Re-certification under the MDR and IVDR

Frequently Asked Questions

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Question 1: What is re-certification under the MDR/ IVDR[1]?

Under the EU Medical Devices Regulation ("MDR", 2017/745) and the In Vitro Diagnostic Medical Devices Regulation ("IVDR", 2017/746), certificates are valid for five years. At the end of this period, manufacturers must submit a re-certification dossier (even if the product and its manufacturing process have not significantly changed) to demonstrate continued compliance. This process focuses primarily on assessing changes made since the previous certification and the experience gained from post-market activities, rather than repeating the full conformity assessment. If any substantial changes had occurred during the certificate period, they would already have been notified to and reviewed by the Notified Body (NB) through the established change notification process. Without a valid certificate, medical technologies cannot be placed on the market.

For Technical Documentation (TD) certificates, this process requires manufacturers to resubmit extensive documentation and undergo a comprehensive review by a NB, often comparable in scope and depth to the initial conformity assessment. This places a significant burden on both manufacturers and NBs in terms of time, financial resources and the reassessment of technical documentation, clinical evidence and quality management system data. If any substantial changes occurred during the certificate period, they would already have been notified to and reviewed by the NB through the established change notification process. While these updates are reflected within the technical documentation, their review should be limited to verifying the relevant changes, rather than re-examining the entire file.

By contrast, for Quality Management System (QMS) certificates, the MDR/IVDR require re-certification at least every five years and renewal based on an NB reassessment in line with the applicable procedure. Unlike for technical documentation or type examination certificates, the Regulations do not prescribe a specific set of manufacturer submissions for QMS renewal, leaving the depth and documentation to the NB's documented procedures.

Question 2: Why was re-certification introduced?

The concept is not new in Europe: under the former Directives[2], certificates also had a limited validity. The MDR and IVDR expanded both the scope and depth of re-certification. The stated rationale was to ensure that evidence remains up to date, to verify compliance with evolving requirements, and to confirm continued conformity in light of post market surveillance data.

The shift from the Directives to the Regulations represents a fundamental change in ethos. Under the Directives, technical documentation was largely static, so periodic reevaluation had a clear logic. By contrast, the Regulations are built on the principle of continuous reassessment of safety and performance, with mechanisms that already give NBs routine, detailed and ongoing visibility of device conformity throughout the product lifecycle (see Annex 1).

1) MDR Art 56 & Art 120 & Annex VII 4.8; 4.11 // IVDR Art 51 & Art 110 & Annex VII 4.8

2) Directive 93/42/EEC (MDD), Directive 90/385/EEC (AIMDD), Directive 98/79/EC (IVDD)

Question 3: Is re-certification useful in practice?

The re-certification is intended to add additional scrutiny for NBs to confirm manufacturers' continued compliance.

In practice, re-certification largely duplicates work already performed through annual announced and unannounced surveillance audits, competent authority inspections, technical documentation sampling, change notifications, Post-Market Surveillance (PMS)/ Periodic Safety Update Report (PSUR) / Summary of Safety and (Clinical) Performance (SS(C)P) (including Post-Market Performance Follow-up (PMPF) / Post-Market Clinical Follow-up (PMCF), where applicable) and trend reporting. For high risk IVDs (Class D), NBs and EU Reference Laboratories already perform lot by lot verification (batch testing). This means that production lots already are subject to an additional safety procedure.

In this context, **re-certification creates unnecessary and additional administrative burden without a meaningful safety benefit**. The added value for patient safety is therefore negligible, while the regulatory burden and time/resource investment is substantial. Critically, it diverts NBs and manufacturer resources from higher value oversight (signals, changes, new technologies).

Beyond the duplication, re-certification generates several unwanted side effects:

- **Patient access risks:** delays in re-certification may interrupt the supply of safe devices, impairing continuity of care.
- **Unfair penalty for early MDR/IVDR adopters:** devices certified at an early stage under MDR and IVDR face re-certification sooner than those benefitting from transitional provisions, creating inequity.
- **Tender exclusion:** companies risk being excluded from public tenders if their certificates are due to expire, even for unchanged, safe products.
- **Lack of harmonised implementation among designating authorities and Notified Bodies:** variations in interpretation and application of MDR and IVDR requirements across Member States result in non-harmonised re-certification procedures and limited predictability for manufacturers.
- **Market impact considerations:** higher compliance costs and administrative complexity in the EU affect all manufacturers, particularly SMEs. These challenges may lead some companies to delay, limit, or deprioritise[3] certain product launches in Europe compared to markets where regulatory pathways are more predictable or cost-efficient.
- **Reduced international reliance:** although CE marking remains widely used to support device registrations across more than a hundred countries, formal reliance on it has been weakening in recent years. In several key markets, such as Australia and Brazil, formal reliance pathways have evolved away from an exclusive focus on the EU framework, supporting alternative jurisdictions as additional reference systems instead. MDSAP RAC members (the US, Canada, Australia, Brazil) have gained international trust and recognition, while China is also making strides in promoting reliance on its own approvals, particularly within the Asia-Pacific region.

3) MedTech Europe 2024 Regulatory Survey: key findings and insights - https://www.medtecheurope.org/resource-library/medtech-europe-2024-regulatory-survey-key-findings-and-insights/

Question 4: Why do stakeholders expect a ‘certification bottleneck’ in 2027–2028 for medical devices and 2026–2029 for IVDs?

Certificates issued from 2021 will begin to expire from 2026, with significant peaks expected in 2027–2028 for MD and 2026–2029 for IVD and on a rolling basis every 5 years moving forwards[4].

This creates simultaneous waves of re assessments at the same time that NBs are still managing legacy transitions, initial MDR/IVDR certifications and change notifications. The risk is a capacity cliff where compliant, safe, unchanged products lose certificates for procedural reasons.

The impact is particularly acute for small and medium enterprises (SMEs) and for niche, lower volume devices essential to care continuity.

Question 5: Can the re-certification requirement be removed from the IVDR/MDR?

Yes, but it requires legislative change.

Re-certification is explicitly written into the MDR and IVDR. Removing it would therefore mean amending the Regulations (and potentially some adjacent horizontal instruments). This would not leave a regulatory gap, since the MDR/IVDR already foresee and implement strengthened lifecycle oversight mechanisms that ensure continuous conformity monitoring.

Feasible policy shape:

- Shift from calendar-driven full re-assessments to continuous, risk-based surveillance already embedded in the Regulations. Certificates remain valid during the device lifetime unless targeted review is needed.
- Use targeted reviews only when triggered by significant changes, new safety signals, or evidence gaps, rather than arbitrary five-year deadlines.
- Clarify and harmonise the NB approach via secondary legislation so all NBs apply consistent procedures.
- The MDR and IVDR already establish comprehensive and continuous oversight mechanisms including regular surveillance audits, unannounced audits, inspections from Comp Authorities, vigilance reporting, PMS/PSUR evaluation, change notification procedures and technical documentation sampling which together provide ongoing assurance of device conformity and safety.
- Therefore, removing the 5-year re-certification requirement should not entail creating new or additional PMS or audit obligations, but rather recognise that the existing lifecycle controls already fulfil this function effectively.

4) ~15,000 first-time MDR certificates still must be issued by end of 2028. During the same time period, Notified Bodies must issue 5,599 re-certifications for already MDR-issued certifications (amongst other post-market activities), costing the EU industry at least 112 million Euros in Notified Body fees alone (based on 20,000 Euro median re-certification fees, not counting internal costs and other post-market activities). Most IVDR certificates are yet to be issued but NB resources both for undertaking QMS audits and providing administrative services are expected to be shared with MDR, which could be anticipated to lead to issues also for the IVD sector. See European Commission “Study supporting the monitoring of availability of medical devices on the EU market” https://ppri.goeg.at/Study_MD_Availability

International practice:

- Major jurisdictions, including the US, Japan, Canada and others, do not require a full re-certification at fixed intervals.
- Instead, devices remain on the market as long as they continue to meet ongoing obligations (e.g. QMS audits, vigilance, PMS reporting).

- Relying on continuous compliance rather than arbitrary re-certification dates would align the EU more closely with global best practice and strengthen the CE mark as a credible reliance tool internationally.

Question 6: Would removing re-certification reduce patient safety?

In short: no.

What matters most is a strong, well-resourced Notified Body system and effective market surveillance, not duplicative paperwork (see Annex 2).

The current MDR/IVDR framework already ensures continuous oversight: annual and unannounced audits, technical documentation sampling, change assessments, PMS/PSUR/SSCP (including PMPF/PMCF), vigilance, trend reporting, and inspections by Competent Authorities. For high-risk Class D IVDs, production lots are additionally subject to NB and EU Reference Laboratory verification.

Safety signals are captured through robust post-market surveillance and vigilance processes, with appropriate oversight. NBs can suspend or withdraw certificates at any time if risks emerge.

Re-certification therefore only duplicates documentation reviews without providing additional safety value. Eliminating it would reduce bureaucracy and free up resources, while maintaining robust, responsive, and risk-based controls. Moreover, periodic re-certification can divert attention and resources from timely implementation of corrective or preventive actions identified through ongoing post-market surveillance and audits.

Question 7: What are the safe alternatives to re-certification?

- **Continuous, risk-based surveillance:** Oversight should be proportionate to device risk and applied throughout the lifecycle, with harmonised expectations and predictable timelines across Notified Bodies. This ensures ongoing compliance without unnecessary calendar-driven reviews.

- **Targeted reviews when warranted:** Full reassessments should only be triggered by new or emerging safety concerns, serious vigilance findings, or evidence that the overall benefit–risk balance may have changed. Updates resulting from design, intended purpose, or manufacturing changes are already addressed through the existing change notification and review processes.

- **Lifetime certification with clear exit routes:** certificates should remain valid, as long as the device continues to comply and is subject to continuous surveillance by the Notified Body. The MDR and IVDR include clear provisions allowing Notified Bodies or competent authorities to suspend, restrict, or withdraw certificates or device placements in cases of non-compliance or identified safety risks.

Question 8: What happens if we keep re-certification unchanged?

- Major capacity crunches are expected with certificates issued from 2021 and beginning to expire from 2026, with significant peaks expected in 2027–2028 for MD and 2026–2029 for IVD and on a rolling basis every 5 years moving forwards. See Question 4.

- This will create queues, administrative delays, and potential product withdrawals often unrelated to safety concerns.

- Planning uncertainty will hit manufacturers, with SMEs particularly at risk, and many may prioritise non-EU markets where regulatory lifecycles are more efficient (e.g. US, Japan).

- Already today, the EU is at risk of becoming a second or even third-launch market, meaning it will not have the same ‘automatic’ access to first in class and best in class products as it used to enjoy, or even losing access to certain technologies altogether, reducing patient access and weakening Europe’s competitiveness.

- Public tenders and procurement may exclude otherwise safe devices because of soon-expiring certificates.

- Health systems could face stockouts and reduced treatment options with no demonstrated safety gain.

Question 9: What is industry asking for?[5]

To improve safety, efficiency and patient access, **the legislative reform of the MDR and IVDR should eliminate the limited validity of certificates** and replace re-certification with a risk-based model that takes into account the novelty of the technology.

Devices should only be reassessed when necessary – for instance in cases of safety concerns, significant changes transforming the device, or emerging incident trends – since robust ongoing surveillance mechanisms are already in place. See Question 5 for more details.

The current system already provides strong oversight over the full life-time of a device. The need for a renewal of the certificate should be based on an actual risk posed by the device post-market, including safety concerns or changes which are substantial enough to trigger a new conformity assessment of the product or the quality management system. Such an approach would maintain safety while eliminating inefficiencies and supporting innovation.

Question 10: Why is it so urgent now to find solutions?

- Major capacity crunches are expected with certificates issued from 2021 beginning to expire from 2026, with significant peaks expected in 2027–2028 for MD and 2026–2029 for IVD and on a rolling basis every 5 years moving forwards. Legal changes take time. Administrative fixes alone won't absorb the volume.
- Patient access: many legacy-but-essential devices risk leaving the market due to unpredictability, cost and NB delays, not safety.
- Competitiveness: companies are already sequencing launches away from the EU because predictability is lower.
- NB delays: remove non-value-adding work.

Question 11: Will doctors or patients see negative effects if re-certification was removed?

In short: no.

- Safety oversight remains active (surveillance, PSUR/PMS incl PMPF/PMCF, vigilance, inspections) – see Annex 2.
- Likely positive effects if replaced by robust lifecycle oversight. Fewer administrative cliffs mean fewer stockouts and more stable choice of technologies.
- Clinicians would benefit from predictability (fewer sudden discontinuations of familiar products).
- Patients benefit from continuity of care and access to incremental innovations (e.g. software updates) that are not clogged by calendar-driven re-reviews.

5) MedTech Europe Leaflet
Open letter to Oliver Varhely
Administrative Burden report

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. **www.medtecheurope.org**

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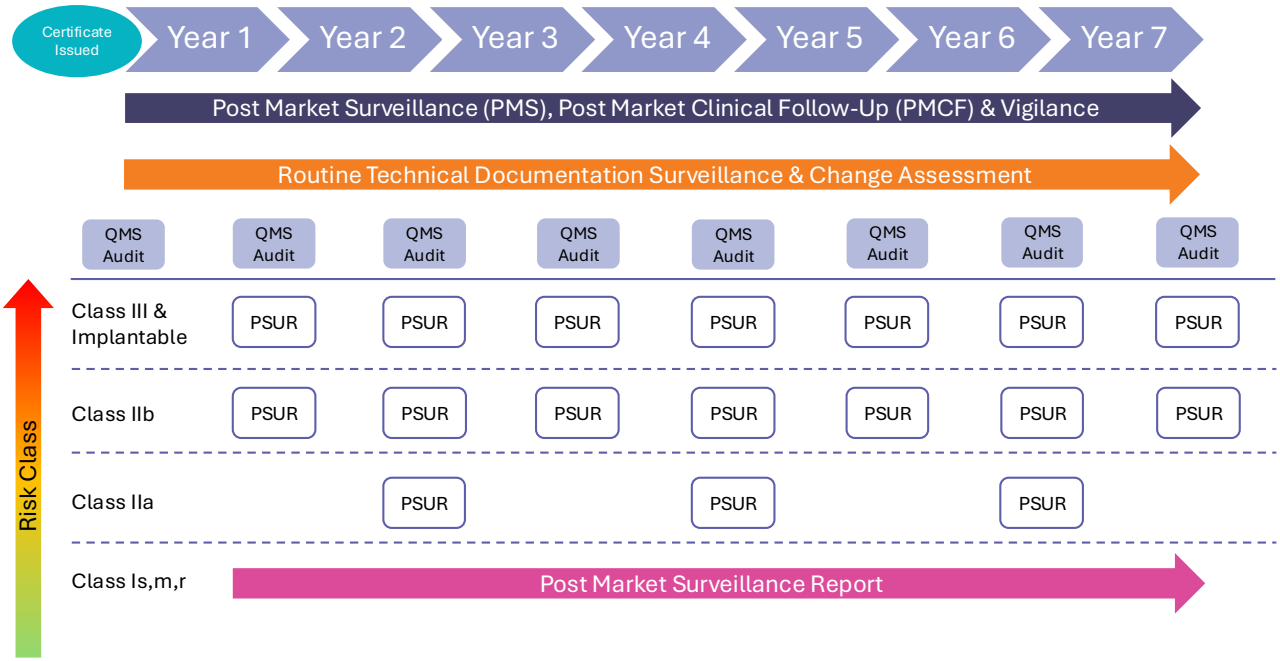
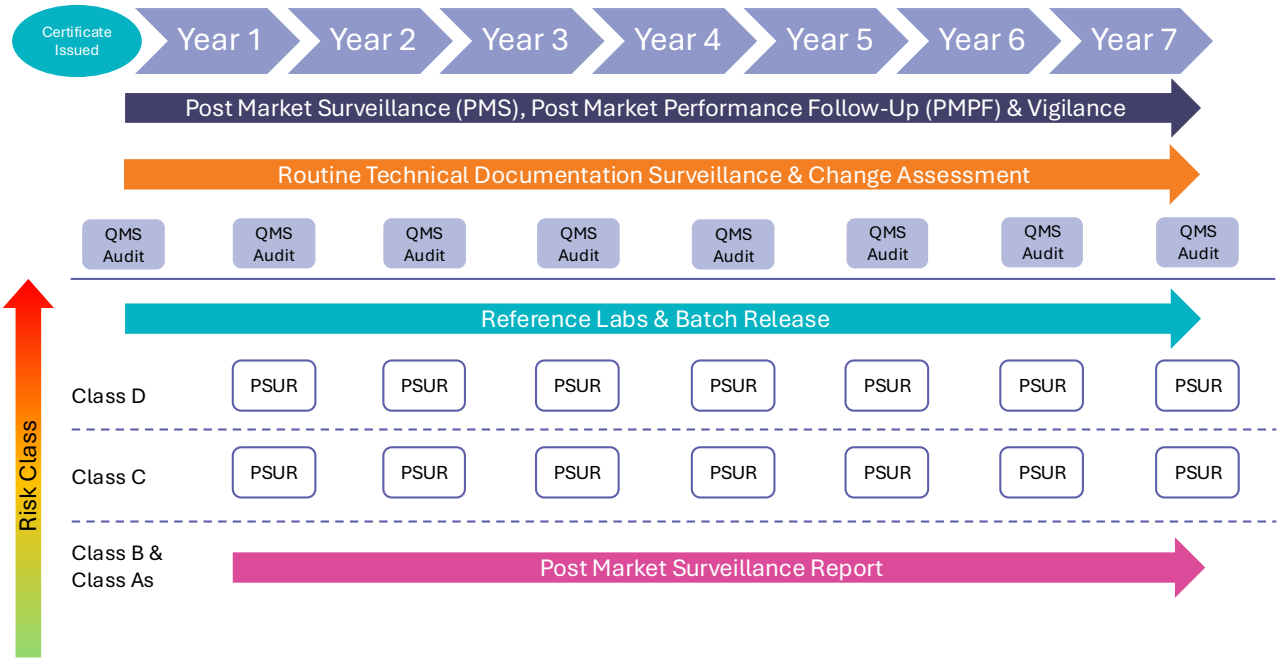
Annex 1

Medical Devices – Continuous Surveillance – Current State



IVDs – Continuous Surveillance – Current State



Annex 2

Continual lifecycle requirements vs. 5-year re-certification (MDR/IVDR)

This table provides a comparison between the 5-year re-certification process under the MDR/IVDR and the ongoing, continuous lifecycle requirements that already ensure the safety and performance of medical devices and IVDs. It explains how continuous monitoring, audits, and post-market activities already achieve the intended safety objectives, making 5-year re-certification largely redundant.

Requirement Category	Continual lifecycle requirements (MDR/IVDR)	5-year re-certification (Art. 56 MDR / Art. 51 IVDR)	Activity redundant to Lifecycle requirement?
Surveillance Audits	Periodic NB surveillance at least every 12 months; covers QMS effectiveness, representative product/TD sampling, PMS & vigilance follow-up. Annex IX §3.3; Annex VII §4.10.	Renewal audit includes broad QMS review per NB procedures (Annex VII §4.11).	**Largely duplicative** of initial certification + annual surveillance; limited added safety value given continuous oversight.
Unannounced Audits	NB performs unannounced audits at least once every 5 years; may include suppliers; focus on operations, product identity, components/materials; testing of products on the market; may be combined with surveillance. Annex IX §3.4.	Not part of re-certification; separate legal obligation.	**Not applicable** to re-certification; different purposes (direct production check).
Technical Documentation (TD)	TD must be kept up to date throughout lifecycle (Art. 10(4)), follow Annex II–III; PMS results feed into TD; PRRC ensures obligations are fulfilled (Art. 15; MDCG 2019-7/Rev.1).	NB re-assesses continued conformity using representative sampling of TD and code coverage; depth is risk-based; full TD review may be performed for selected high-risk scopes per NB procedure (Annex VII §4.11).	**Redundant:** TD is continuously reviewed via change control + surveillance; NB and CAs have vigilance/PSUR access (Art. 92(2)), giving a live safety view.
PMS system & PMS plan	Mandatory PMS system/plan, integrated with risk management and clinical/performance evaluation; Annex III; Arts. 83–86 MDR / 78–81 IVDR. Verified in annual surveillance.	NB re-checks PMS effectiveness at renewal using evidence already reviewed in surveillance/PSUR cycles.	**Duplicates continuous PMS oversight.** No additional safety value.
PSUR	Required for MDR classes IIa/IIb/III (Art. 86) and IVDR classes C/D (Art. 81); update cadence: at least annually for MDR IIb/III, every 2 years for MDR IIa; at least annually for IVDR C/D. Submission/review: via EUDAMED to NB for MDR class III and implantables and for IVDR class D; NB evaluation available to CAs via the system.	Included as evidence in re-certification dossiers but already assessed periodically by NB (where submission required) during the 5-year cycle.	**Redundant:** periodic NB review already provides cumulative safety picture.
PMS report (PMSR)	MDR class I / IVDR classes A–B: PMSR updated when necessary and made available to CA/NB upon request; checked during surveillance audits. Arts. 85 MDR / 80 IVDR.	May be referenced at renewal but evidence is already verifiable during routine surveillance.	**Redundant:** oversight ensured via surveillance + request powers.
PMCF / PMPF	Continuous collection/assessment of clinical or performance data; plans and evaluation reports are part of TD and PMS docs (MDR Annex XIV Part B; IVDR Annex XIII Part B; MDR Annex II §6.1(d); Annex III).	Reviewed again at renewal as part of clinical/performance evidence set already under surveillance.	**Redundant:** ongoing evaluation continuously feeds risk/benefit; renewal re-reads the same stream.

Requirement Category	Continual lifecycle requirements (MDR/IVDR)	5-year re-certification (Art. 56 MDR / Art. 51 IVDR)	Activity redundant to Lifecycle requirement?
SSCP / SSP	Prepared, NB-validated, published in EUDAMED; periodically reviewed and updated as necessary based on PMS/vigilance (Art. 32(3) MDR; Art. 29(3) IVDR). No legal "annual update" requirement.	NB checks currency/ consistency with TD at renewal.	**Largely redundant:** lifecycle updates already ensure currency; renewal adds no distinct safety check beyond alignment.
Labelling / IFU	Must meet Annex I Ch. III requirements; updates assessed via change control during lifecycle; eIFU per Reg. 2021/2226 where applicable. (legal basis not altered at renewal).	NB verifies current labelling/ IFU remain compliant and consistent with approved TD; detailed review occurs when changes were implemented/approved during cycle.	**Redundant:** substantive assessments already occur at the time of change notification.
Change Notifications	Significant changes to device/QMS/ TD notified and approved before implementation under Annex IX §§2.4 & 3.5 and Annex XI (Part A §7); assessed continuously; NB also considers PMS/vigilance in surveillance (Annex VII §4.10).	At renewal, NBs commonly review the cumulative impact of approved changes to confirm the current device still fits the certified scope; this aggregates prior approvals rather than introducing new safety data.	**Procedural overlap:** cumulative check can be, and is, handled in surveillance; renewal repeats the aggregation.
Market surveillance by competent authorities	National CA activities (Arts. 93–100 MDR / 88–95 IVDR) run in parallel; NB has access to vigilance data for its certified devices (Art. 92(2) MDR / Art. 87(2) IVDR).	Independent of renewal.	**Not applicable** to re-certification; parallel authority oversight.
EUDAMED transparency	Public and authority access to device, actor, certificate, vigilance and market surveillance data (Arts. 33–34 MDR / 30–31 IVDR); PSUR submissions and NB evaluations routed via the electronic system for MDR class III/ implantables and IVDR class D; class IIb PSURs are also submitted to NB (evaluation available to CAs).	Used as an information source at renewal; not specific to the renewal trigger.	**Not applicable** as a re-certification requirement; it supports lifecycle oversight continuously.

Is 5-Year re-certification necessary or redundant?

Where re-certification may add value

Over a 5-year period, non-substantial/ non-reportable changes might be implemented incrementally and approved through change notifications. In some cases, these changes may slowly shift the overall profile or risk of the device compared to what was originally certified. The 5-year re-certification could provide an opportunity for the notified body to:

- Reassess the device holistically rather than reviewing changes in isolation,
- Verify the device continues to meet state-of-the-art standards, particularly when new standards are published. Confirm that the certificate still accurately reflects the current version of the device and its intended use. For manufacturers with weak PMS practices, the 5-year re-certification serves as a critical checkpoint. As per Art 51.4 of the IVDR and Art 56.4 of the MDR, the NB can suspend, withdraw or impose restrictions at any time if the requirements of the regulation are no longer met.
- Note: All the above elements can be effectively assessed as part of ongoing surveillance audits, ensuring continuous compliance without relying solely on the 5-year re-certification cycle.

Re-certification introduces significant burden while offering minimal additional value for most devices

- PSUR provides relevant information to confirm that cumulative changes have not altered the device's fundamental risk profile, safety, or performance beyond what was initially approved

- Change notifications during the device lifecycle are already being assessed by the notified body -either on ad hoc basis for substantial changes or during annual surveillance for non-substantial changes.

- The clinical and safety value is best achieved by continuous interaction between post-market clinical and risk-management to maintain an up-to-date benefit-risk profile. This lifecycle base approach minimizes the added value of the fixed time-line recertification.

- Re-certification results in duplicative assessments of data and documentation already evaluated including technical documentation, QMS, clinical and PMS and Vigilance data.

- Nearly all information examined during re-certification is already subject to continuous scrutiny through established IVDR/MDR lifecycle processes (PMS, PMCF/PMPF, PSUR, SSCP, surveillance audits). The re-certification exercise therefore duplicates existing evidence reviews, with only marginal new input, while diverting notified body capacity from higher-risk or innovation-driven areas.

- Cost is high as is the level of burden on the manufacturers' own internal resources. For example, by end of 2028, Bodies must issue 5,599 re-certifications for already MDR-issued certifications (amongst other post-market activities), costing the EU industry at least 112 million Euros in Notified Body fees alone (based on 20,000 Euro median re-certification fees, not counting internal costs and other post-market activities).

Overall conclusion

Mandating re-certification for all certificates/Devices adds significant administrative burden and cost without delivering proportional value. Certificate validity should follow the lifetime of the device unless a targeted review is needed, when triggered by significant changes, new safety signals, or evidence gaps. Eliminating fixed certificate validity periods and replacing re-certification with a risk-based assessment approach would enhance patient access to innovative devices while ensuring continuity of supply and availability.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