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MDR and IVDR – The countdown has started

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Who we are

DIERKS+ COMPANY

- Dierks+Company focuses on providing legal advice to healthcare and life sciences
- We pursue a common goal with our clients – to improve lifes!
- We help companies to overcome barriers, to develop innovative solutions to complex legal challenges in Europe, and to position their products and services in the appropriate regulatory environment

MDR and IVDR – The countdown has started

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- Key changes
- Transitional provisions

- Key changes
- Transitional provisions

- New challenges
- New documents
- New everything

MDR and IVDR – The countdown has started

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The New Provisions

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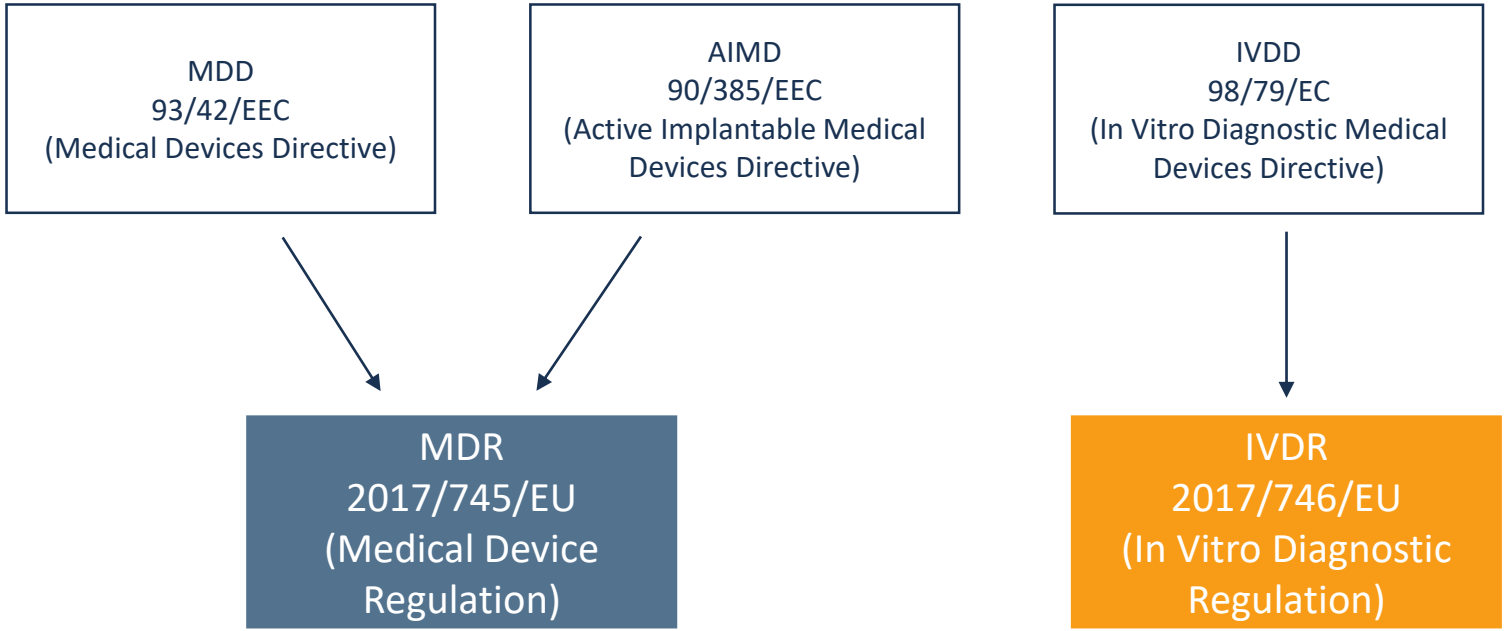

Transitional Periods for MDR & IVDR

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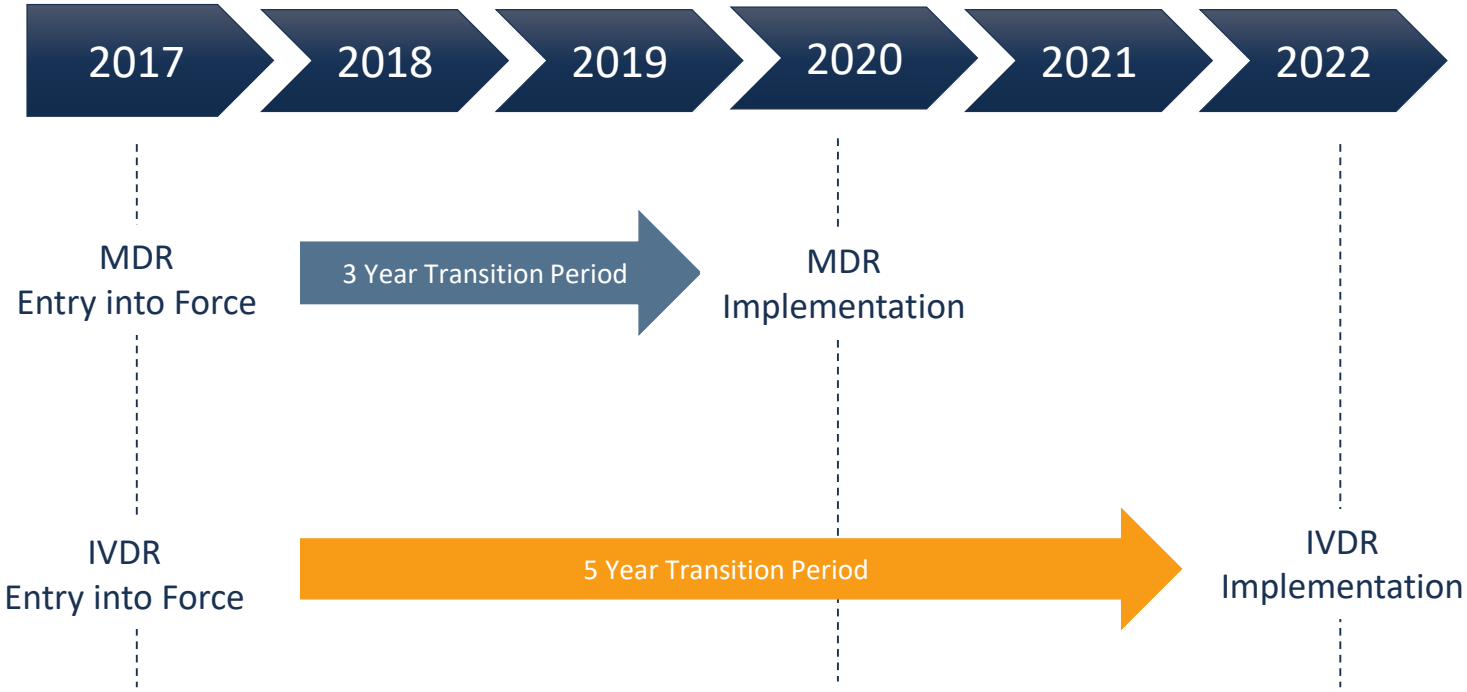

MDR
Key Changes

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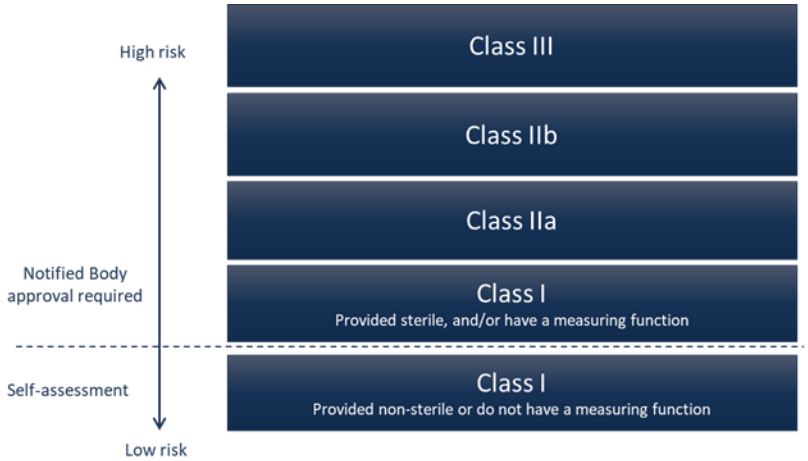
- Product scope expansion:
  - Active implantable devices (previously regulated in AIMD)
  - Products without intended medical purpose (e.g. coloured contact lenses) and accessories of medical devices
  - Software serving the purpose of diagnosis and therapy

- Classification
  - Classification structure unchanged
  - Classification rules expanded
  - Reclassification of devices according to risk, contact duration and invasiveness due to changes in definitions and basic principles



MDR
Key Changes

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- More rigorous clinical evaluation & documentation
  - Clinical investigations to be conducted if insufficient clinical evidence to support claims both on safety and performance
  - New and tighter criteria for demonstrating equivalence:

    More clinical data must be obtained from clinical investigations of the device
  - Post-market clinical follow ups (PMCF)
  - Expanded requirements for technical documentation
- Traceability & transparency
  - Registration of economic operators: Single Registration Number (SRN) and product registration: Unique Device Identification Number (UDI) mandatory
  - Devices and Economic Operators registered in publicly accessible database EUDAMED (summaries for safety and performance for class III medical devices)

MDR
Key Changes

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- Notifying Bodies under MDR
  - Transformation from industry partner into market surveillance apparatus
  - Stricter designation criteria and supervision of NBs themselves
  - Reapplication for designation under the new rules (deadline was 26 Nov 2017)
  - Manufacturers may be affected by loss of NBs designation or voluntary withdrawal

- Identification of “qualified person”
  - Person responsible for all aspects of compliance with requirements of MDR within organization must be appointed
  - Duty to document specific qualifications of this individual relative to the task
  - Appointment subject to review by NBs

MDR
Key Changes

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- Specifications
  - MDR grants EU Commission or expert panels authority to publish so called Common Specifications *(="… a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with legal obligations applicable to a device, process or system.")*
  - Common Specifications applicable in addition to Harmonized Standards and seen as State of Art
  - Have to be included in evaluation process by NBs

- No "grandfathering" provisions
  - Under MDR all currently approved devices must be recertified in accordance with the new requirements
  - 3 year transitional period

MDR

Transitional Regime (Article 120 MDR)

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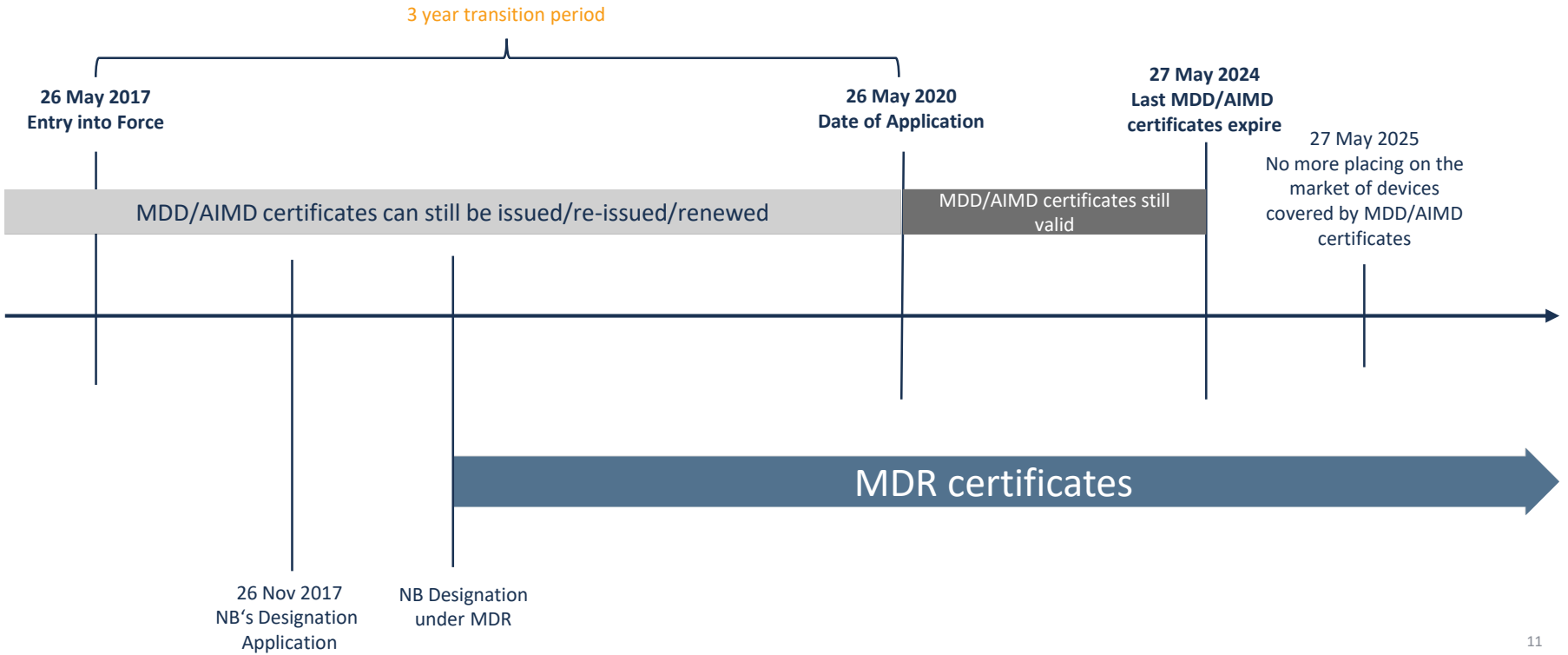

MDR

Transitional Regime (Article 120 MDR) – In a Nutshell

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+ No requirement to re-certify under MDR by Date of Application (26 May 2020) of the new Regulation

+ Certificates issued **prior** to the entry into force of MDR remain valid for the period indicated on the certificate (except certificates under Annex 4, Directive 90/385/EEC or Annex IV Directive 93/42(EEC), which expire at the latest 2 years after the date of Application)

+ Certificates issued **during** the transition period remain valid for the period indicated (maximum 5 years), but expire at the latest 4 years after Date of Application)

+ Devices legally placed on the market under the Directives prior to the Date of Application may be made available up to 4 years after that date

IVDR
Key Changes

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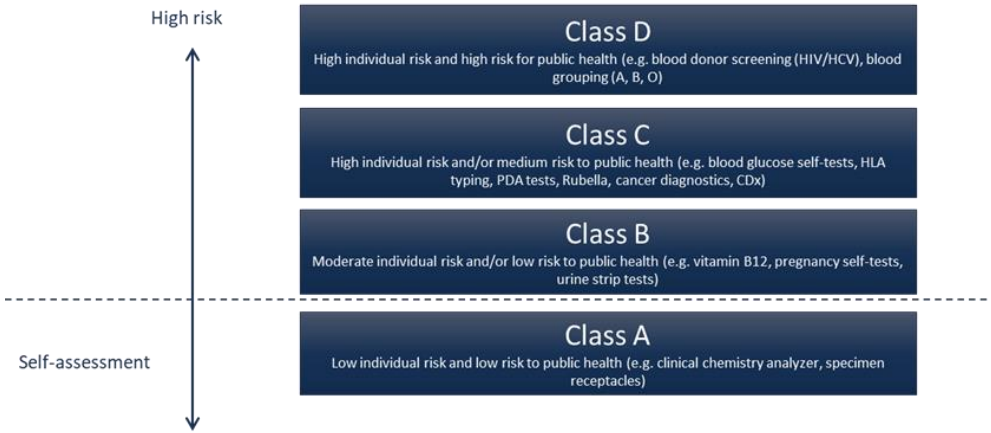
- Product scope expansion, e.g.:
  - Diagnostic services (including internet based services)
  - Genetic testing devices
  - Tests measuring predisposition for specific disease or medical treatment susceptibility
  - Lifestyle tests with indirect medical purpose
- Reclassification of devices according to risk
  - Move from list-based to risk-based approach that follows GHTF rules
  - New classification structure with 4 risk categories: A (low-risk) to D (high risk) and 7 classification rules
  - Estimated that 80% of IVDs will require reassessment



IVDR
Key Changes

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- More rigorous clinical evaluation & documentation
  - Clinical performance studies for evidence of safety and performance proportionate to device's assigned risk class
  - Collect and retain post-market clinical data / ongoing assessment of safety risks
  - Studies and post-market documentation: significant investment of time and resources
  - Technical documentation of devices more detail and new requirements

- Traceability & transparency
  - Registration of economic operators: Single Registration Number (SRN)
  - Product registration: Unique Device Identification Number (UDI)
  - Devices and Economic Operators registered in publicly accessible database EUDAMED
    - Summary for safety and performance for class C and D products

IVDR
Key Changes

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- Greater Scrutiny of and by Notified Bodies
  - IVDR increases scrutiny of manufacturers by NBs (e.g. unannounced audits, product sample checks)
  - Reclassification for products: more IVD will have to include NB into conformity assessment
  - Stricter scrutiny of NBs themselves as IVDR defines rigorous designation procedures (reapplication for designation under the new rules)
  - Manufacturers affected by loss of NBs designation or voluntary withdrawal due to increased requirements

IVD key changes

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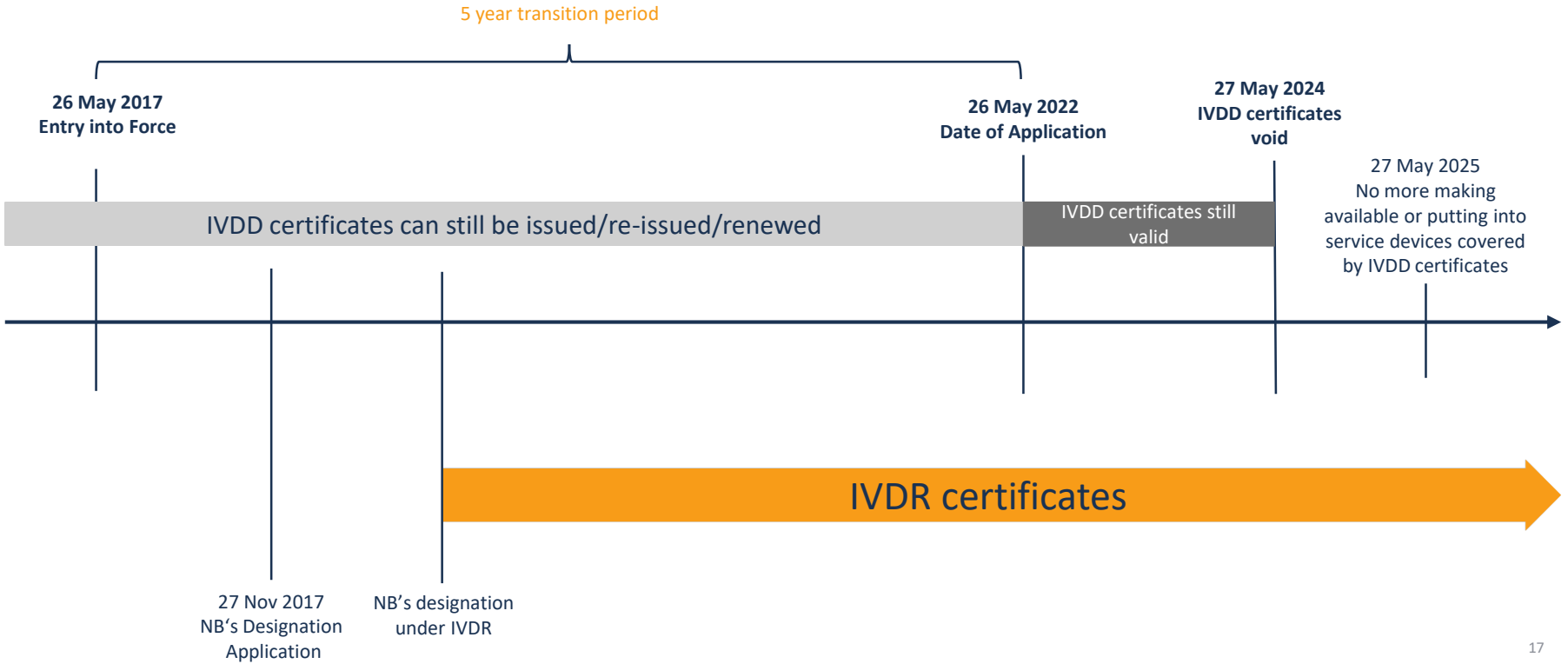
- Identification of “qualified person”
  - Appointing of person within organization responsible for all aspects of compliance with requirements of MDR
  - Duty to document specific qualifications of this individual relative to this task
  - Subject to review by NBs

IVDR

Transitional Regime (Article 110 IVDR)



IVDR

Transitional Regime (Article 110 IVDR) – In a Nutshell

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+ No requirement to recertify under the IVDR by the date of application of the new Regulation

+ Certificates issued **prior** to the Entry into Force of IVDR remain valid for the period indicated on the certificate (except certificates under Annex VI of Directive 98/79/EC, which expire at the latest 2 years after the Date of Application (26 May 2022)

+ Certificates issued **during** the transition period remain valid for the period indicated (maximum 5 years), but expire at the latest 2 years after the Date of Application

+ Devices legally placed on the market under the Directives prior to the Date of Application of IVDR may be made available up to 3 years after that date

MDCG – started in Nov 2017

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- 3 meetings so far, Topics include:
- Implementation, by COM acts and at national level: forbidden, useful or mandatory? Notification!
- Interoperability of EUDAMED
- Manufacturer Incident Report Form
- Guidance and forms on designation of NB processes
- Harmonising other standards to MDR/IVDR: "Annex Z"
- Common specifications for the groups of products without intended medical purpose Annex XVI
- CS for IVD Class D HCV Testing and Nucleic Acid Amplification in qualitive HIV assays
- HTA Legislative proposal
- 1 Stakeholder meeting
- Draft guidance on Basic-UDI and nomenclature

Impact of MDR & IVDR

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+ Goal was to bring about robust, transparent, predictable and sustainable regulatory framework and ensure a very high level of safety within healthcare industry while continuing to support innovation

+ Until changes completely implemented some bumps in the road are to be expected

+ Higher demand for NBs services while total number of NBs expected to decrease - might lead to delays both in assessments of devices already on the market as well as newly developed devices

Impact

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+ Increased costs due to extensive obligations stipulated by the new Regulations

  – threat to SMEs

+ Steep increase in complexity in comparison with the old provisions

  – manufacturers need to put in place strategies to tackle the issue

+ Violating obligations laid down in the Regulation can result in the ban of a device from the Common Market by the Commission until deficit in compliance is remedied

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Untwisting Complexity in Healthcare and Life Sciences