

Urgent Need for Reform: Key Points from the Hearing on the Medical Device Regulation (EU MDR)

EU Medical Device Regulation (MDR) – A system at its limit. Patients wait, doctors despair, manufacturers struggle – bureaucracy blocks innovation.



Thursday 27/03/25
Spinelli 7H1
10:00 to 12:00

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(non-attached member of the European Parliament)

10-Point Plan for Optimising the MDR

1. **Risk-Based Assessment and Oversight**

Notified bodies should be required to apply risk-based approaches. For example, an effort of 12.5 person-days for assessing simple products (e.g. cannulas) by a large expert team (clinicians, biologists, technicians) is disproportionate.
2. **Administrative Support for SMEs**

Small and medium-sized enterprises (SMEs) require targeted administrative and regulatory support. For instance, the establishment of a dedicated “SME Office” in Brussels would be a practical measure.
3. **Harmonised Oversight of Notified Bodies**

The supervision of notified bodies should be uniformly regulated across the EU. In addition, an ombudsman office in Brussels could mediate disputes between manufacturers and notified bodies.
4. **Reduction of External Regulatory Costs**

Rising regulatory costs pose a significant burden, particularly for SMEs. Overinterpretation of requirements should be avoided to help reduce these costs.
5. **Optimised Market Surveillance**

Periodic Safety Update Reports (PSURs) and repeated clinical evaluations should only be required for low-risk products (e.g. cannulas and tubing) in specific cases, not by default every two years.
6. **Proportional Sampling of Technical Documentation**

Regular sampling of technical documentation (5% per year and product group or at least one file annually) is disproportionate for small portfolios, especially where no significant changes have occurred. Reviews should be conducted only when justified.
7. **Revision of Classification Rules**

The MDR classification rules are in part outdated and do not reflect current realities. There is urgent need for revision, particularly for low-risk products (e.g. brain spatulas) and software/AI-based devices. Products without direct clinical effect should be assessed differently.
8. **Simplification of Clinical Data Requirements**

Greater recognition should be given to Article 61(10) MDR, which allows clinical evaluations without explicit clinical studies—particularly for simple medical devices.
9. **Avoid Overinterpretation of Requirements**

Example: The interpretation of Annex II 3)b) should not mandate that validation documents from contract manufacturers be held by the legal manufacturer, especially where this could jeopardise intellectual property or supplier know-how.
10. **Summary of Key Demands:**
 - Avoid regulatory overinterpretation
 - Consistently apply risk-based approaches
 - Align regulatory scrutiny with the actual product risk rather than solely with formal classification