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Agenda

Introduction

1. Impact of the MDR on mhealth apps qualification
2. Impact of the MDR on mhealth apps classification
3. Essential requirements & clinical evidence
4. Unique Device Identification (UDI)

Q & A

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Introduction

Introduction

Why is the medical devices legislation relevant for the mobile health industry?

- "Medical device" (current definition):
  - Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, […]

Introduction

Why is the medical devices legislation relevant for the mobile health industry?

- "Medical device" (current definition):
  - Having one of the following intended purposes :
    - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
    - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
    - Investigation, replacement or modification of the anatomy or of a physiological process,
    - Control of conception,
  - ... And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Introduction

Why is the medical devices legislation relevant for the mobile health industry?

- Today: EU medical devices **DIRECTIVE** 93/42 (no direct effect)
  - (Stand-alone) software : Limited regulation within the EU directive 93/42
  - Mobile health applications : May fall within "(stand-alone) software" ; absence of specific legally-binding rules (guidelines only)
- To be replaced by an EU medical devices **REGULATION** (direct effect)

Aim of this presentation: focusing on new rules in the MDR which are specific to the mobile health industry

Not all rules, not all new rules (i.e. the examples presented today are not the only changes brought by the MDR for the industry)

Introduction

The MDR: state of play

- Initial MDR draft proposals dated 26 September 2012
- Last consolidated version of MDR proposal dated 09 August 2016 (available online)
- The jurist-linguist translation ended on 17 October 2016 – Practically speaking, the main aspects of the text are fixed
- Issues likely to be arranged through implementation – Several delegated acts of the European Commission are expected to address these issues
- Final publication : expected by Q2 2017 or later
- Entry into force of the MDR (transition period): 3 years → Q2 2020 or later

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1. Impact of the MDR on mhealth apps qualification

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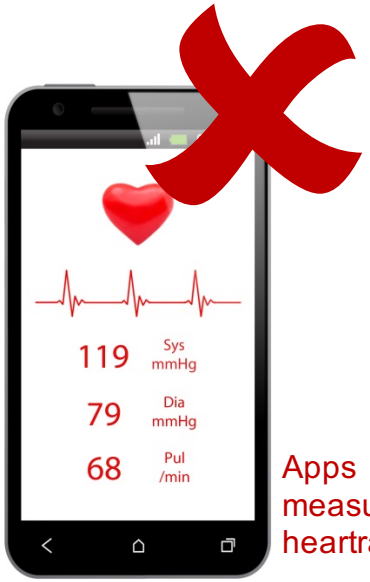
Recital (18a) of the MDR : clarification

- " It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is qualified as a medical device, […]

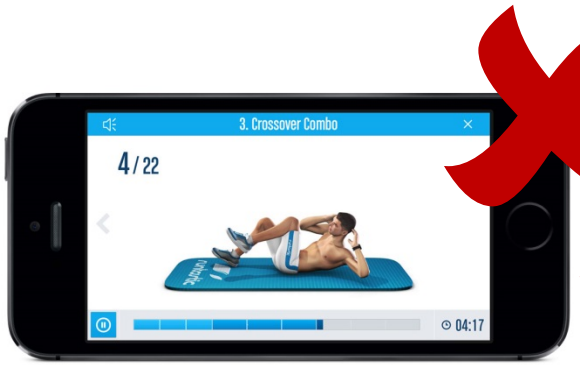
1. Impact of the MDR on mhealth apps qualification

Recital (18a) of the MDR : clarification

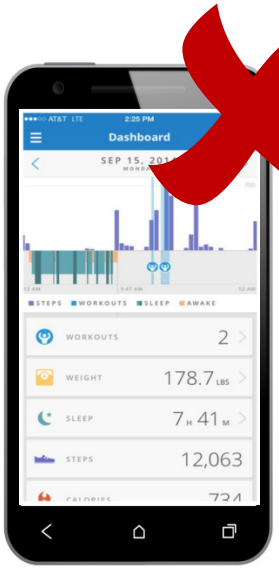
- … While software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being application is not a medical device."



Apps measuring heartrate



Workout apps



Sleep monitoring apps

1. Impact of the MDR on mhealth apps qualification

Borderline cases?

- Examples: electronic medical record apps ; apps for the communication between patient and caregivers while giving birth ; video appointment software
- Today: guidance can be found in the MEDDEV guidance on stand-alone software (July 2016) and EU manual on borderline classification (September 2015)
- Under the MDR: adaptation of existing guidelines + further guidance to be adopted

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2. Impact of the MDR on mhealth apps classification

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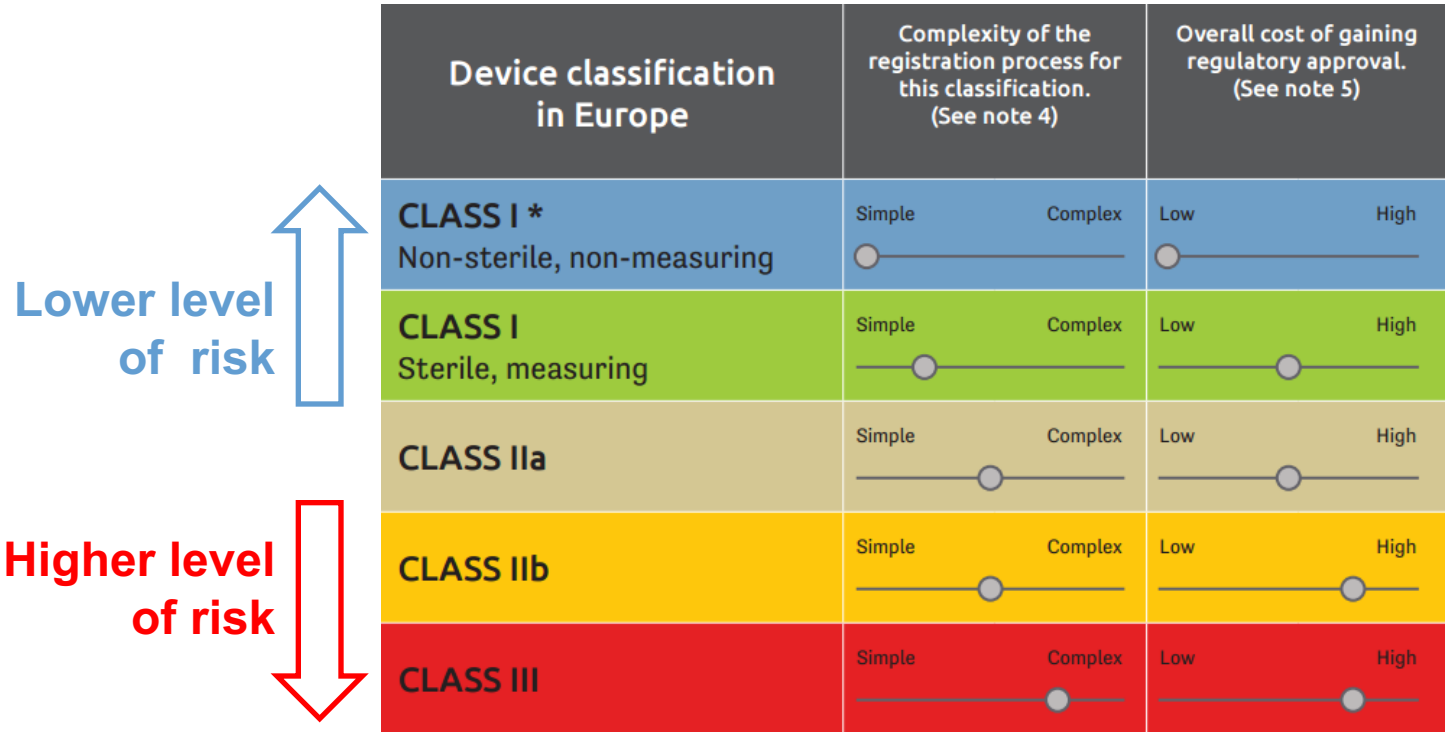
Classification of mobile health applications

- Classification ≠ Qualification



2. Impact of the MDR on classification

Classification of mobile health applications

- New rule 10a (MDR proposal), dealing specifically with software classification:
  1. Class IIa for software intended to provide information used to take decisions with diagnosis or therapeutic purposes
     - Unless the decisions have an impact that may directly or indirectly cause death or irreversible deterioration of state of health (→Class III), or serious deterioration of the state of health or surgical intervention (→Class IIb)
  2. Class IIa for software intended to monitor physiological processes
     - Unless it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient (→Class IIb)
  3. All other software: Class I

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3. Essential requirements & clinical evidence

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3. Impact on essential requirements and clinical evidence

Essential requirements

- Essential requirements = general safety and performance requirements imposed by the law

3. Impact on essential requirements and clinical evidence

Essential requirements

- New rules relevant for mhealth apps manufacturers / designers (examples):
  - Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts *MDR, Annex I, article 11.2, (e)*
  - Software intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise) *MDR, Annex I, article 14.3.*
  - In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance *MDR, Annex I, article 14.1.*

3. Impact on essential requirements and clinical evidence

Clinical evidence

- Clinical evidence = evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance

3. Impact on essential requirements and clinical evidence

Clinical evidence

- New rules relevant for mhealth apps manufacturers (examples):
  - The technical documentation should include detailed information on software verification and validation :
    - Describing the software design and development process and evidence of the validation of the software, as used in the finished device
    - Including summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release
    - Addressing all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer

MDR, Annex II, article 6.1.

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4. Unique Device Identification (UDI)

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Under the MDR: the UDI becomes compulsory for all medical devices

- The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard
- It allows the unambiguous identification of a specific device on the market
- The UDI is comprised of the DI (device identifier) and the PI (production identifier)
- In addition to the existing labelling requirements for medical devices

Increased traceability

Easier recall

Improved patient safety

4. Unique Device Identification (UDI)

Under the MDR: the UDI becomes compulsory for all devices

- Examples:

4. Unique Device Identification (UDI)

New specific rules for software

- Placement criteria: "*on a readily accessible screen for the user in an easily readable plain-text format (e.g. an "about" file or included on the start-up screen)*"
  MDR, Annex V, C, 6.5.2.
- Obligation to affix a new UDI-ID (e.g. in case of a new or modified operating platform, or new user interface, modification of the intended use of the software)
  MDR, Annex V, C, 6.5.1a.
- Obligation to affix or a new UDI-PI (e.g. upon minor software revision such as bug fixes or usability enhancements which are not for safety purposes)
  MDR, Annex V, C, 6.5.1b.

Conclusions

New specific rules for software

- Prepare yourself
  - Once the text is published → 3 years transition period for MDR
- All areas are not covered by the MDR (examples)
  - Data protection → EU data protection regulation and EU (draft) Code of Conduct on privacy for mobile health applications
  - Cyber security → EU (draft) Code of Conduct on privacy for mobile health applications
  - Apps quality and assessment → EU (draft) guidelines on assessment of the reliability of mobile health applications

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Thank you

Questions ?

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