Commission Delegated Regulation (EU) 2026/1359 and Delegated Regulation (EU) 2026/1451 amending Regulation (EU) 2017/745

We would like to bring to your attention an important regulatory development under the Medical Device Regulation (EU) 2017/745 (MDR). On 29 June 2026, two Commission Delegated Regulations were published in the Official Journal of the European Union:

- Delegated Regulation **(EU) 2026/1359 - Art.52(4)** - expanding the list of Class IIb implantable devices exempt from the requirement to perform an assessment of the technical documentation for every device.
- Delegated Regulation **(EU) 2026/1451 - Art.61(6) point (b)** - expanding the list of implantable devices and Class III devices exempt from the requirement to perform clinical investigations.

The Regulations will enter into force 20 days after publication.

Expansion of Device Types under MDR Article 52(4) Delegated Act (EU) 2026/1359

Background

Under the current MDR provisions, Article 52(4) states that Class IIb implantable devices shall apply Annex IX Section 4 as their route to conformity, with the exemption of the following devices:

Sutures	Staples	Dental fillings	Dental braces	Tooth crowns	Screws
Wedges	Plates	Wires	Pins	Clips	Connectors

These “well-established technologies” (WET) device types were recognized as having well-understood clinical performance and safety profiles which allowed for a route to conformity that would allow for sampling of the technical documentation and change control based on the capability of the quality management systems.

New Delegated Act – expanded scope

The European Commission has now adopted a Delegated Act allowing the expansion of the list of exempted devices in Article 52(4). Under this new Delegated Act, the list of device types eligible under Article 52(4) has been broadened beyond the original examples. The scope now includes a wider range of implantable Class IIb devices as listed below:

Cannulas	Catheters	Feeding tubes	Suture pledgets	Suture sleeves	Suture buttons
Bone wax	Bone fillers	Bone substitutes	Stem centralizers	Diaphyseal obturators	Radiography markers
Transpalatal distractors	Nails	Anchors	Spinal posterior fixations	Textile braids	Dental implants
Dental barriers	Suspensory fixations	Cinches	Gastrostomy buttons	Fiber ligatures	Orthodontic devices

The rationale for this expansion is based upon the devices having:

- Common, simple, and stable design.
- Well-known safety profiles and they have not been associated with safety issues in the past.
- Well-known clinical performance characteristics, and they are considered standard of care devices with little evolution in indications and the state of the art; and
- A long history on the Union market.

Important Distinction – Article 52 vs Article 61 Delegated Acts

- This Delegated Act under Article 52(4) relates specifically to conformity assessment procedures and allowable routes to conformity.
- It is distinct and separate from the Delegated Act under Article 61(6)(b), which relates specifically to clinical evidence requirements and when clinical investigations are not mandatory.
- The list in Article 18(3) remains unchanged and this Delegated Act has no impact on those devices. The newly added devices within this Delegated Act still require an implant card.

The lists of devices within each Article should be considered independently when defining your regulatory strategy.

What this means for manufacturers

This Delegated Act gives more flexibility in selecting a route to conformity and allows certification of the listed devices through a quality systems certification route. Importantly, however, this route is limited to **Class IIb implantable devices only.** The Delegated Act does not affect classification or the classification rules. If the device is a Class III device, then the new Delegated Act does not allow for conformity assessment excluding Section 4 of Annex IX. Some of the devices described in the Delegated Act could be Class III; despite this, it is only those devices classified as Class IIb implantable that are eligible.

What is the impact in changing the route to conformity

This change will allow devices that previously had to be placed on a "product certificate" to be placed on a "quality management system certificate" without an accompanying product certificate.

Certification type	**Annex IX including Section 4**	**Annex IX excluding Section 4**
Technical documentation review	Maximum 5 yearly Renewal cycle	Sampled during certification cycle 5% of devices within the general device group during a certification cycle At least one surveillance audit per year per manufacturer (one audit over full certification scope)
PSUR (implantable devices) Prepared and assessed by the NB	Once per year	Once per year
Certificate cycle	Maximum of 5 years	Maximum of 5 years
Change control	Review triggered if GSPRs are impacted	Change to device range or changes to quality system are substantial
New device addition (same EMDN)	New devices reviewed and added to certificate scope	Devices within product worst cases and similar technology can be added as non-substantial changes

The impact will differ for each manufacturer and depend on the scope of its certificates, so please communicate with BSI early to fully understand the impact of any changes to route to conformity.

Expansion of Device Types under MDR Article 61(6)(b) Delegated Act (EU) 2026/1451

Background

Under the original MDR provisions, Article 61(6)(b) allows certain implantable devices to demonstrate conformity with the General Safety and Performance Requirements (GSPRs) without the need to conduct clinical investigations, provided that sufficient clinical data is available.

Historically, this provision applied to a limited and clearly defined group of well-established technologies, including:

Sutures	Staples	Dental fillings	Dental braces
Tooth crowns	Screws	Wedges	Plates
Wires	Pins	Clips	Connectors

These device types were recognized as having well-established clinical performance and safety profiles, reflecting their longstanding use in clinical practice

New Delegated Act - Expanded Scope

The European Commission has now adopted a Delegated Act under Article 61(6), which enables the expansion of this list.

Under this new Delegated Act, the list of device types eligible under Article 61(6)(b) has been significantly broadened beyond the original examples. The scope now includes a wider range of implantable and Class III devices as listed below:

Cranial perforators	Cranio-blades	Catheter passers	Patties and strips

Magnets for implantable pulse generators	Port plugs	Stylets and stylet guides	Needles
Needle holders	Forceps	Cannulas	Atrioseptostomy balloon catheters
Catheters coated with anticoagulants	Blood bags incorporating anticoagulants	Port catheters	Introducers
Dilators	Ventricular drains	Feeding tubes	Suture pledgets
Suture sleeves	Suture buttons	Gastrostomy buttons	Bone tacks
Bone wax	Bone fillers	Bone substitutes	Stem centralizers
Diaphyseal obturators	Radiography markers	Fiber ligatures	Tubal extraluminal ligation devices
Transpalatal distractors	Nails	Anchors	Spinal posterior fixations
Textile braids	Dental implants	Orthodontic devices	Dental barriers
Dental veneers	Suspensory fixations and cinches	Reusable surgical instruments	Springs for skull enlargement

Guidewires	Pressure wires	Pacing wires and leads	Snares
Lead caps	Fixation and connector tools	Endovascular embolization coils	Embolization particles
Cables	Shunts	Internal defibrillation paddles	

The rationale for this expansion is based upon the devices having:

- Common, simple, and stable design.
- Well-known safety and they have not been associated with safety issues in the past.
- Well-known clinical performance characteristics and they are standard of care devices with little evolution in indications and the state of the art; and
- A long history on the Union market.

Important Distinction – Article 61 vs. Article 52 Delegated Acts

This Delegated Act under Article 61(6)(b) relates specifically to the clinical evidence requirements and clarifies the circumstances in which a clinical investigation may not be necessary to demonstrate conformity. This Delegated Act should be considered separately from the Delegated Act under Article 52(4), which addresses conformity assessment procedures. Manufacturers should consider these two frameworks independently when determining the appropriate regulatory and clinical evidence approach for their devices.

What This Means for Manufacturers

As a result, there is now a wider group of devices for which clinical investigations are no longer mandatory. However, it is important to emphasize that, **while clinical investigations may no longer be mandatory, they may still be necessary.**

The responsibility remains with the manufacturer to:

1. Define a Clinical Evaluation Plan (CEP) per Annex XIV Part A of the EU MDR 2017/745.
2. Identify the GSPRs that require clinical data***** and determine what constitutes sufficient clinical evidence.

*****As per Article 2(48), clinical data may come from a variety of sources, including:

- Scientific literature.
- Clinical experience.
- Equivalent devices.
- Post-market data.

If sufficient clinical evidence can be demonstrated through these routes, manufacturers may then justify market access without the need to conduct new clinical investigations.

However, if sufficient clinical evidence **cannot be demonstrated in line with Article 61(1)**, then manufacturers may determine, through their clinical evaluation, that **clinical investigations are still required** to fill evidence gaps.

Considerations for Ongoing or Planned Clinical Investigations

We recognize that some manufacturers:

- May already be conducting clinical investigations, or
- Have planned such studies to support market access.

Considering the new Delegated Act:

- This does **not** automatically invalidate or render such studies unnecessary
- These activities may still be appropriate depending on:
    - The availability of clinical data.
    - The strength of the clinical evidence strategy.

Manufacturers should carefully assess whether:

- Existing data is sufficient, or
- Continued data generation remains justified.

Impact on Other Requirements

Annex XIV Part B: Post-Market Clinical Follow-up (PMCF)

The Delegated Acts are not envisioned to change PMCF plans as manufacturers must still ensure ongoing collection and evaluation of clinical data with the aim of confirming the safety and performance throughout the expected lifetime of the device and continued acceptability of the benefit-risk ratio. Any decision to reduce or modify PMCF activities should be **appropriately justified**.

Article 18: Implant card and information to be supplied to patients with implanted devices

The Delegated Acts do not amend the requirements of Article 18. Only the following implants are exempted from these obligations:

Sutures	Staples	Dental fillings	Dental braces	Tooth crowns	Screws
Wedges	Plates	Wires	Pins	Clips	Connectors

Article 32: Summary of safety and clinical performance (SSCP)

The Delegated Acts do not amend the requirements of MDR Article 32 for the Summary of Safety and Clinical Performance (SSCP). The obligations remain unchanged; meaning if your device needed an SSCP before - it still does. For those "new" Class IIb implantable WET devices that no longer require a product certificate, they will be validated as scheduled based on the sampling plan for devices on a QMS certificate.

Article 54: Clinical evaluation consultation procedure (CECP)

The Delegated Acts do not amend the requirements of MDR Article 54 and the Clinical Evaluation Consultation Procedure (CECP). Article 54 applies to the conformity assessment of Class III implantable, and Class IIb active devices intended to administer and / or remove a medicinal product (ARMPs). Exemptions for not following CECP are limited to those as described in Article 54(2). WET device status is NOT an exemption.

Article 86: Periodic safety update report (PSUR)

The Delegated Acts do not amend the requirements of MDR Article 86 for the Periodic Safety Update Report (PSUR). Manufacturers are still required to update their PSUR annually for Class IIb and Class III devices.

Engagement with BSI - Structured Dialogue

Given the complexity and potential impact of these changes, we strongly encourage clients to engage with us.

Through your Scheme Manager, you may request a Structured Dialogue with BSI.

This allows you to:

- Present your clinical and regulatory considerations to BSI as to why the device may be considered WET.
- Determine the impact of your chosen route to conformity on assessment burden.
- Obtain our perspective, as a Notified Body, on your clinical data approach.

- Ensure early alignment for what is sufficient clinical evidence ahead of a conformity assessment.

Please note:

- In line with Annex VII, Section 1.2.3 we must maintain independence and impartiality.
- Therefore:
    - We can consider and provide feedback on your proposed approach.
    - We cannot define or create the solution on your behalf.

In practical terms, we can comment on your proposed methodology, but the responsibility for defining that methodology remains with you as the manufacturer.

BSI Position

As a Notified Body, we welcome this pragmatic regulatory approach, which supports:

- More efficient routes to demonstrate compliance.
- Greater flexibility in clinical evidence generation.
- Continued assurance of safety and performance.
- More proportionate scrutiny for devices that have long-established safety profiles and with little evolution in indication and state of the art.
- Clarification over additional devices that are considered “Well-Established Technology”.

Next Steps

We recommend that clients:

- Review their device portfolios against the expanded scope.
- Reassess clinical evaluation strategies.
- Consider whether planned or ongoing investigations remain appropriate.
- Engage with BSI where clarification or alignment is beneficial.

If you are a BSI client and have any questions or would like to arrange a Structured Dialogue, please contact your Scheme Manager.
If you are not yet a BSI Client, please contact us at medicaldevices@bsigroup.com and we'll be happy to assist you.

We’re organizing a dedicated webinar in early September to further explore the practical implications of these two Delegated Acts. Stay tuned for registration details.

Kind regards,

Lisa A. Colton
Sr. Clinical Regulatory Lead, Clinical Compliance
Regulatory Services, BSI

Tim Marriott
Technical Team Manager, Orthopaedic & Dental Devices
Regulatory Services, BSI