



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

Philippe Lartigue

COCIR EU Regulatory Affairs Focus Group Chair

Introduction to COCIR



MEDICAL IMAGING

- Computed Tomography scanners
- Ultrasound
- Nuclear Imaging
- Radiation therapy equipment
- Magnetic Resonance Imaging
- Imaging Information Systems
- Medical X-Ray equipment

RADIATION THERAPY

- Brachytherapy
- Nuclear Medicine
- Proton Therapy
- Systemic Radiation Therapy
- External Beam Radiation



- Patient Monitoring
- Intensive Care equipment
- Electro Surgery

ELECTROMEDICAL EQUIPMENT

- Medical Imaging Information Technology
- Enterprise Information Technology
- Hospital Information Systems
- Clinical Information Systems
- Electronic Health Records
- Telemedicine
- Mobile Health

DIGITAL HEALTH



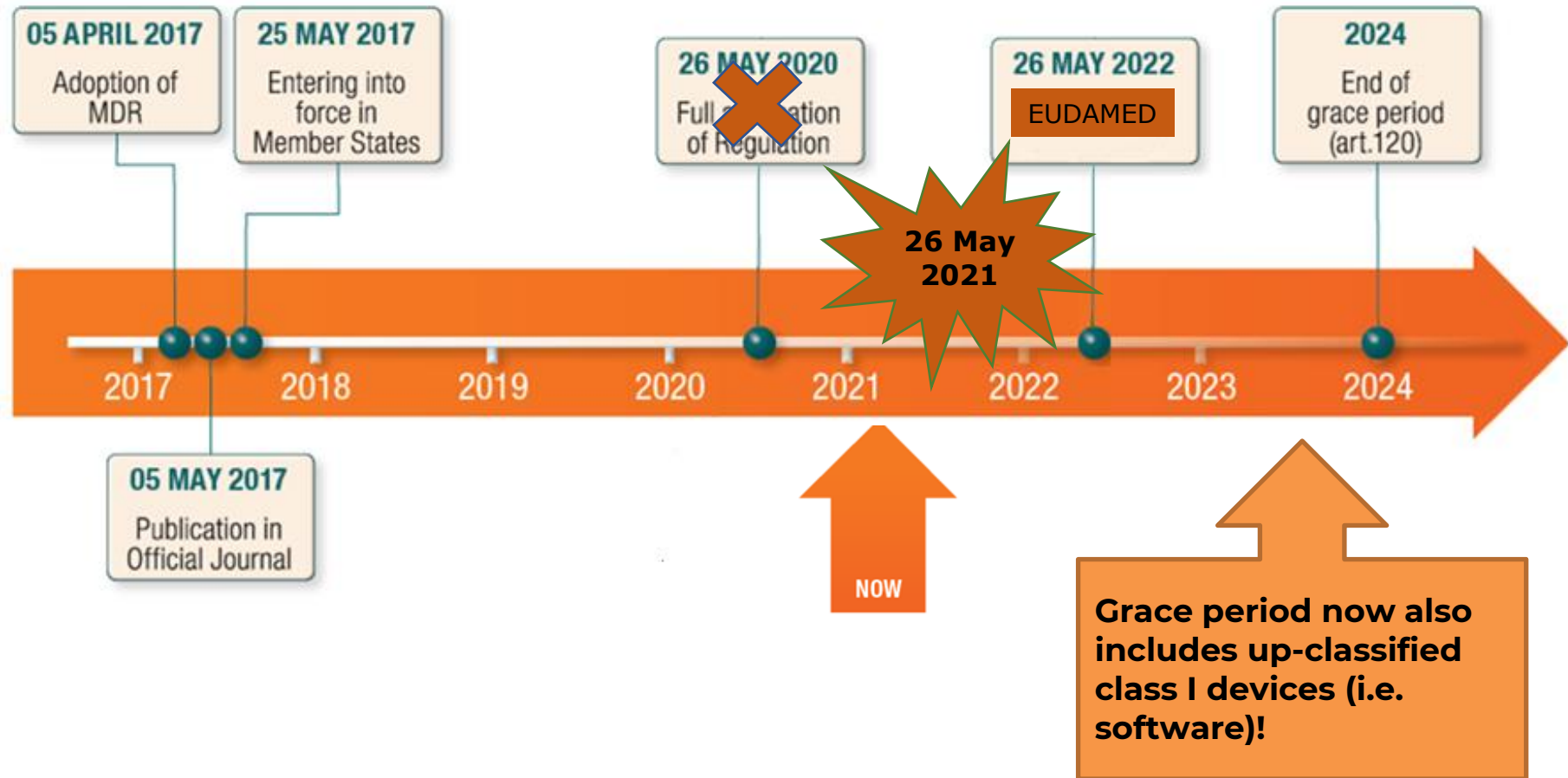
- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe
- COCIR covers 4 key industry sectors
 - Medical Imaging
 - Radiotherapy
 - Health ICT
 - Electromedical
- Our Industry leads in state-of-art advanced 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](#)



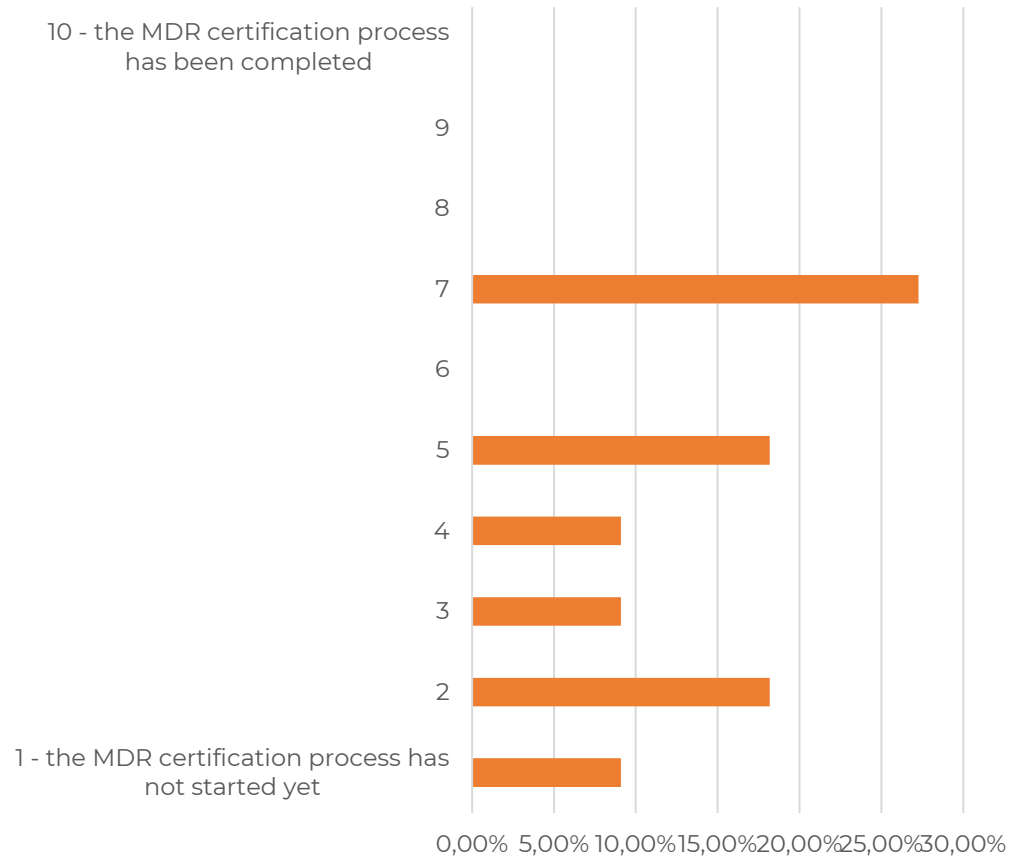
Transitional Provisions (“Grace Period”)



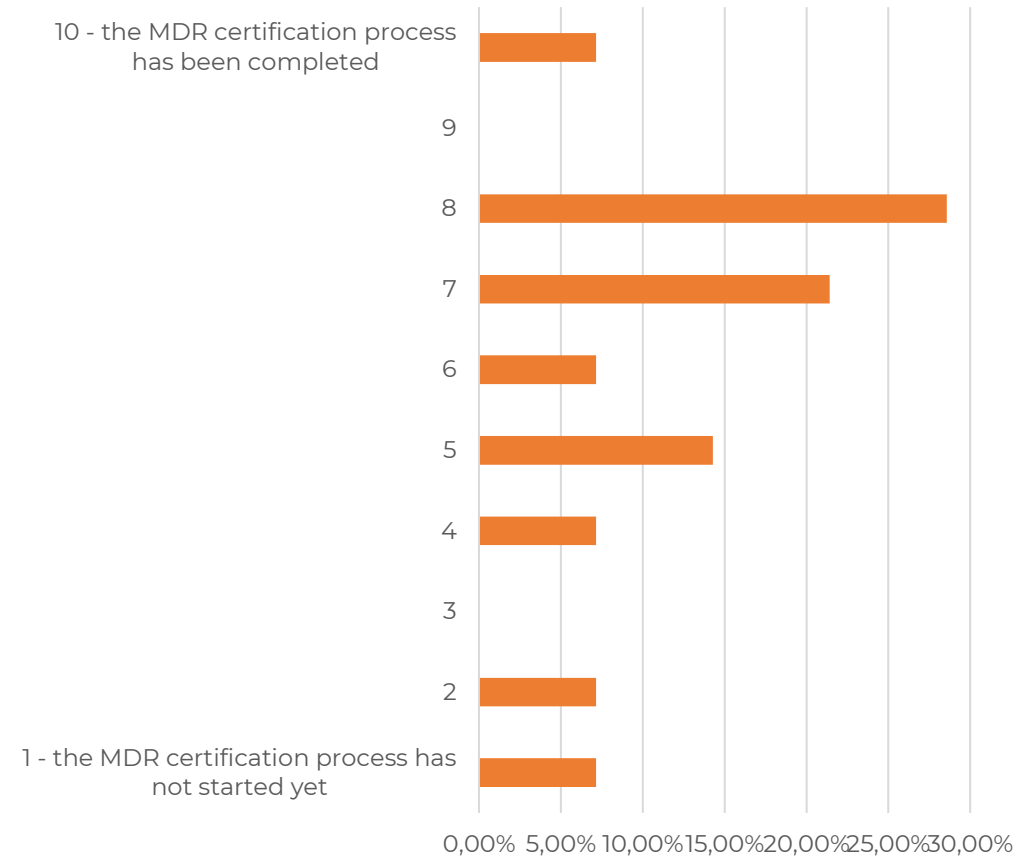


How advanced is the initial MDR certification process for your organisation?










February 2020



February 2021



Implementation status of the MDR

UNIQUE DEVICE IDENTIFICATION (UDI)		<ul style="list-style-type: none"> • Several guidance documents published • Striving for convergence with global efforts at IMDRF level
EUDAMED		<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • Draft Standardization request published • Requirements for harmonization of the standards very restrictive
TRANSITIONAL PROVISIONS		<ul style="list-style-type: none"> • Corrigendum #2 extended the scope of grace period to up-classified class I devices • Guideline on registration of legacy devices published
CLINICAL EVALUATION AND INVESTIGATIONS		<ul style="list-style-type: none"> • Gap: transposition of MEDDEV 2.7 / 1 rev. 4
MEDICAL SOFTWARE		<ul style="list-style-type: none"> • Guidance on qualification & classification of SW published • Guidance on cybersecurity published • Guidance on Clinical evaluation of SW published
POST MARKET SURVEILLANCE AND VIGILANCE		<ul style="list-style-type: none"> • Field Safety Notice and MIR form published • Several guidance documents and template delayed (PSUR) • No clarity on possible delegation of activities between economic Operators (eg.pre-evaluation of incidents to distributors)
ECONOMIC OPERATORS		<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • 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



спасибо
danke 謝謝
ngiyabonga
teşekkür ederim
dank je
gracias
tapadh leat
bedankt
hvala
mauruuru
thank you
moichchakkeram
dziękuje
sagolun
sukriya
kop khun krap
go raibh maith agat
arigatō
takk
dakujem
merci
merci
obrigado
terima kasih
ευχαριστώ
감사합니다

