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INTELLIGENCE RÉGLEMENTAIRE ET CONFORMITÉ DES PRODUITS DE SANTÉ

MD & IVD

REGULATIONS (EU) 2017/745 & 746

Survival Kit

IMPLEMENTATION TIMELINE : What is done, what's coming next ?

www.nexialist.fr

March 2019

MD & IVD

Foreword

Since the publication of **Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR)** by the European Commission in may 2017, many guides and other documents have been issued to help their implementation. Indeed, we are now half-way from the **legal deadlines** before regulations become mandatory.

In that race to implementation, the European Commission issued an **informative rolling-plan*** of actions already done or to be coming. Here is the graphic and interactive translation made by nexialist to help you to understand this transition. These three charts represent the path traveled and coming, **hyperlink** were added to give you a quick document access.

Have a good reading !

**Source : https://ec.europa.eu*

MD & IVD

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Summary

Acronyms

EEA : European Economic Area
EU : European Union
EUDAMED : European Database on Medical Devices
EURL : European Union Reference Laboratories
IVD : In-Vitro Diagnostic
IVDR : In-Vitro Diagnostic Regulation (EU) 2017/746
MD : Medical Device
MDCG : Medical Device Coordination Group
MDR : Medical Device Regulation (EU) 2017/745
NB : Notified Bodies
NBOG : Notified Body Operations Group
OJEU : Official Journal of the European Union
UDI : Unique Device Identification
Q : Quarter
SCHEER : Scientific Committee on Health and Environmental Risk

Legend

Hyperlink : Documents identified by nexialist
Hyperlink : Corresponding articles of the regulations

Regulations (EU) 2017/745 & 746 // Implementation Timeline : What is done ?

✓ **Q3 2017**

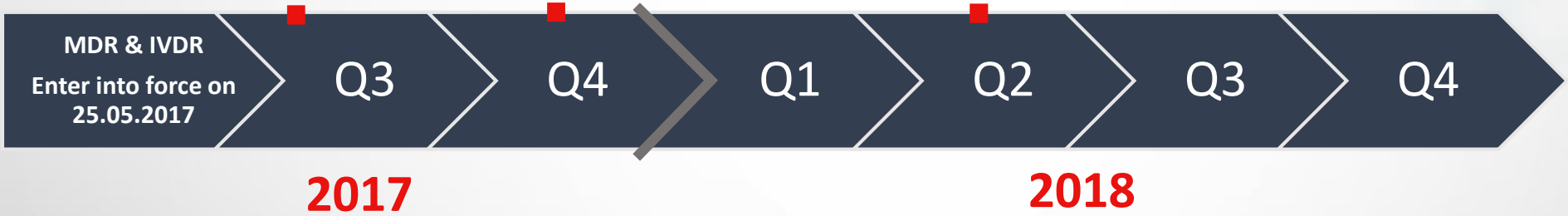
Mandate SCHEER committee to prepare guidelines of phthalates : Hyperlink
SCHEER's opinions expected by mid 2019: Annex 1 section 10.4.3 MDR

✓ **Q4 2017**

« NB scope of designation »
Article 42 (13) MDR, Article 38 (13) IVDR
Implementing Regulation (EU) 2017/2185
NBOG MDR FORM
NBOG IVDR FORM
Expert advisory structure : Setting of MDCG
Article 103 MDR - Minutes

✓ **Q2 2018**

EUDAMED « Implementation plan » Article 34 (1) MDR



✓ **Done during 2018**

« Communication Campaign »
- Factsheet for IVD and MD manufacturers
- Implementation modele for MDR
- Transition Timelines from the Directives to the Regulations - MDs and IVDs
- Factsheet for Authorised Representatives, Importers and Distributors of MDs and IVDs
- Factsheet for Authorities in non-EU/EEA States on MDs and IVDs
- Factsheet for the Procurement Ecosystem of MDs and IVDs

EU Regulations 2017/745 & 746 // What's coming next ?

✓ **Q1 2019**

- **Expert advisory structure : Setting of MDCG subgroups** Article 103 MDR - 10 Subgroups List
- **« EU MD's nomenclature » :** Article 26 MDR, Article 23 IVDR Guidance MDCG – MD nomenclature
- **EUDAMED « drawing up of functional specifications »** Article 34 (1) MDR - EUDAMED functional specifications

▪ **Q2 2019**

- **« Standardization mandate » :** Article 10 R (EU) No 1025/2012
- **« UDI System : designation of issuing entities »** Recital 94 – Article 27 (2) MDR, Recital 94 – Article 24 (2) IVDR
- **Implementing act – Common specifications related to reprocessing of single-use MD – Public consultation** Article 17 (5) MDR

▪ **Q3 2019**

« Setting up of experts panels » : No Comitology Involved - Recital 94 Article 106 (1) MDR

Q1 Q2 Q3 Q4

2019

▪ **Q4 2019**

- **« Reprocessing of single use MD » :** Article 17 (5) MDR → National sovereignty
- **« Definition of fees for the advice provided by expert panel » :** Article 106 (13) MDR
- **EUDAMED Change management and maintenance rules :** Article 33 (8) MDR , Article 30 (1) IVDR
- **« Common specifications for IVD Class D » :** Articles 9 and 48 (6) IVDR

▪ **Q4 2019 (until Q1 2020)**

- **« Rules to facilitate fulfilment of tasks by EURL and to ensure their compliance with criteria » :** Article 100. 8 (a) IVDR
- **« Setting up of new structures under IVDR : EURL » : No Comitology Involved -** Recital 94 – Articles 48 (6) and 100 (1) IVDR

EU Regulations 2017/745 & 746 // 2020 : A regulatory Odyssey

+ 2 YEARS BEFORE IVDR LEGAL DEADLINE 26/05/2022

- **Q1 2020**
  - **« EUDAMED : Setting of helpdesk »** Article 33 (8) MDR **:** to be done just before **-> « EUDAMED : go-live » (as soon as a notice is published in the OJEU) :** Article 34 MDR
  - **EUDAMED « Audit of functional specifications » :** Article 34 (2) MDR
  - **« Common specifications for products without a medical purpose » :** Articles 1 (2) and 9 (1) MDR

26/05/2020 - LEGAL DEADLINE
(EU) 2017/745 MDR become mandatory

2020

- **Q2 2020**
  - **« Definition of fees for the advice/testing activities performed by EURL » :** Article 100 (8) b MDR
  - **« Notified bodies designation » to be finished by may 2020 :** Article 42 MDR
  - **« Setting up of experts laboratories » : No Comitology Involved :** Article 106 (7) MDR

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La santé de demain se construit aujourd'hui

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