MDR
SW Classification

MEDICAL DEVICE & IN VITRO DIAGNOSTICS

REGULATORY AFFAIRS SOLUTIONS STRATEGIES

CE plus GMBH
MEDICAL DEVICES • IVD
Regulatory Affairs & More

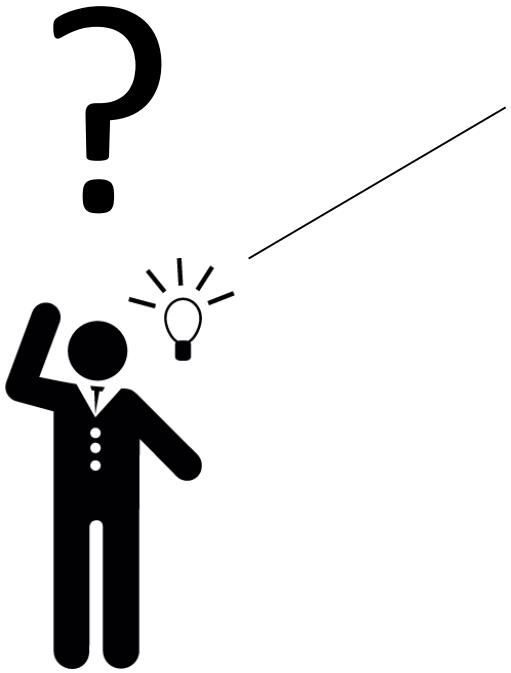
Company / Speaker

- About CE plus
  - Service Provider for Regulatory Affairs
    - Medical Devices
    - In Vitro Diagnostics
    - Active Implantable Devices
  - Focus: CE-marking
    - Regulatory Strategies (e.g. Definition of Intended Use)
    - Technical File
    - Clinical Evaluation
    - Risk Management
    - Usability
    - Requirements Engineering
    - Software Documentation

- About the speaker
  - Oliver Hilgers
    - Head of Active Medical Devices / Medical Software department
    - 10ys experience in regulatory affairs
    - Certified Professional for Medical Software
    - Member of EC Software Working Group

Classification: Software as a Medical Device

- When does a “Health Software” become a Software as a Medical Device?



Medical Device

MDR Article 2 (1)

'medical device' means any instrument, apparatus, appliance, **software**, implant, reagent, material or other **article intended by the manufacturer** to be used, alone or in combination, for human beings for one or more of the following **specific medical purposes:**

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Medical Device

MDR Article 2 (1)

- Medical Device (in a nutshell)
  - **If the manufacturer of a device claims a medical benefit for its product**
  - and the device achieves this medical benefit by physical means
  - than its very likely a medical device

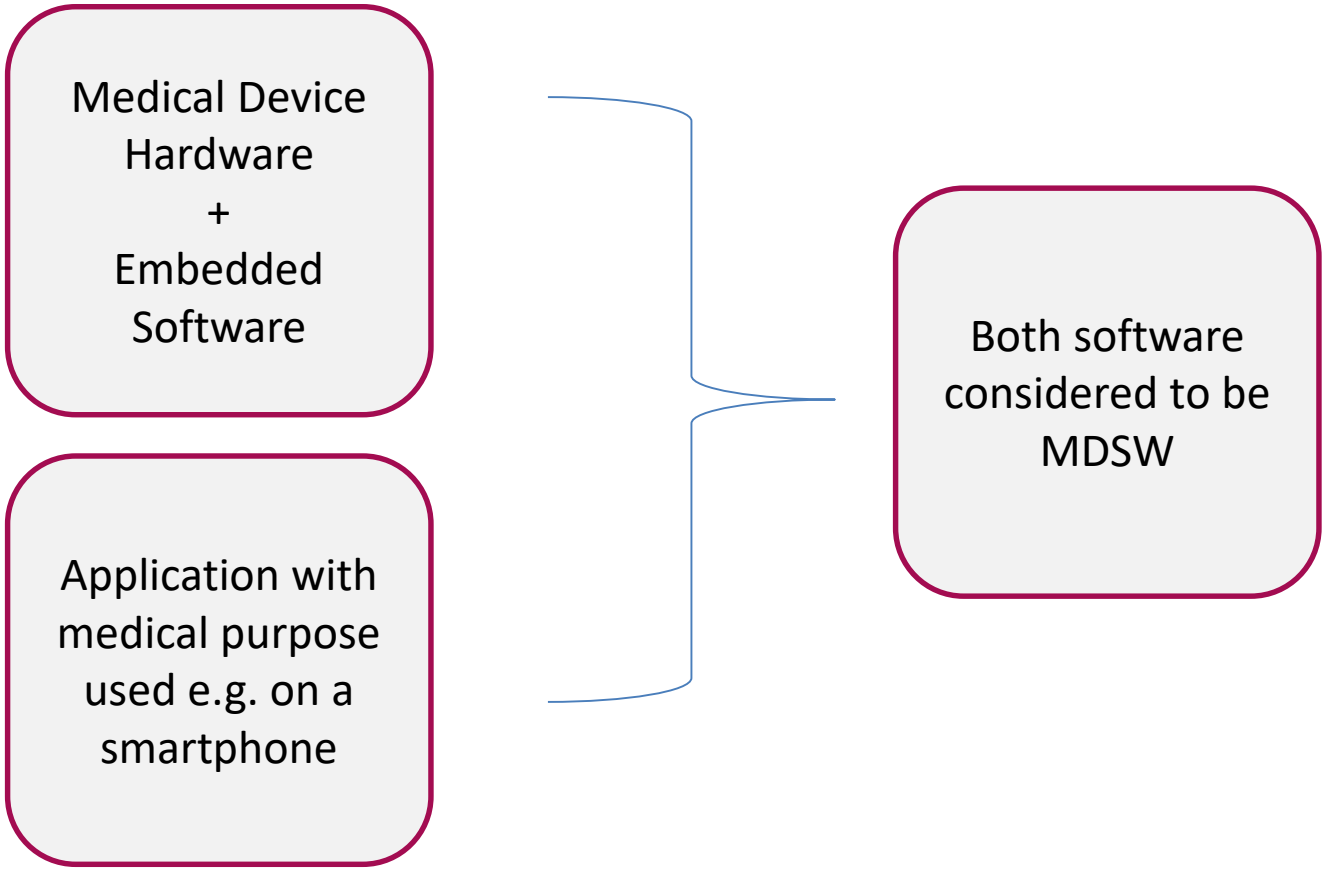
- this device can also be a software/app!

Medical Device Software (MDSW – not confirmed yet)

Medical device software (MDSW) is all software that is intended to be used, alone or in combination, for a medical purpose specified in the definition of a "medical device" in the MDR or IVDR, regardless of whether the software is independent or is driving or influencing the use of a (software or hardware) device.

MDSW is not an accessory to a medical device since it fulfills itself the definition of a device (being, alone or in combination, intended to be used for a medical purpose).

Medical Device Software (MDSW – not confirmed yet)



Medical Device Software (MDSW – not confirmend yet)

If MDSW is part of a Medical Device it may be placed on the market as a device in its own right if it allows more than exclusively driving or influencing the hardware device

Example:

Software within an ultrasound device used for diagnosis purposes. If the software does not only support the actual purpose of the hardware (allow visualization) but also provides its own analysis of images (e.g. highlights suspicious areas by itself or provides direct diagnosis) than this might lead to another classification pathway.

Medical Device

MDR - Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software are classified as class I.

(EU) 2017-745

Rule 11 – how to apply

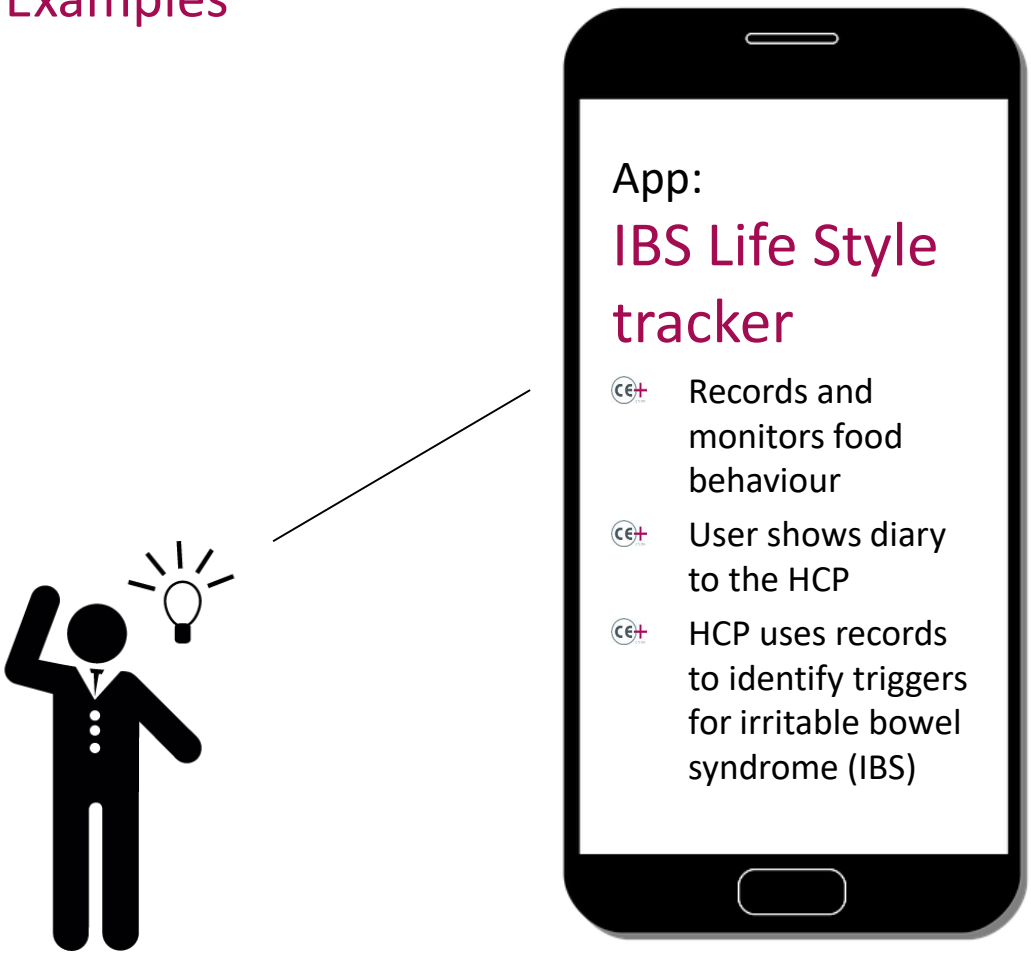
MDR Rule 11

(note: draft – not confirmed yet)

RULE 11		Significance of information provided by the MDSW to healthcare situation/ Significance of incorrect decision Related to diagnosis/therapy.		
		High Treat or diagnose ~ IMDRF 5.1.1	**Medium** Drives clinical management ~ IMDRF 5.1.2	**Low** Informs clinical management. (Everything else)
State of Healthcare situation or condition	**Critical situation or condition** ~ IMDRF 5.2.1	III	IIb	IIa
	Serious situation or condition ~ IMDRF 5.2.2	IIb	IIa	
	Non-serious situation or condition (everything else)	IIa		

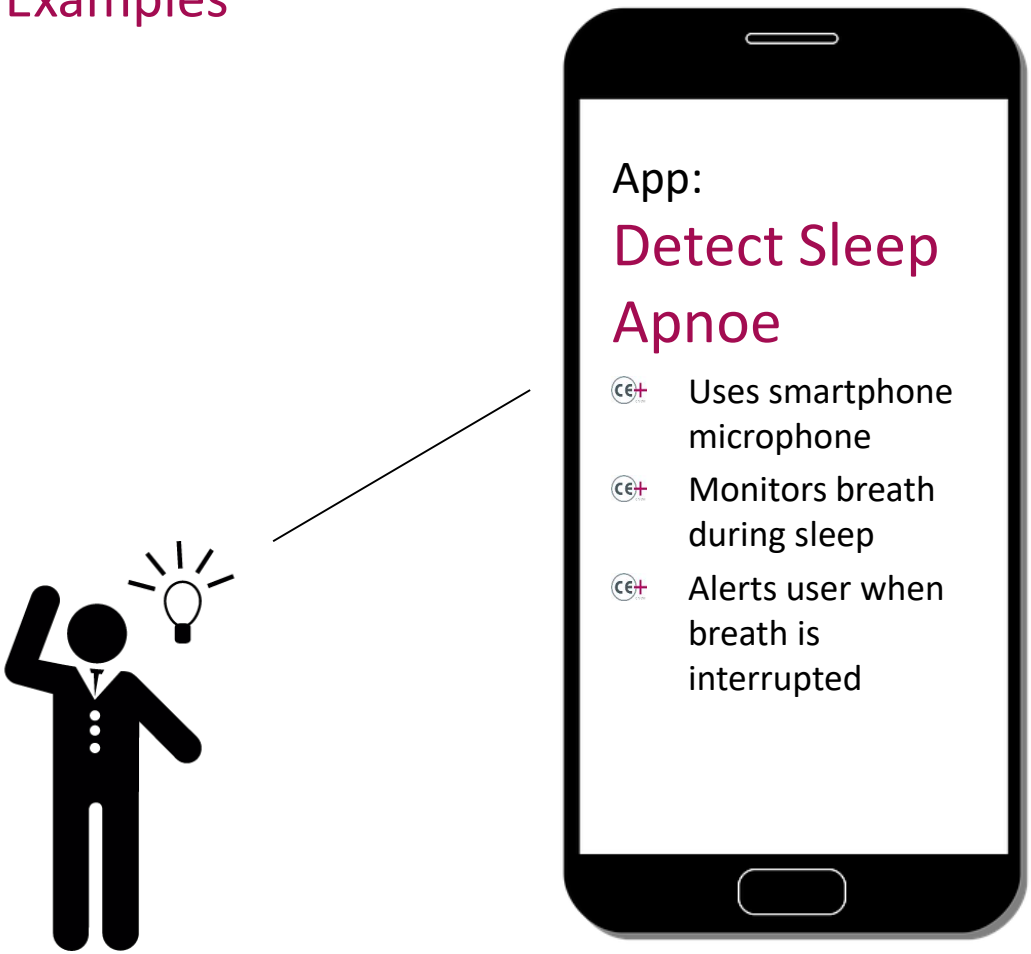
Classification: MDSW

Examples



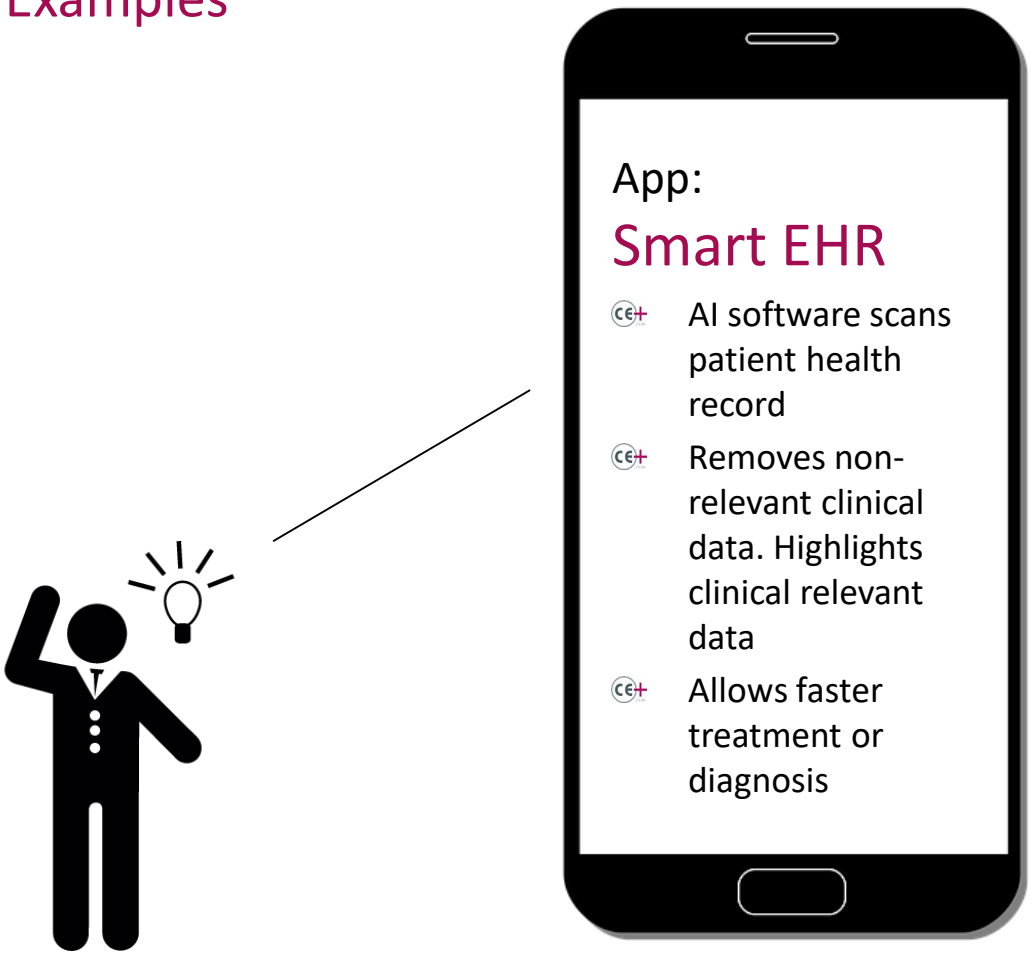
Classification: MDSW

Examples



Classification: Software as a Medical Device

Examples



Summary

- Most likely no class I software under MDR
- Evaluate your software based on Rule 11 and the MDCG interpretation
- Manufacturer of MDD class I software should contact a Notified Body to
  - discuss classification
  - create roadmap for new conformity assessment if necessary
    - MDR Technical File
    - EN ISO 13485 certification
- Otherwise the manufacturer needs to remove his app from the market (e.g. App/Play Store) before May 26th 2020!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