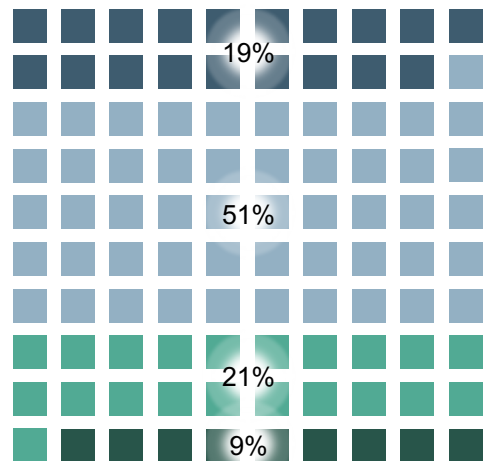


EU proposed extending transition period of the new Medical Devices Regulation (MDR) to 2027/8 to avoid shortage of essential medical devices and removing so-called sell-off date*.

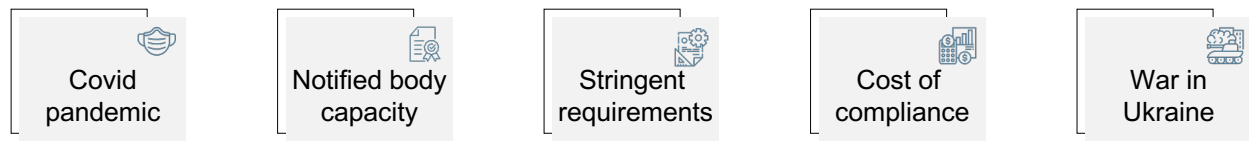


- ~ **4'300** certificates will expire by end of 2023
- ~ **12'000** certificates will expire by May 2024
- ~ **5'000** more can be approved by May 2024
- < **2'000** applications have been approved by now

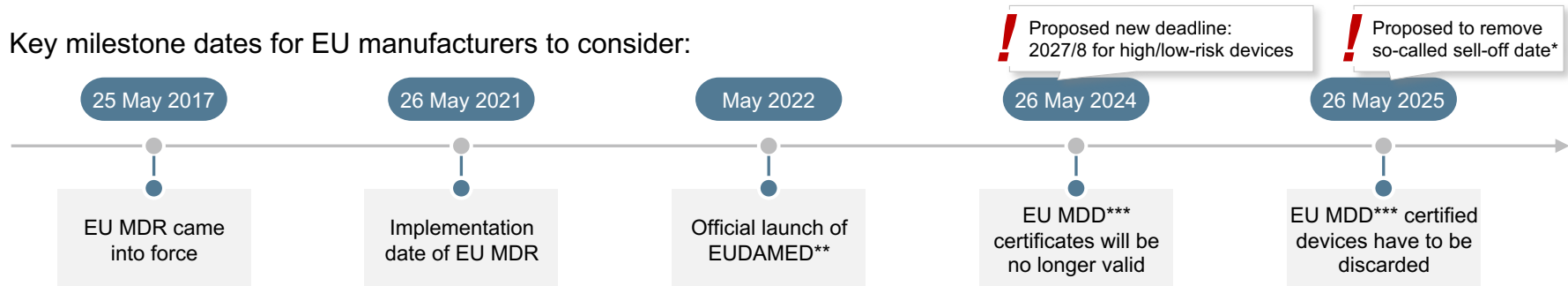


Only 7'000 out of 23'000 devices (30%) can be approved under EU MDR by May 2024.

Reasons for delayed implementation of EU MDR:



Key milestone dates for EU manufacturers to consider:



Sources: European Commission, Reuters, TSN business intelligence.

*sell-off date: deadline to discard devices certified according to MDD. **EUDAMED: European database on medical devices. ***MDD: European Union Medical Devices Directive.