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CHAMBERS EUROPE 2016

TRANSITIONAL REGIME, BOTTLENECKS AND MAJOR MDR ITEMS IMPACTING TRANSITION

Axon Seminar
10 May 2017

health
food
technology

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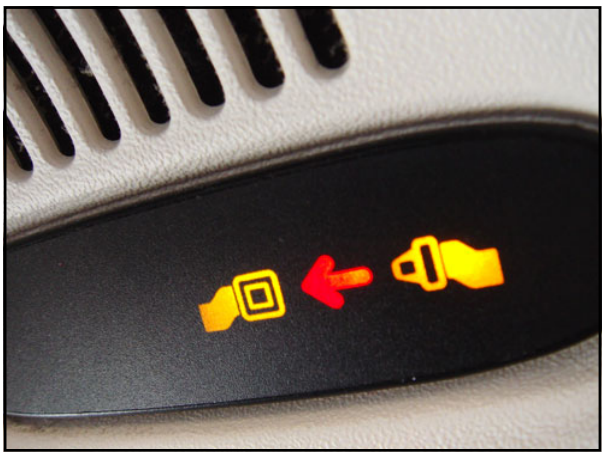

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REGULATIONS

* **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC** ([1]) 1

* **Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU** ([1]) 176

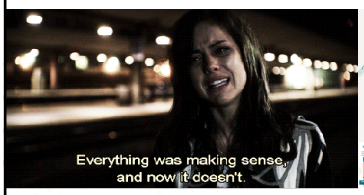
([1]) Text with EEA relevance.

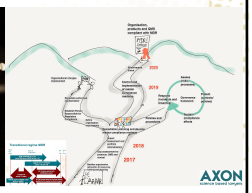
EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other Acts are printed in bold type and preceded by an asterisk.

We have a final text, and now?

- Overcome inertia and start attacking this thing – it will be a lot of work
- Not ready in time means no more placing product on the market - there is no grandfathering





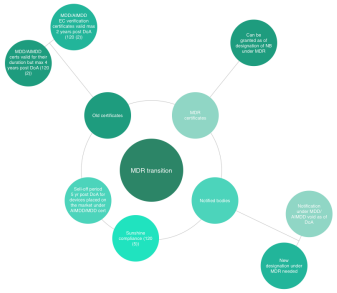
If I ask companies about their transition plan, they mostly answer:

You do not want to end up here – bankrupt or sold to a competitor

Agenda

- Transitional regime
- Bottlenecks
- Other major items

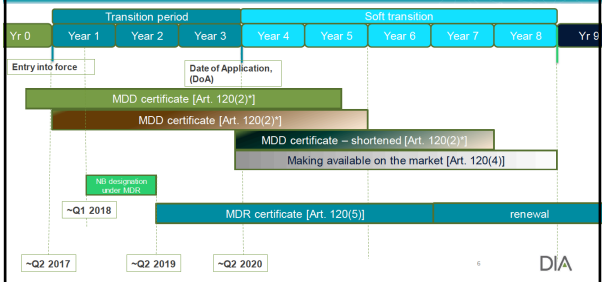
Transitional regime: Article 120



Transitional regime

Transition details and timelines

**From DoA of MDR, NO significant changes and PMS, Vigilance EO requirements of MDR to be met*



Slide: Gert Bos at DIA Euromeeting 2017

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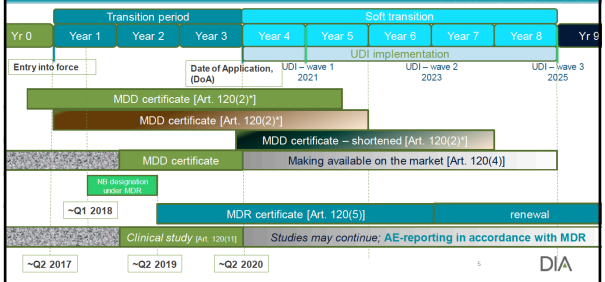

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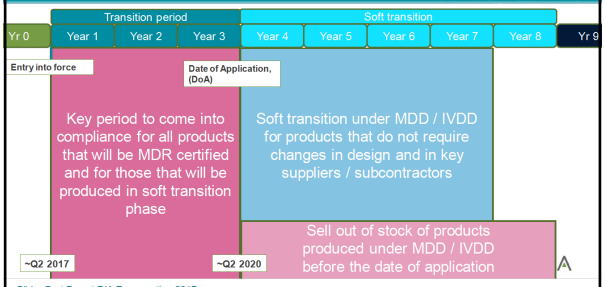
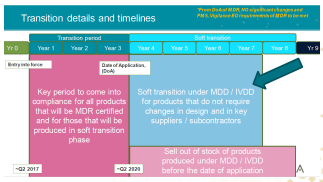


Slide: Gert Bos at DIA Euromeeting 2017

Bottlenecks 'soft transition'

- Be careful with 'soft transition'
- Article 120 (3) restrictions
  - No significant changes in design and intended purpose
  - MDR level controls and obligations
  - Notified body cannot be changed anymore



3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

Transitional regime bottlenecks – not for class I

- Transitional regime works only for existing certificates or certificates obtained during transitional period
  - Big problem for any device currently class I partially (M/S) or fully self-certified
    - Notably software and substance based devices
  - Every up-classified currently class I device must be MDR certified before DoA
    - In other words: the group with the least experience with CE certification processes will need to get it right in the shortest timeframe and with notified bodies that are just starting to settle in their new MDR designation

Transitional regime bottlenecks – careful with MDD/AIMDD certs

Relying on article 120 (3) 'soft transition' basically means that your device is 'locked' for the rest of the duration of the certificate

- No 'significant' changes to design or intended purpose possible
  - This is already interpreted as that no certificate amendment during that period is possible (e.g. no change of crucial supplier)
- Still have to meet MDR formalities
- Joined at the hip with your notified body (cannot change during soft transition)

> 3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.
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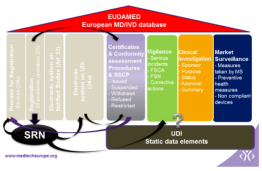
Designation of notified bodies

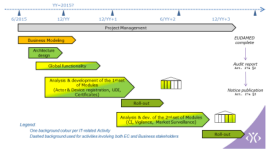
- No MDR certificate without MDR notification
  - Unknown currently: will all NBs be notified at the same time or in a particular order?
- Notified body capacity
  - Will my notified body complete MDR certification before DoA?
    - If not, what alternative will it offer?
    - Will it differ if it's not my fault certification is not complete?
  - Will I be able to predictably and reliably 'reserve' conformity assessment capacity?
  - Will I be able to jump ship to another notified body if things go wrong pending MDR certification?

Will Eudamed be ready in time?

First Step: Get a Single Registration Number (SRN)



Commission Draft roadmap 1/4: Overview (MD only)



Concurrent privacy by design requirements under GDPR

- General Data Protection Regulation has already entered into force, transitional period ending 25 May 2018
- Will apply to any device that processes personal data, both on hardware and software level – possible overlaps with MDR
  - Requires privacy by
    - Design
    - Default
  - Requires cybersecurity measures

Other major items

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PRODUCT	PROCEDURAL	COMPANY/LEGAL
Definitions scope check • Check if existing products are affected by definition changes • Check if non-regulated products are now in scope of MDR	PMS • PMS plan • PMS reports • PSURS • PMCF • Validation of PMS updates with notified body	Liability • Manufacturer • AR • Review corporate liability cover and decide on sufficient coverage for potential MDR liabilities
Classification rules • check for substantial amendments (e.g. rule 10a for software)	Vigilance • Amend procedures to new deadlines and requirements in MDR	Prescribed AR role and contract requirements • contract requirements (impact on intra-group role of AR) • implement in QMS
Documentation amendments • Technical documentation ○ New requirements for content, organization and control of documentation • Declaration of conformity in accordance with Annex III model in MDR ○ Include UDI	EUDAMED and related • Registration of products and economic operators • UDI ○ Make UDI transition plan for staggered UDI introduction under MDR • Traceability • Monitor development and rollout of EUDAMED and impact on transition plan • Monitor EUDAMED interface specifications • Systems check to determine if they can handle EUDAMED used formats for output and input	Supply chain regulation changes • impact on existing and future third party agreements (importer, distributor) • various economic operator roles within The manufacturer • Is the manufacturer importer, distributor for third parties? • Does the manufacturer assemble procedure packs / systems?
Revisit clinical evidence review per product • new clinical evaluation requirements • equivalency requirements • well-established technology for purpose of MDR? • Additional PMCF needed? • Update clinical evaluation for each device (also from new MEDDEV 2.7/1 rev 4) • "remediate, replace, retire" decision for each product	QMS • Concurrent ISO 13485:2016 implementation (transition until March 2019)? ○ Check ISO 13485:2016 implementation initiatives and define dependencies with MDR QMS requirements ○ Check timing of renewal of existing ISO 13485 certificates • requirements of MDR are considered in management review, output of review is recorded; • changes to QMS are planned to make sure that the integrity of the QMS, and the safety and performance of devices under the control of that QMS, are maintained; • training on the requirements of the MDR and new/modified procedures of the QMS are documented, delivered, recorded and shown to be effective ○ Have personnel had the necessary training on the Regulation, as appropriate for their responsibilities?	New roles required re-orientation on existing roles • Person Responsible for Regulatory Compliance ○ Define responsibilities in QMS ○ Appoint person(s) with required qualifications • In case of multiple persons, define responsibilities for each • Personnel for interacting with EUDAMED database

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	○ Are the personnel that undertake internal audits trained in the new requirements? ○ What records are available of this training? • close loop on implementation: internal audits to confirm effective implementation of any new or revised procedures. • new procedures ○ define new procedures needed and existing procedures to revise ○ timing of creation or amendment of procedures • Monitor MDCG guidance on notified body assessment of technical documentation for devices selected on a representative basis (sampling) becoming available	
Conformity Assessment • New requirements for • Class III implants and class IIb active devices intended to administer and/or remove a medicinal product (clinical evaluation consultation procedure) ○ Does an exemption to clinical evaluation consultation procedure apply? • Class IIb implants • Class I reusable surgical instruments	Clinical investigations • new clinical investigation regime different from ISO 14155:2012 – make gap assessment in clinical investigation procedures	Monitor national implementation of MDR • (re)Designation of competent authorities • implementation of single use reprocessing regime • implementation of hospital produced devices regime • implementation surrounding new clinical investigation regime • Implementation of national penalty regime • Implementation of national fees for surveillance system
Labeling • Gap assessment of labelling and IFU requirements per device ○ address hazardous substances labelling requirements • Implant cards (and their language requirements) • Summary of safety and performance for class III and implantable devices • Layman summary of clinical investigation for publication in EUDAMED • Device label • IFU • UDI	MDR transition plan validation • Impact assessment per business unit • Validate with notified body	
Dangerous substances		Set up procedures for dealing with certain third parties • Parallel import relabel/repack requests

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• Check for substances that are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, or endocrine disrupting properties • Document a justification for use per product		• Parts and component suppliers and maintenance/repair companies
Define impact on products • Existing ○ invest or abandon? • Pipeline ○ need to pivot on regulatory assumptions? ○ clinical investigations • Future ○ commercial and regulatory assumptions still viable?		

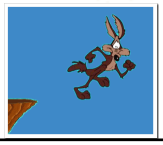
BASIS

- Transitional regime opted for
  - Certificates issued during transitional period (94 (2) 2nd regime of DoA+max4)
  - Phase out products / later priority products (94 (5a) regime of lawful on market and DoA+max5)
  - Manage possible temporary concurrent application of MDD and MDR
- Notified Body management for transition
  - Availability of slots for (re)certification into MDR
    - Existing products to remain on market
    - New product coming to market
  - Availability of slots for certification under MDD
    - Existing products for 94 (2) 2nd certificate DoA + max 4 years
- Commercial plan to exploit transitional period
  - Corporate level
  - Business unit level
- Define and validate transition plan contingency measures
  - Frontloading of supply chain
  - Change of notified body
  - Acceleration of clinical evidence
- Monitor legal developments
  - Implementing and delegated acts under MDR
  - Development of guidance on national and EU level
  - Development of Common Specifications (in addition to standards)
- Define dependencies with General Data Protection Regulation requirements
  - Privacy by design requirements (e.g. impact on software)
- Define dependencies transition plan with other markets relying on valid CE mark
  - Middle-East, Asia, Australia, Canada

No grandfathering

THERE IS NO GRANDFATHERING !

- All devices on the market are phased into the new system by the end of transitional period
- This mean that you have to do a new conformity assessment under the new rules for all devices currently on the market or remove the product from the market



#Brexit

- Is your notified body located in UK?
  - After Brexit the NB may not be notified anymore if no mutual recognition deal is in place
- Is your business dependent on the UK market?
  - Watch for a mutual recognition deal to shape up

THANKS FOR YOUR ATTENTION

AWARDED MOST INNOVATIVE LAWFIRM 2013

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