Boston® Materials –

MDD – MDR
Are you prepared?

What is changing and what are the change drivers?

Visit MDR workshops on Saturday 28th April at EFCLIN in Dubrovnik!

Current Medical Device Directive (MDD)

23 articles, 60 pages

New Medical Device Regulation (MDR)

123 articles, 175 pages

May 2017 › 3 yrs transition › 2020

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Meet us at our MDR-café for support.

CURRENT MDD	NEW MDR
■ Limited clinical evidence required, general acceptance of data from similar devices ■ No Regulatory Authority involvement with submission approval ■ Strong data protection	■ Clinical trial data before CE marking for implants/high risk devices , similar to FDA ■ FDA PMA type approval (scrutiny process) for high risk/implantable devices (data access) ■ Data transparency, including publication of clinical trial data and safety summaries
■ Format of Technical Files not defined	■ Technical documentation content and structure defined in the law
■ Vigilance reporting timelines similar to FDA (30 days)	■ Vigilance reporting timelines reduced to 15 days
■ Limited traceability requirements in the supply chain	■ Implementation of UDI (similar to US), EU medical devices database, traceability obligation
■ Basic labeling requirements	■ Specified, expanded content for DFU, required patient implant cards, medical device statement in labels
■ Labeling requirements for some hazardous substances	■ Possible ban or phasing out of a large number of hazardous substances (phthalates, boric acid)
■ Weak control of Notified Bodies (although this is rapidly changing already)	■ Very strict requirements and control over Notified Bodies, small Notified Bodies will likely disappear

Join us for coffee!
Get support!
Win great prices!

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