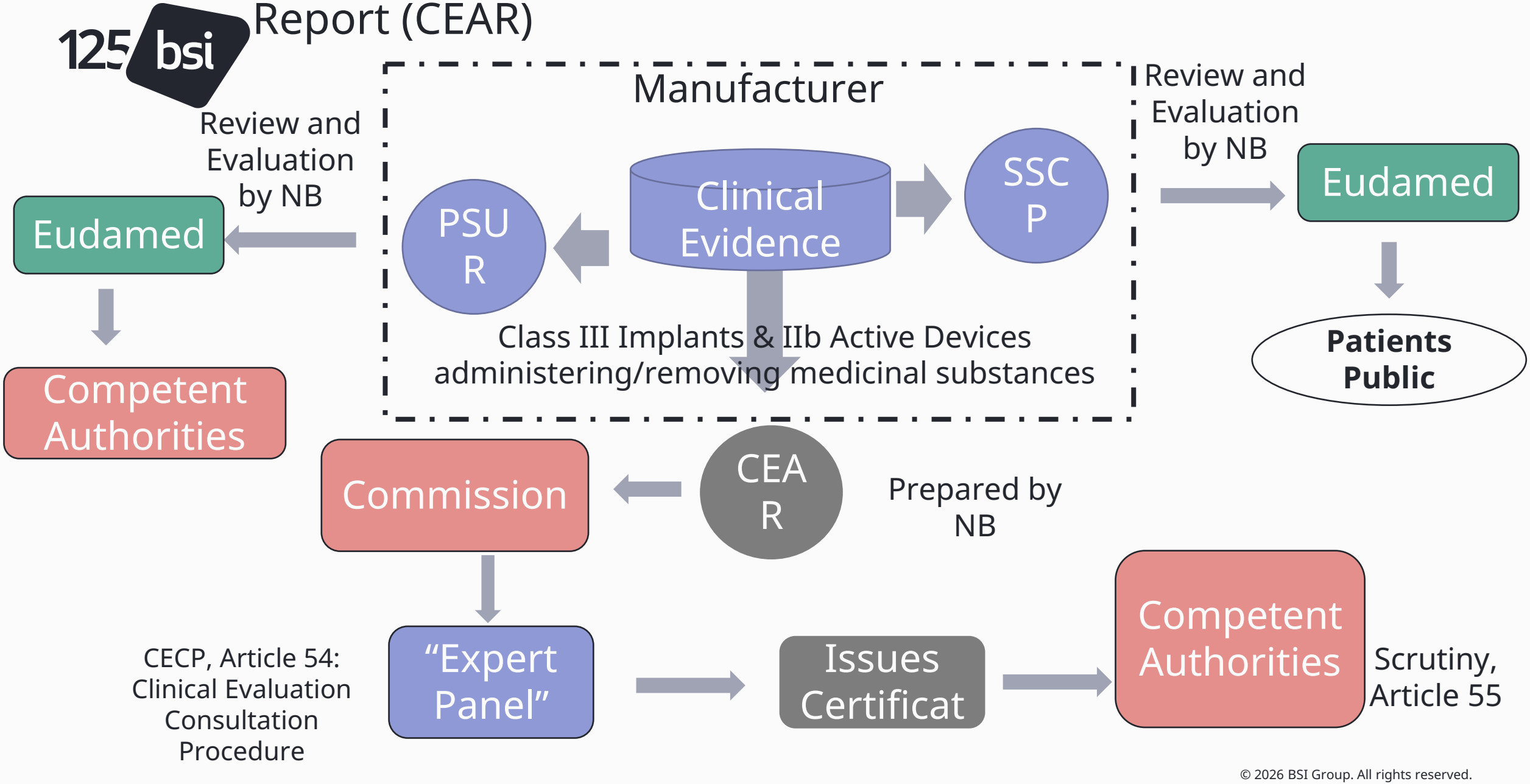
— the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and

— the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

Common gaps in the documentation:

- Declaring and justifying modifications; presenting evidence in support of arguments for equivalence
- Consideration of changes in the state of the art: it may be possible to claim v3.0 is equivalent to v1.0 but is the clinical evidence still valid?

Clinical Evaluation/PSUR/SSCP/Clinical Evaluation Assessment Report (CEAR)



Article 61(2) MDR 2017/745: Voluntary use of expert panel

Expert Panels: Advice on Orphan Device Status and Clinical Evidence according to article 61 (2)

Article 61(2) MDR provides the possibility for a manufacturer, prior to its clinical evaluation and/or investigation, to consult an expert panel with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation. The scope of MDR Article 61(2) is limited to class III devices and class IIb active devices intended to administer and/or remove a medicinal product.

Link to the expert panels for scientific advice:
https://www.ema.europa.eu/en/events/information-session-pilot-expert-panels-scientific-advice-manufacturers-high-risk-medical-devices

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2025
EMA/23357/2025
European Medicines Agency

Guide to manufacturers on the procedure for requesting advice from Expert Panels on clinical investigations and/or clinical development strategies for high-risk medical devices

Advice to manufacturers for high-risk medical devices

Clinical Evaluation of Orphan Medical Devices MDCG 2024-10 Guidance

Scope of MDCG 2024-10


Medical Devices

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

[Link to MDCG2024-10]

*This document provides guidance to manufacturers and notified bodies on the clinical evaluation pursuant to the MDR of medical devices and accessories for medical devices that qualify as 'orphan devices' (OD) and medical devices **and accessories** for medical devices that have **an orphan indication,** within the meaning of this guidance.*

Custom-made devices, in-house devices, products without an intended medical purpose listed in MDR Annex XVI and in vitro diagnostic medical devices are outside the scope of this guidance.

*Please note, this document gives guidance on the clinical evaluation of orphan devices which require clinical data to demonstrate conformity with GSPRs. **Guidance is not provided** in this document for those specific circumstances where **MDR Article 61(10)** applies to an orphan device.*

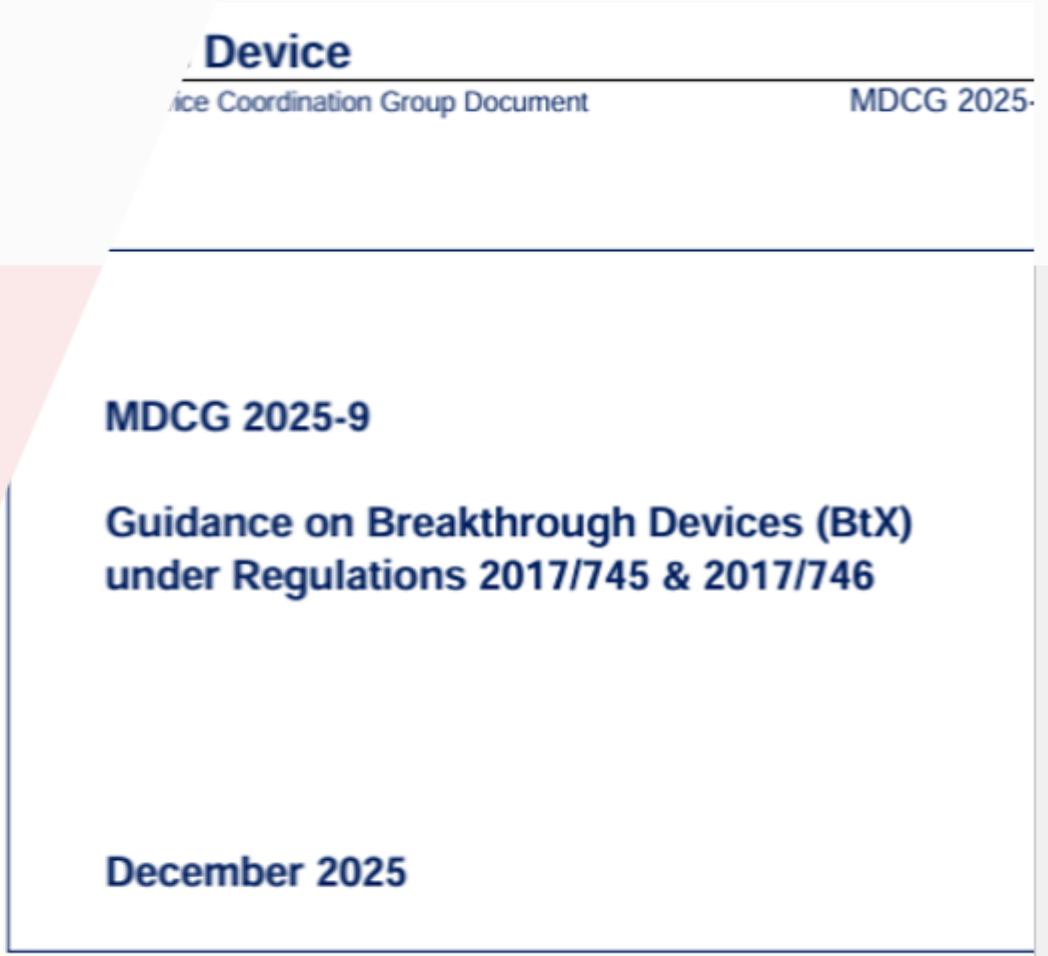
MDCG 2025-9 Breakthrough devices

Policy Intent Behind the Breakthrough Guidance

MDCG 2025-9 released in December 2025. developed by EU Commission, Member States, Notified Bodies, Patient/Physician Representatives & Industry.

The intent of this guidance ...

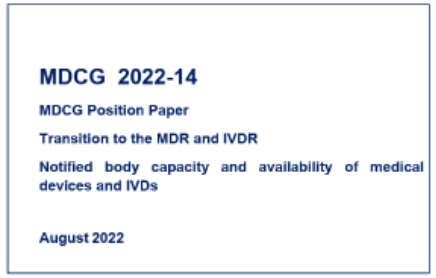
- Accelerate patient access to high-impact, novel technologies addressing unmet medical needs.
- Provide a structured route for earlier market availability while maintaining MDR safety and performance principles.
- Reinforce EU competitiveness and innovation in Medtech.



Structured Dialogue

What is Structured Dialogue?

Per Annex VII (Section 1.2.3) Notified bodies are not permitted to provide services that may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they ***shall not offer or provide consultancy services*** to the manufacturer, or be ***linked to any organisation which itself provides consultancy services***


MDCG 2022-14

MDCG Position Paper

Transition to the MDR and IVDR

Notified body capacity and availability of medical devices and IVDs

August 2022

MDCG 2022-14:

The MDCG encourages notified bodies and manufacturers to organise structured dialogues before and during the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body. Such dialogues should not be considered consultancy service.

O&D Capacity and lead times

Technical Documentation assessments

Lead time for Technical Documentation assessments is measured as the average time BSI is able to start the review once complete technical documentation is submitted to BSI.

Last update: March 2026

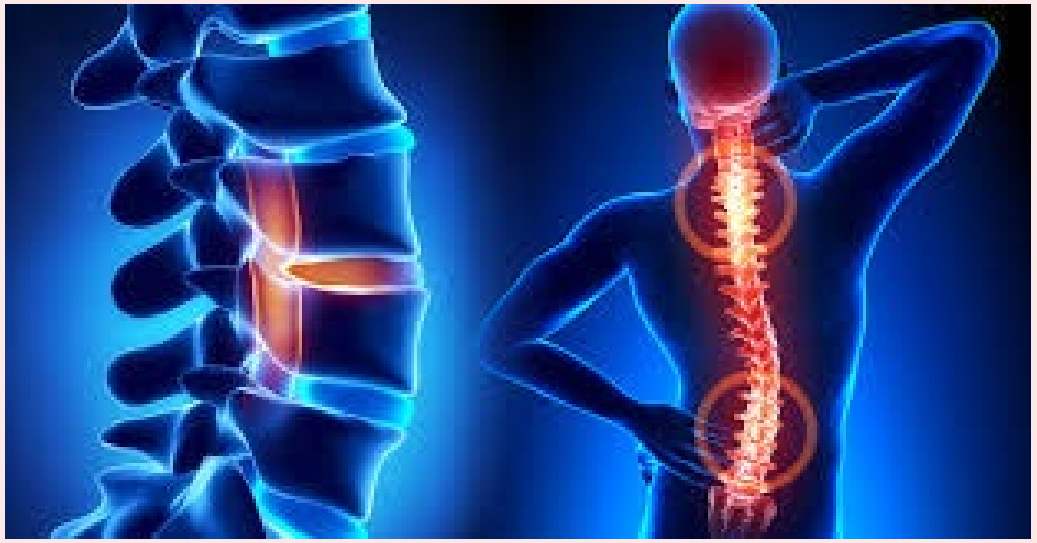
Technology Team	Type of devices	Device codes	Lead time	Change as of previous update
Orthopaedic and Dental Devices	Orthopaedic devices	MDN 1102, MDN 1205, MDN 1208, MDS 1006, MDS 1007, MDS 1013	1 month	No change
	Dental devices	MDN 1103, MDN 1209, MDS 1006, MDS 1007	1 month	No change

Clinical requirements/ Guidance

Documentation	Classification	Article/ Annex	MDCG Guidance	Notified Body review
Clinical Development Plan	All classification	Annex XIV Part A (1) Annex XIV Part B	MDCG 2020-6 (legacy devices)	Initial review and renewal review (at least each 5 years)
Clinical Evaluation Plan	All classification	Article 61 (1)	MDCG 2020-6 (legacy devices)	Initial review and renewal review (at least each 5 years)
Clinical Evaluation Report	All classification	Article 61(1) Annex IX Chapter II Annex XIV Part A	Meddev 2,1,1/rev 4 MDCG 2020-5 (equivalence) MDCG 2020-6 (legacy devices) MDCG 2020-13 (CEAR)	Initial review and renewal review (at least each 5 years)
PMCF Plan	All classification	Annex XIV Partie B	MDCG 2020-7	Initial review and renewal review (at least each 5 years)
PMS Plan	All classification	Article 84 Annex III (1.1)		Initial review and renewal review (at least each 5 years)
PMCF Report	All classification	Article 61 (11) (12) Annex XIV Part B	MDCG 2020-8	Initial review and renewal review (at least each 5 years)
Summary of Safety and Clinical Performance (SSCP)	Class III and all implantable devices	Article 32	MDCG 2019-9	Initial review and renewal review (at least each 5 years)
Periodic Safety Update Report (PSUR)	Class IIa, IIb and III	Article 86 Annex III (1.2)	MDCG 2022-21	Annually for class III and class IIb and at least 2 years for class IIa

Best practice guidance for manufacturers which covers the documentation needed for clinical evaluation in the clinical toolkit: https://www.bsigroup.com/en-IE/products-and-services/medical-devices/clinical-and-performance-evaluation/

Clinical Safety and performances objectives



Intended clinical benefit and objectives

- ‘Clinical benefit’ is defined in the Article 2 of the MDR
- It is expected that the clinical benefit is clearly defined and that there is sufficient clinical evidence to support it
- Safety and performance objectives should be defined in the context of the state of the art
- Objectives should be clinically meaningful and measurable, allowing for comparison of the device under assessment with other state of the art alternatives

Do the defined objectives clearly relate to the clinical benefit(s)?

Objectives should be quantified according to;

1. Magnitude (extent, amount intensity) and should be measurable and patient-specific
2. Probability based on patient populations should be considered. Statements to reflect the general population may not be appropriate *(think meaningful!)*
3. Duration - Think quantity!

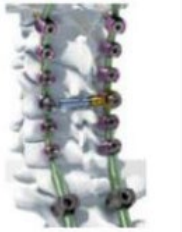
For example, the manufacturer of pedicle screws/Spinal fusion plate/ Interbody fusion devices can define some objectives such as

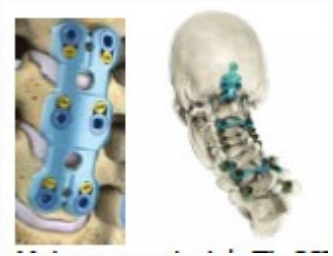
- Performance: Significant improvement of PROMs score such as VAS, ODI, NDI, SF 36, EQ 5D at xx years
- Safety: Number of Adverse events at xx years (e.g: breakage, rod sliding, infection, adjacent disc disease, etc)

Lifetime

The manufacturer must determine the expected lifetime of their device and declare it within the device's technical documentation. Furthermore, they must provide evidence to verify and support their claims

It should be noted that the claim of expected lifetime should be considered in relation to state of the art. The manufacturer may also need to consider the device’s therapeutic and implantation lifetime.





For example, the manufacturer of pedicle screws/Spinal fusion plate/ Interbody fusion devices will design them to meet specific load conditions while the bone heals (functional lifetime). However, they will remain in place until the patient’s death, years or decades later (the biological lifetime).

- MDR Annex I, GENERAL SAFETY AND PERFORMANCE REQUIREMENTS, 6.
- MDR article XIV Part B6.1 (a),
- EN ISO 20417: Medical devices — Information to be supplied by the manufacture
- MDCG 2022-21: Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety a nd essential performance.
- MDCG 2019-9, Rev. 1, Summary of safety and clinical performance, A guide for manufacturers and notified bodies, March 2022.
- MDCG 2020-8 Post-market clinical follow-up (PMCF) Plan Template, A guide for manufacturers and notified bodies, April 2020.
- NICE Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip, Technology appraisal guidance (TA304), 26 February 2014
- https://www.team-nb.org/wp-content/uploads/2023/12/Team-NB-PositionPaper-Lifetime-Medical-Device-20231127.pdf
- EN ISO 14971: 2019/A11:2021 Medical devices – Application of risk management to medical devices

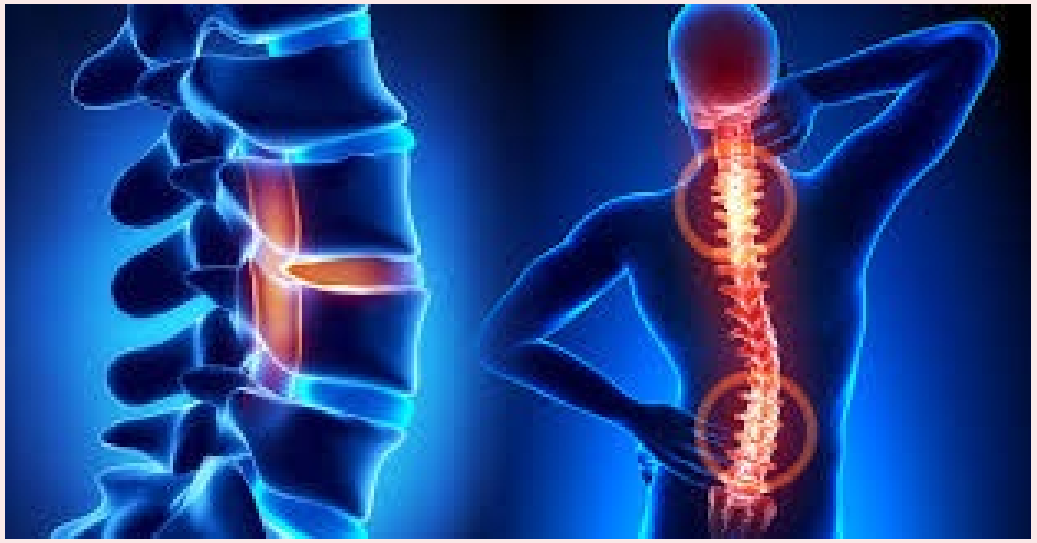
Long term safety and performance

Devices may get to the market with clinical data that does not cover the lifetime of the device. In this situation, a PMCF study may need to look at longer term data. The PMCF study here may be asking questions to include:

- Are there residual risks occurring later in the lifetime of the device?
- The difference in the device performance at the later stage of lifetime compared to time of implant?
- Does the risk to the patient change with age or change in severity of disease?

A PMCF study may not be the most appropriate method for gathering clinical data in such situations, so registry data may be an option where they exist

Source of clinical data (PMCF studies, registries, literature, PMS etc)

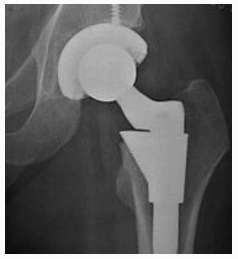
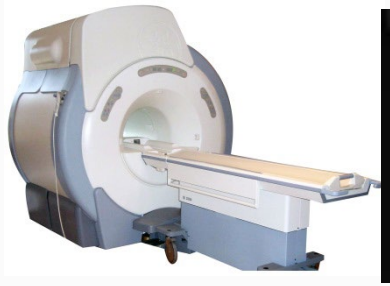
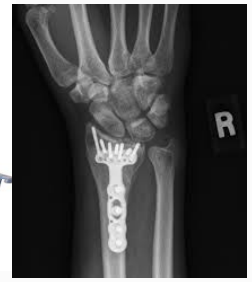


Poll 3: Which type of clinical data have you provided for spinal devices?

1. Clinical Data on equivalent devices
2. Clinical data from literature on your devices
3. Clinical data from PMCF specific study
4. Clinical data from PMS surgeon survey
5. Clinical data from registries

PMCF studies and risk

- Selected methods should be **justified,** low quality surveys for example may only be appropriate for lower risk devices, or established technologies
- Refer to MDCG 2020-7 and MDCG 2020-8



RISK, DURATION, INVASIVENESS

or UNKNOWNS

POST MARKET CLINICAL FOLLOW UP

SPECIFIC	GENERAL
• Prospective trials (e.g. Expansion of pre-market study, New prospective clinical trial) • Device registries • Retrospective studies	• Literature Review • Complaints/vigilance • Patient / surgeon questionnaires • Field surveys

When is a PMCF Study required?

- **CE mark based on equivalence**
- **Novel technology**
- **Long term safety or performance unknown**
- **High risk population**
  e.g. patients with an implantable device (active or non-active
- Risks identified from other data sources
- To assess performance and/or safety of the device in a more representative population of users and patients.
- Occurrence of clinical events (e.g. delayed hypersensitivity reactions, thrombosis

PMCF Study is **always** mandatory

Important considerations for Registries

Inclusive data often reflecting ‘true use’ of the device

Efficiency & cost savings with fast results

Ethical acceptance for established devices

Retrospective data collection offers minimal healthcare professional input

Important considerations for Registries

Observational data is typically open to greater bias

Limited intervention of data source

Data entry may lack detail outside of controlled environment

Typically, data is focused on safety rather than performance

Longer term data may be difficult to capture without intervention

Spine Registries

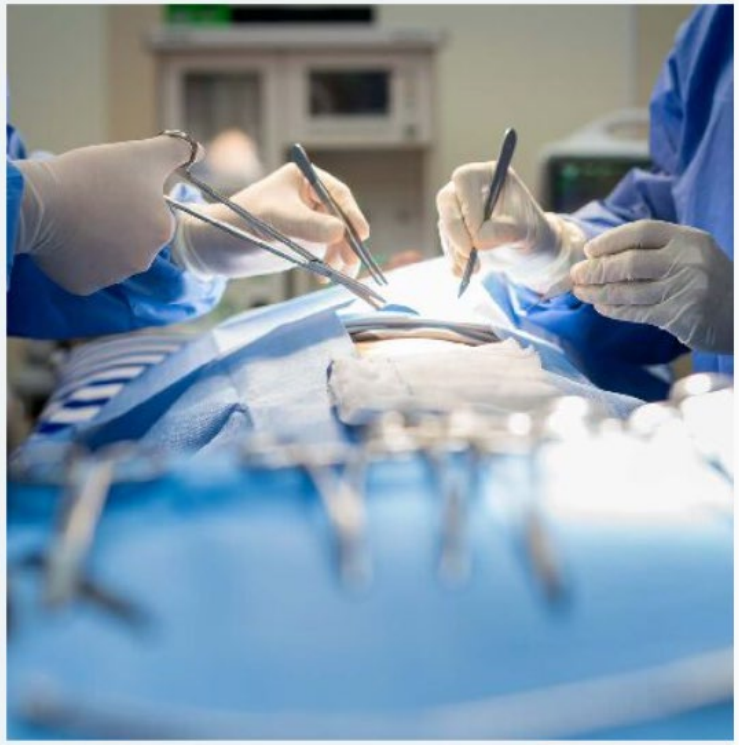
There are currently some spine registries at country level such as British Spine Registry, Australian Spine Registry, American Spine Registry, etc.

The aim of International Spine Registries is to collect clinical data on spine area to support general state of the art but as well to collect clinical data on spinal devices using powerful model to provide high level of evidence.

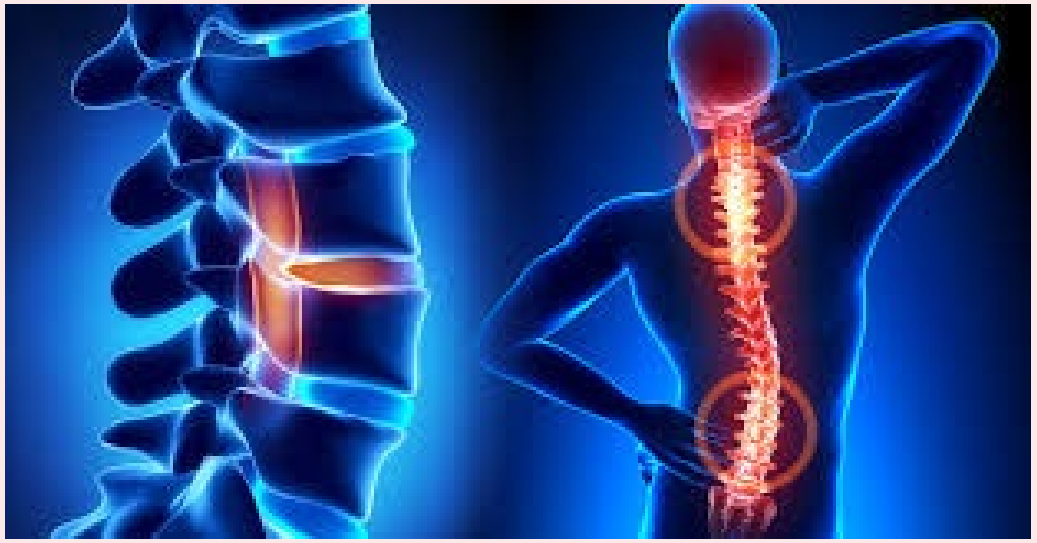
1st International Spine Registries meeting occurred in March 2023 and at least one annual meeting during the Eurospine. We had our 4th meeting in October 2025 at the Eurospine

Member of ISR team are surgeons representing their countries, spinal company stakeholders, Medtech, ODEP, Spine Tango, British Spine Registry, Australian Spine Registry, American Spine Registry, RIPO, NEC, European Commission and Notified Body (BSI)

To date, some policy papers have been drafted: Minimum data set, PROMs, implants identification



Frequent issues in Submission/ Conformity assessments



Frequent issues in Submission/ Conformity assessments

State of the art: Alternative therapy not discussed, clinical data not up to date/appraised/demonstrated

Safety and performance objectives: Not quantitavely defined, not defined/aligned with state of the art

Clinical data: Limited or no clinical data supporting intended use/indications claimed of devices under review/ variants in the system

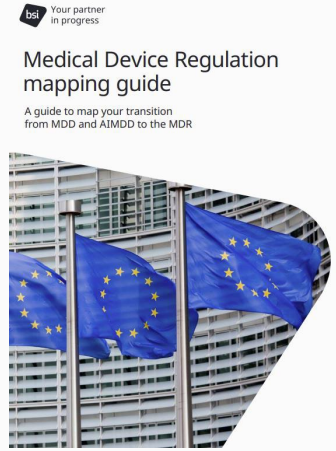
Risk/Benefit not sufficiently discussed considering state of the art and clinical data of devices

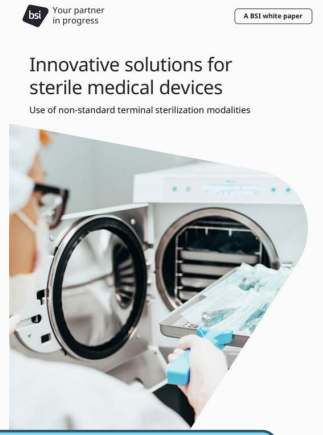
Incomplete PMS/PMCF plan

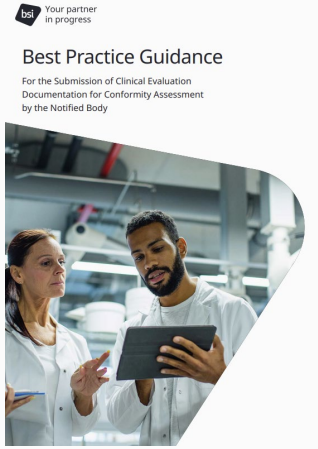
💡 Takeaway

- **Most part of spinal devices have been up classified under MDR 2017/745.**
- **Safety and performances objectives should be defined in line with state of the art (Quantitative, Qualitative).**
- **Sufficient clinical data should be provided to demonstrate safety and performance of spinal devices over the lifetime claimed for all intended use/indication.**
- **PMCF activities are required on all spinal devices.**

Our Resources - Webinars and whitepapers







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Thank You. Questions and Feedback

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