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MDR COUNTDOWN: 7 MONTHS UNTIL APPLICATION

Axon MDR Seminar
2 October 2019

health
food
technology

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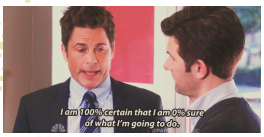
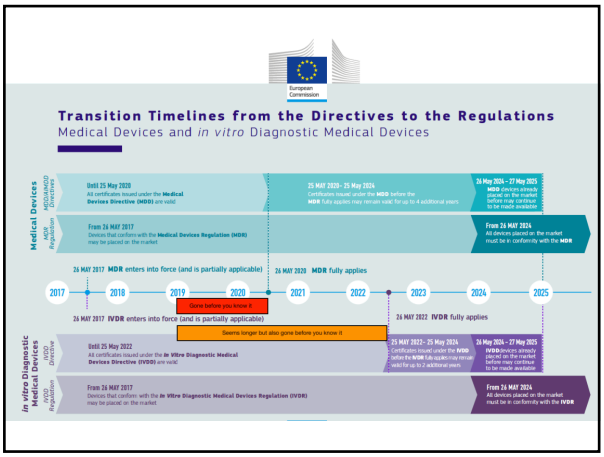
Clock is ticking towards DoA for MDR

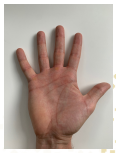
- We are well past two thirds of the MDR implementation period
- Five notified bodies accredited for MDR
- Some big notified bodies threw in the towel for MDR and (AI)MDD



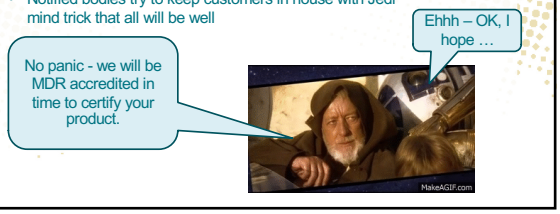
"How did it get so late so soon? Its night before its afternoon. December is here before its June. My goodness how the time has flewn. How did it get so late so soon?"
~Dr. Seuss



Implementation deadlines



- First companies with up-classified class I devices or missed windows for (AI)MDD recertification are finding that they will not have an MDR certificate in time for DoA
  - Software, inhalers, reusable surgical instruments
- Notified bodies try to keep customers in house with Jedi mind trick that all will be well



Implementation generally

Which	What
Known knowns	• MDR text • Rolling Plan that keeps changing • When to apply at notified body for (AI)MDD recert? • Corrigendum – dots, commas and no transition amended
Known unknowns	• Corrigendum no 2 – class Ir but anything else? • Common specifications • Implementing acts • What standards will be harmonised? • A lot of guidance (except MDCG stuff on UDI, PRRC, implant card and CAMD Q&A) • Eudamed functionality by March 2020 – but which parts? • National implementation – but which member states and how? • Your notified body accredited to the scope you need? • Your notified body ready to accept MDR or MDD cert (re)application? • Your notified body not shutting down on you?

Unknown unknowns	• National enforcement in case of
	  • bottleneck induced shortages
	  • notified body failing to deliver MDR certificate timely

All over the place unpredictably crazy	• Brexit – plan for a hard Brexit and have plans B and C • Switzerland and Turkey MRA mechanisms

Implementation

- Steady stream of UDI related guidance by MDCG
- Not that helpful PRRC guidance
- Recent SSCP guidance
- More CS are slowly becoming available
  - Annex XVI products
  - Reprocessing
- Implementing decision on expert panels for PFKAS (Procedure Formerly Known As Scrutiny (Clinical Evaluation Consultation Procedure)
- Member States national legislation – NL, DE

Extension of deadlines?

- Rumor: Corrigendum 2 in the works
  - Will likely concern a 'correction' of article 120 (3) MDR as regards class Ir devices and need to have a Ir certificate by DoA (26 May 2020)
- Will likely cover entire soft transition period (26 May 2020 - 27 May 2024)
- No other extensions foreseen but more persistent rumors
  - Other up-classified class I devices may be covered too

Notified bodies landscape

- MDR : five notified bodies designated, of which sometimes significant scope restrictions
  - E.g. not Annex X (type examination) (BSI and Dekra Germany)
  - E.g. not class III devices (IMQ)
  - E.g. not breast implants (TUV SUD and Dekra Germany)
  - E.g. no active implants (Dekra Germany and TUV Rheinland)
- IVDR: none yet but likely soon
- Rumors rumors rumors – 20 NBs designated by the end of the year?
- More NBs on the way further to the next MDCG meeting

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 0124	DEKRA Certification GmbH	Germany
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

Notified bodies landscape

- Issues start to arise with notified bodies (partially) laying down service in sight of MDR deadline
  - LRQA, UL, AMTAC/Intertek but also others
  - Orphaning not a solution for certificates from UK notified bodies: Commission takes view that hard Brexit ends orphaning by member states
- Notified bodies more and more under capacity pressure
  - A lot of disruptions and certificate issues resulting from lack of capacity (renewal audits missed, sudden extra requirements (especially in clinical) resulting in certificates suspended or not renewed)

Notified bodies landscape

- Concept of 'significant change' still not crystalized
  - Crucial to understand for manufacturers relying on 'soft transition' (2020-2024 exemption under article 120 (3) MDR)
  - Determines M&A structuring for all manufacturers that rely on soft transition
    - anything other than a shares transfer without reorganization will likely cause a significant change that will lead to instant loss of certificates
    - Merger pre-closing or post-closing commitments must be carefully drafted as not to cause a significant change
    - Notified bodies have no time to review anything quickly in view of MDR deadlines

Notified bodies landscape

- BSI UK issues first CE certificate under MDR on 2 September 2019 for class IIa device under rule 20 ('simple' inhaler for medicines upclassified from class I)
- TUV SUD close on their heels with class III software device

BSI certifies first product to the Medical Devices Regulation

E-news: 02 September 2019

World's first MDR conformity certificate

BSI, today announces that it has certified the first product, to the medical devices regulation (EU 2017/745) via its UK notified body (0086).

The product is classified as a IIa device under Rule 20 for the MDR. Prior to the new more stringent legislation coming into force, this was classified as a Class I device and did not need to be reviewed by a notified body.

Manuela Gazzard, Group Director of Regulatory Services at BSI said: "We are delighted to be issuing the world's first conformity certificate under the new MDR. This is testament to our client's commitment to ensuring patient safety remains at the forefront of their product development."

Gary Slack, Senior Vice-President of the notified body at BSI added: "Being the first to achieve designation and now the first to deliver a conformity assessment under the new

Consequences of NB ceasing operation

- Notified body gives max 90 days notice
  - After that period, your CE certificates are invalid, no matter the date on them
  - Within that period you must be certified by another notified body
    - Basically impossible to do within 90 days
    - Be prepared for orphaning scenario (max 12 months under wings of a competent authority pending NB onboarding)
      - Make sure you understand the scenarios and conditions (which CA to go to, how does their procedure work, etc.)
- Commission takes the view that a hard Brexit ends all ongoing orphaning of UK NB certificates (AMTAC, LRQA)

What is there left to do until DoA?

- Know your timing – what needs to happen when and have a strategy for that
- First NBs are up and running and inventing the wheel in the first product and QMS audits: gain experience from that
  - So far only BSI and TUV SUD seem to have been doing QMS audits on a very limited number of manufacturers
  - Approaches seem different based on differences in QMS philosophy
  - Exchange experience where possible and engage branch associations to share information

What is there left to do until DoA?

- Be ready to pivot based on new EU guidance becoming available
- Get the economic operator stuff right
  - PRRC guidance less than comprehensive
  - Industry struggles to understand degree of independence required for AR and PRRC
  - New Market Surveillance Regulation (Regulation (EU) 1020/2019
- Keep your friends (crucial suppliers) close and your notified body closer

What is there left to do until DoA?

- Be ready to implement Eudamed interfacing and process, have SRN (if OUS Union then have AR with SRN first) and prepare for UDI
  - Eudamed big bang release not expected anymore
  - Staged release of modules in four batches (March 2020, November 2020, May 2021, May 2022)
  - Or: Eudamed may not be ready at all
- Be intelligent with long term commitments (e.g. tenders)
  - Can you guarantee supply of every device over the next five years?
  - Do you have a plan B?

What is there left to do until DoA? Plans B

- Have plan B for scenarios:
  - Hard Brexit
  - Switzerland and Turkey not being Union under MDR
  - Notified body calamities
    - NB shuts down / certs invalid as a result of Brexit, Swiss or Turkish dependency
    - NB misses MDR deadline for either (AI)MDD or MDR (re)certification
  - Other problems with organisation / certification status that lead to disruptions
    - Understand supply chain and concept of placing on the market
    - Have supply chain scenarios
    - Understand national exemption regimes for essential devices

Thanks for your attention!

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