

# COUNTDOWN TO THE MEDICAL DEVICE REGULATION

## VIEW OF HOSPITALS ON MDR IMPLEMENTATION

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Dr Paul GARASSUS  
President UEHP

# EU MDR

## Regulation (EU) 2017/745

- UEHP Council Budapest, 11 October 2019 :
  - *“Implementation and Readiness Status of the New Medical Device Regulation 745/2017 (MDR) - why it matters to European hospitals”*,
  - *“Health services and the new health information system in Hungary”*, Dr. Laszlo Felkay, State secretary of the Hungarian Government
- Date of application of the EU MDR - 26<sup>th</sup> May 2021
- Notified Body certificates issued under MDD designation become void (if not already expired) i.e. the last possible date for placing devices on the market according to the MDD - 26<sup>th</sup> May 2024
- Last possible date for putting devices into service according the MDD - 26<sup>th</sup>May 2025
- The new EUDAMED database, the first devices requiring Notified Body approval under the new EU MDR are unlikely to be approved before 2020...

# Hospitals and EU MDR

- Hospitals are in the “waiting room” for EU MDR solution and application, measuring the importance of this challenge
- All managers and practitioners were afraid of potential consequences, expressing the risk **to stop all medical and surgical activities**
- Without MD certification, hospitals will be closed !
- But at the end, the greatest danger was (is) to limit patient access to care and procedures. And this risk doesn't exist... Human lives matter!
- The full engagement of MD Industries was to obtain **delay** to ensure the global process including Notified Bodies development
- Hospitals are at the end of the **supply chain**, in direct contact with patients. As caregiver, it is not possible to consider that authorization questions can block the patient services

# Major actual challenges for hospitals in COVID\_19 times

- **Access** to COVID\_19 patients : no competition between sectors but cooperation according to public health missions, defined by national and regional authorities
- **ICU and Specific COVID\_19 Units**, meaning urgent services transformation (e.g. using Anaesthesia team and ventilators for long stay patients) (*22 % of all stays in Ile-de-France region in Private Sector*)
- With a fully active **supply chain**, without any material shortage
- Medical teams and **workforce**, trained and active but protected too
- Government support for financial engagement dedicated to COVID\_19 stays, **and**
- To offer the same services for acute or chronic diseases, **or**
- To maintain closed hospitals at rest during times when regular activity is stopped (hospitals can't be the second "victim" of COVID\_19 crisis)
- And able to maintain **quality** services for all (*recent e-satis scoring in France*)
- Hospitals are now engaged for **VAX**
- **European cooperation** is active (Portugal)

# The big questions for hospitals in COVID\_19 times

- Access to COVID\_19 patients and No COVID\_19 patients
- The supply chain, including MDR transient period for practical solutions
- **Cybersecurity** in Smart Hospitals  
from “medical” safety to “tech” safety, a global challenge
- **Quality** of medical service must be maintained

