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The Effect and Impact of the MDR Delay

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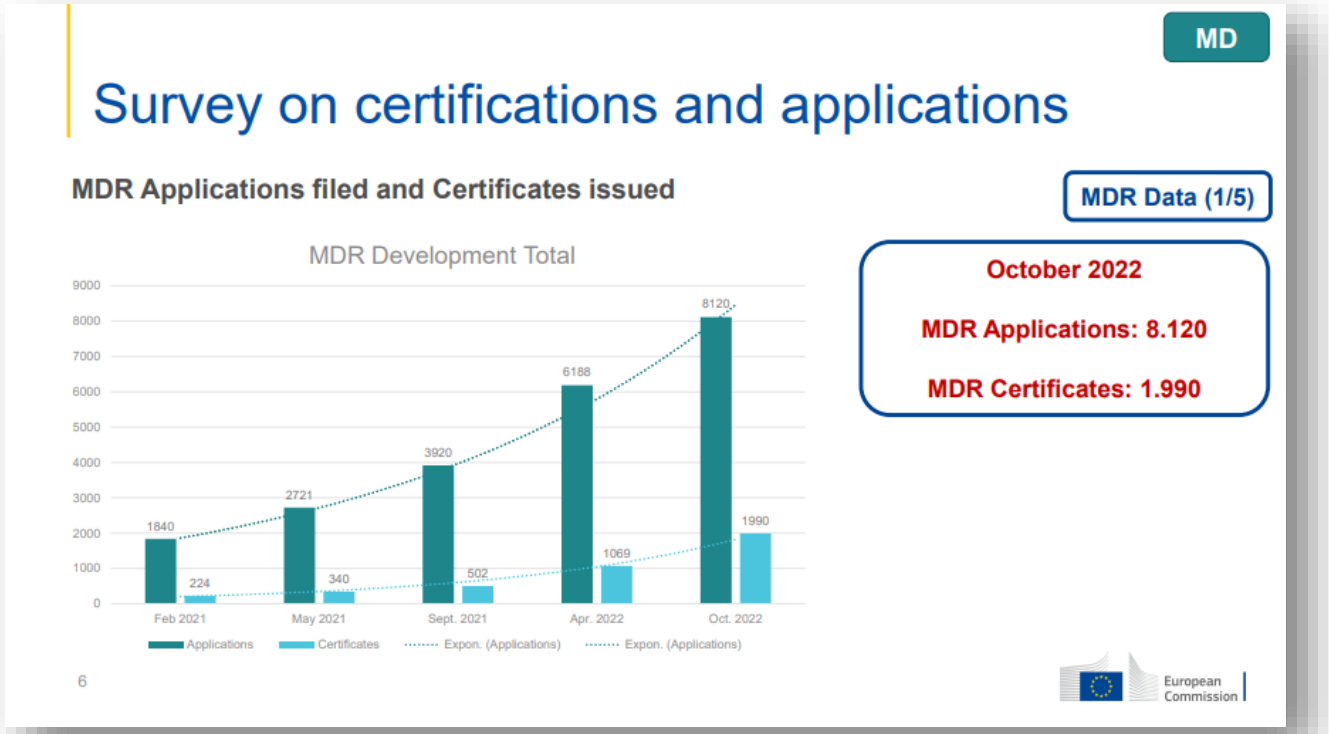
The 2023 amendment: A much-needed relief…



MedTech Europe
from diagnosis to cure

"The amendment of the Medical Devices Regulations' transitional provisions is a needed step forward to help ensure that more medical devices remain available to patients and healthcare systems across Europe. This decision grants Notified Bodies more time to complete certification of more than 500.000 medical devices and accelerates efforts to certify innovative devices in the pipeline," Oliver Bisazza, CEO of MedTech Europe, 7th Mar 23

The benefits of the extended transition for early starters and patients

- *The extension of MDD certificate validity offers more flexibility to more comfortably transition from MDD to MDR, with less need for inventory pre-builds.*
- *Must not decelerate or change submission plans/timelines for obtaining MDR certificates across the portfolio… Continue full steam ahead!!*
- *The abolishment of sell-off provision allows continued supply of products to patients.*
- *Black out period for significant changes remains. Deceleration in execution increases black out period.*
- *Impact outside the EU can remain a challenge.*
- *Conditions and specific circumstances mean that not all can benefit from the extension.*

(1) Council Directive 90/385/EEC ([3]) and Council Directive 93/42/EEC ([4]) constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

What's next?

- *Effective implementation by ensuring a **harmonized and uniform interpretation** of the law across the EU, Notified Bodies, Member States.*
- *Purposeful and efficient implementation by **avoiding bureaucratic burden** and ensuring **clear communication in and outside the EU**.*

MDR and IVDR implementation and governance challenges remain…

- *Continue to work on **application of non-legislative solutions** (MDCG 2022-14) to regain system capacity.*
- *The 2023 amendment provides relief for legacy product only. **Other solutions are needed** to ensure that medical devices and IVDs are certified and made available to patients in a timely, efficient, and predictable manner.*