

MDR & IVDR:

Proposed changes on the table

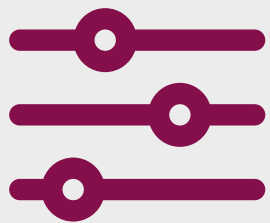
**What could change for medical devices
and IVDs in the EU?**

In December 2025, the European Commission published a legislative **proposal** to amend the MDR and IVDR.



A push for simplification, competitiveness and innovation

The proposal aims to:



Simplify
requirements



Reduce
administrative
burden



Remove
bottlenecks



Support innovation
and availability



Maintain safety and
performance

A more proportionate regulatory approach

Key proposals include:

➤ **PRRC**

More flexible rules

➤ **CE certificates**

Removal of the fixed 5-year validity limit, replacing it with risk-proportionate periodic reviews.

➤ **Clinical and non-clinical evidence**

Broader acceptance

➤ **Well-Established Technologies (WET) -** a legal definition for WET

➤ **Distributors**

Removal of NB certification and prior notification requirements for relabelling and repackaging.

➤ **Classification rules** lower the risk category for specific devices

Less paperwork, more efficiency

Among the proposed changes:

- Narrower scope for **SS(C)P**
- Reduced PSUR update frequency depending on risk class
- Reporting timelines for certain serious incidents extended from **15 to 30 days**
- Clearer rules for **changes after certification**
- Fewer notification/authorisation obligations for certain performance studies

More support for innovation and special patient needs



Relaxed
requirements for
in-house devices



Introduce priority
pathways for
**breakthrough and
orphan devices**



Clarify requirements on
**reprocessing and
refurbishment**

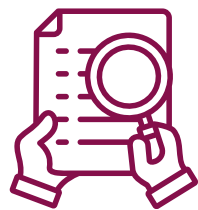


Improve visibility of
**critical supply
disruptions**



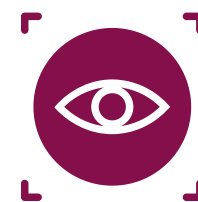
Introduce **regulatory
sandboxes**

Towards more predictable certification system



Technical documentation review

More proportionate



Surveillance burdens

Reduced in justified
cases



Structured dialogue

With Notified
Bodies



Replace on-site audits

Expand the use of
remote audits



NB fee discounts

For micro/small
manufacturers and
Orphan Device
manufacturers

A more digital regulatory framework?

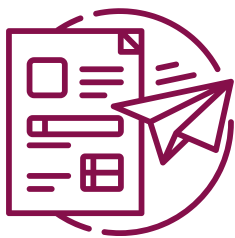
The proposal includes:



Electronic Declarations of
Conformity



Digital technical
documentation



Electronic regulatory
submissions



Broader use of e-IFUs for
near-patient tests



Important: These are proposed amendments, not final rules. The legislative process will determine the final text.

Why work with us?



Multidisciplinary team:
clinical & regulatory affairs
and quality assurance



Pragmatic approach to
guide medtech
developers



Experience with a wide
variety of medical
technologies



Flexible collaboration
model for start-ups, SMEs
and large companies



Optimization of
Time to Market

Do you need **support**
with your MDR & IVDR?

Contact us:
info@asphalion.com