European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR Virtual Session
COUNTDOWN TO THE MEDICAL DEVICE REGULATION
17 February 2021

MDR READINESS – THE INDUSTRY PERSPECTIVE

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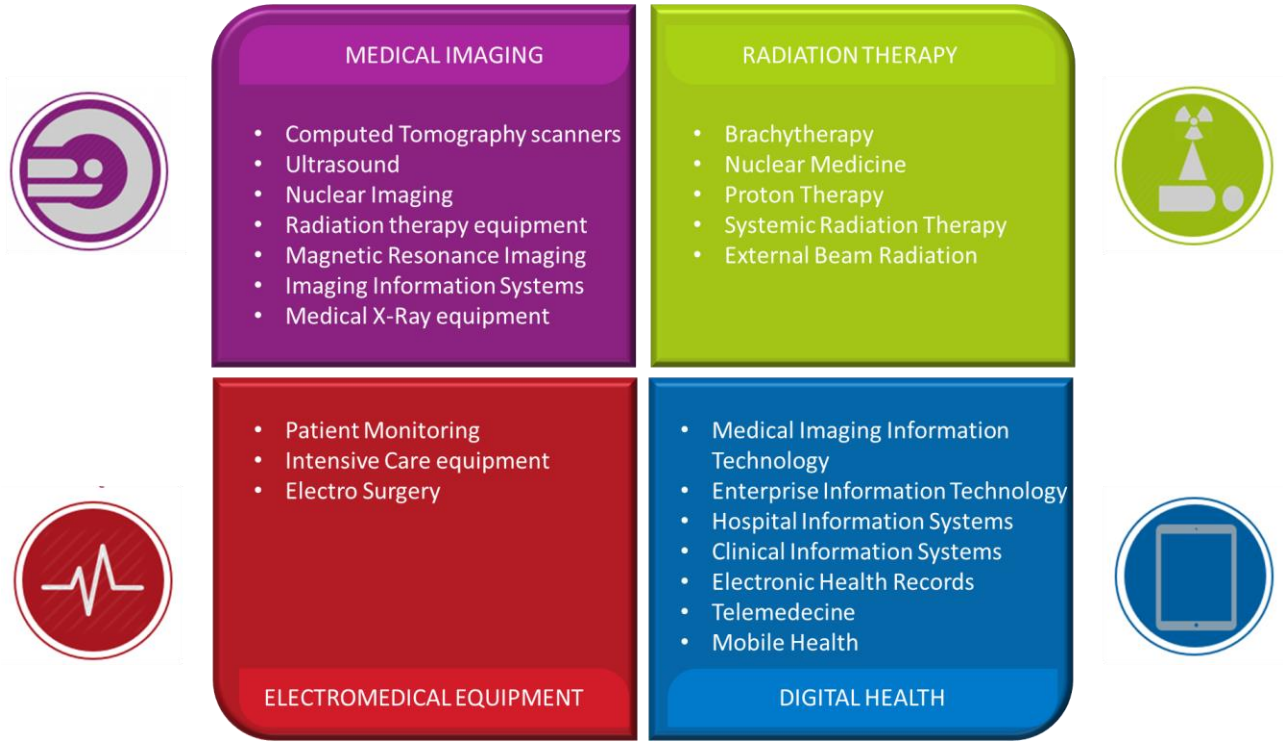
COCIR EU Regulatory Affairs Focus Group Chair

Introduction to COCIR

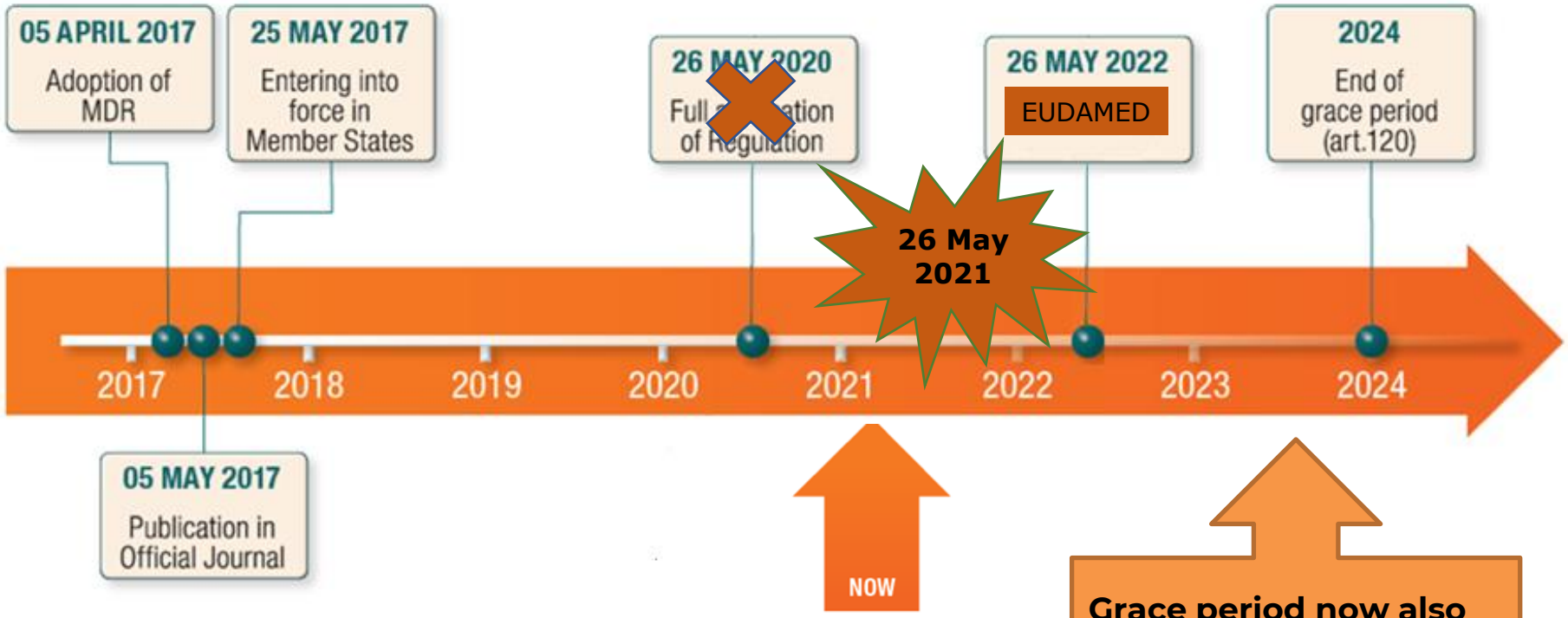


- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe
- COCIR covers 4 key industry sectors
  - Medical Imaging
  - Radiotherapy
  - Health ICT
  - Electromedical
- Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle

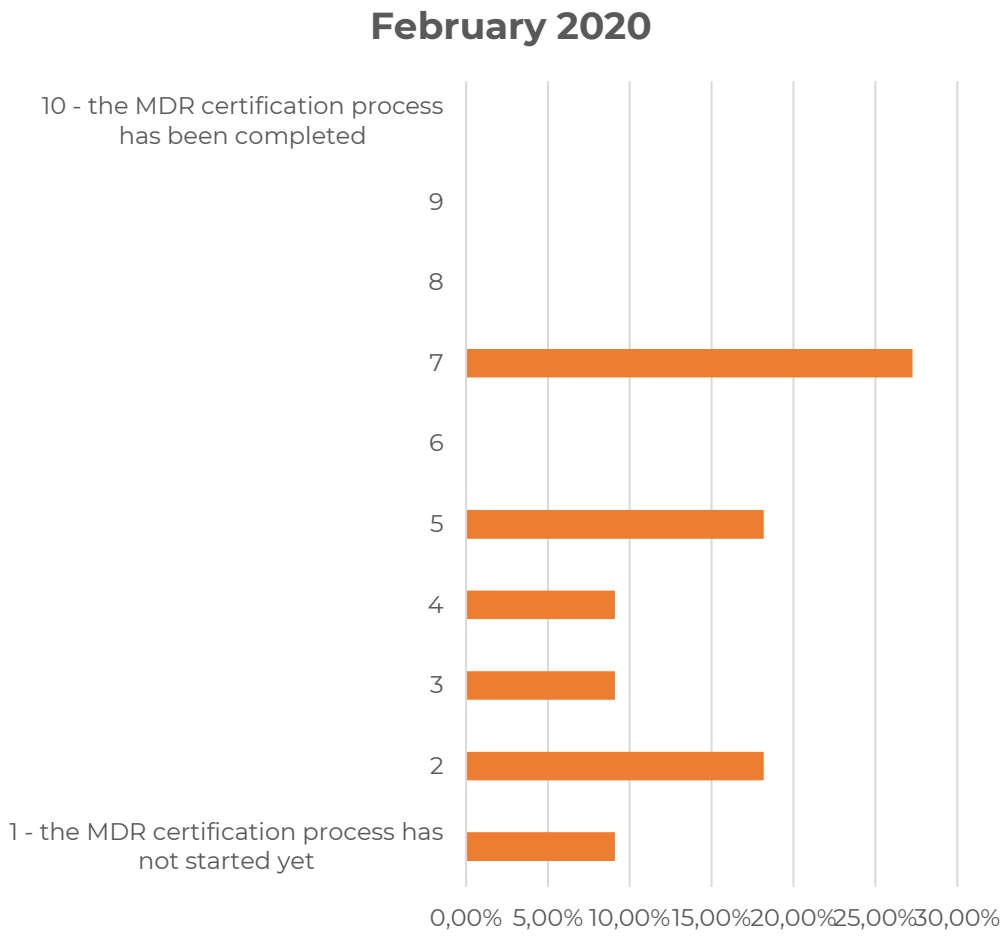
April 2020: postponement of the Date of Application

- Reason: the **COVID-19 outbreak** - to ensure the health and safety of EU citizens, and the continued supply of medical devices
- New Date of Application: **26 May 2021**
- Deadlines for application of the **UDI obligation and the grace period (Article 120)** remain the same
- REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions – download final text here

Transitional Provisions ("Grace Period")



How advanced is the initial MDR certification process for your organisation?



Implementation status of the MDR

UNIQUE DEVICE IDENTIFICATION (UDI)		• Several guidance documents published • Striving for convergence with global efforts at IMDRF level
EUDAMED		• Delayed by 2 years (26 May 2022) • Industry promotes voluntary Actor registration by December 2020 • Risk of proliferation of National requirements on Actor/Device registration
HARMONISED STANDARDS		• Draft Standardization request published • Requirements for harmonization of the standards very restrictive
TRANSITIONAL PROVISIONS		• Corrigendum #2 extented the scope of grace period to up-classified class I devices • Guideline on registration of legacy devices published
CLINICAL EVALUATION AND INVESTIGATIONS		• Gap: transposition of MEDDEV 2.7 / 1 rev. 4
MEDICAL SOFTWARE		• Guidance on qualification & classification of SW published • Guidance on cybersecurity published • Guidance on Clinical evaluation of SW published
POST MARKET SURVEILLANCE AND VIGILANCE		• Field Safety Notice and MIR form published • Several guidance documents and template delayed (PSUR) • No clarity on possible delegation of activities between econimic Operators (eg.pre-evaluation of incidents to distributors)
ECONOMIC OPERATORS		• Uncertainty on sub-contracting of verification activities between different economic operators within the same organisation • No clarity on use of sampling methods by importers
NOTIFIED BODIES		• 19 NB designated for MDR • Remaining uncertainties on MDR interpretation among Notified Bodies

International developments

31 December **EU-UK Trade and Cooperation Agreement** (link)

December Guidance on the **UK regulatory framework** for medical devices after January 2021 (link)

After 30 June 2023 **?**

On-going development of administrative agreement on data protection

Delay in transposition of MDR & IVDR in Turkey

Update of Mutual Recognition Agreement for medical devices

Delays due to political negotiations due to horizontal framework agreement

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Advancing Healthcare