Jornadas REGIC 2024

Retos de futuro en investigación clínica, ¿cómo adaptar la estructura para dar soporte a proyectos tecnológicos?

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Is my Software a Medical Device in the EU?

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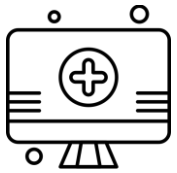

Medical intended purpose

Action on data **different from**:

- **Storage**
- **Archival**
- **Communication**
- **Simple search**

Action for the benefit of **individual patients**

Regulation (EU) 2017/745 (MDR) on medical devices

- Outside scope IVDR
- Non-IVD main data sources

Regulation (EU) 2017/746 (IVDR) on *in vitro* diagnostic medical devices

- Within scope IVDR
- IVD main data source

CE

MDCG 2019-11: Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746

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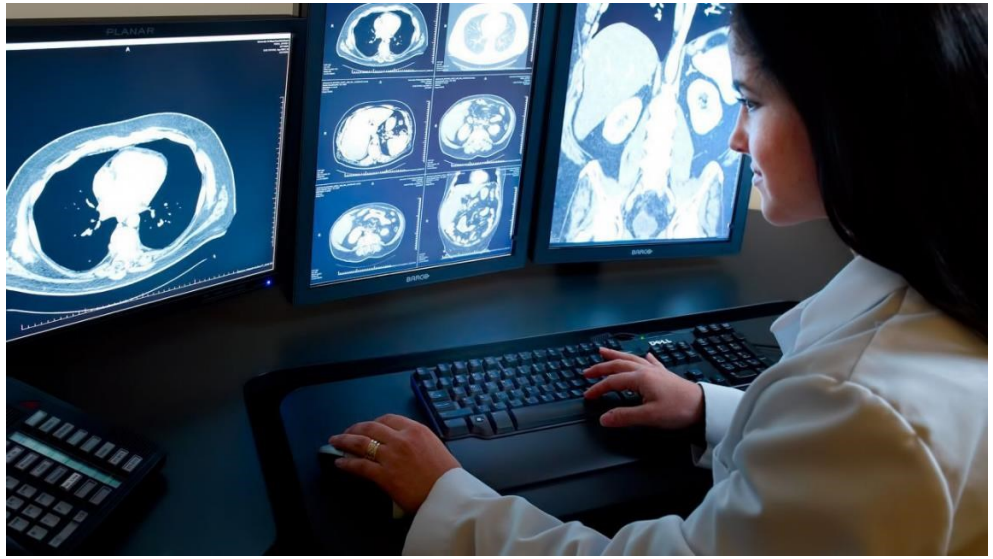
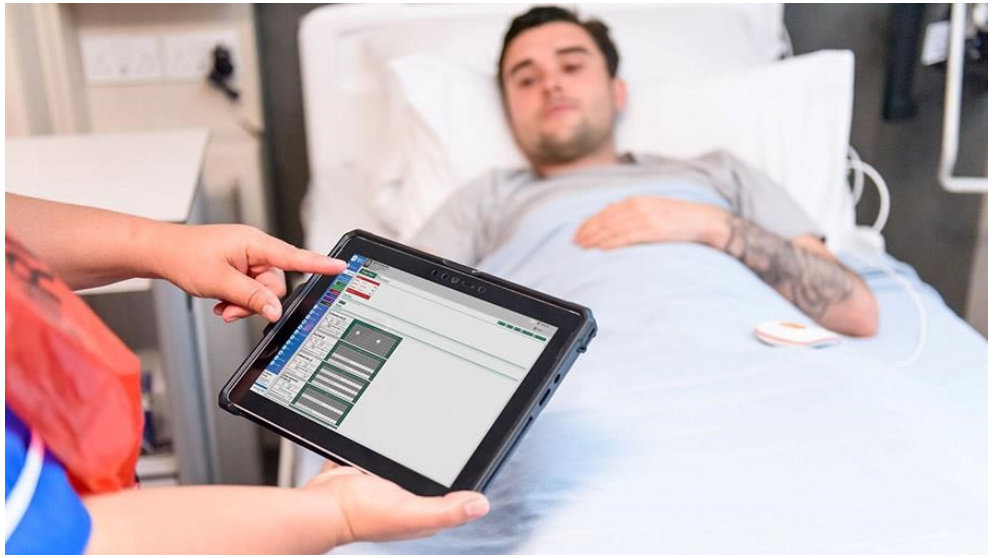
A Picture Archiving and Communication System (PACS), which only **displays and stores** images



An Electronic Patient Record (EPR) system, which solely **replaces paper files**



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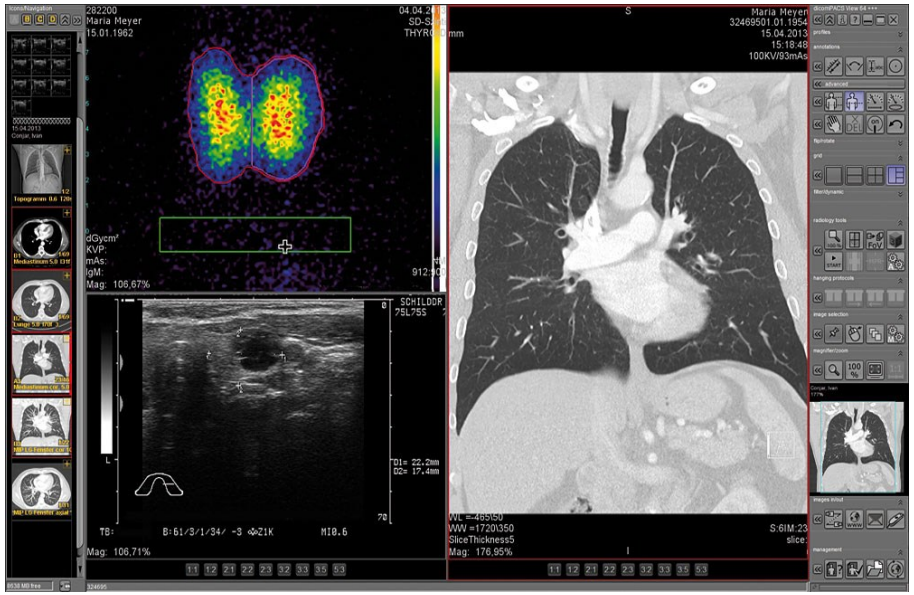
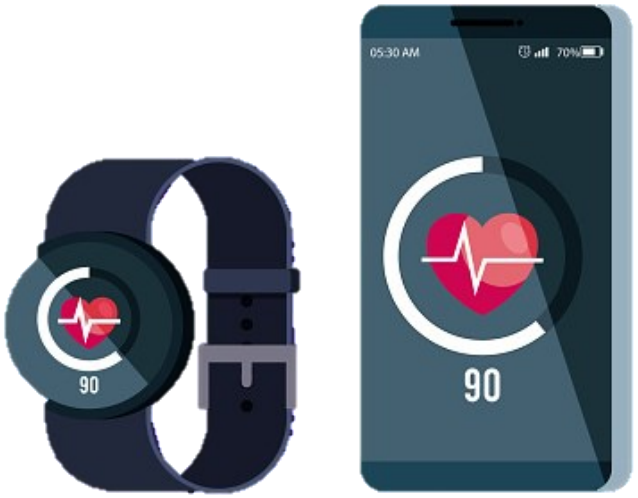
PACS, which enables reporting of **additional treatments** such as radiotherapy, image manipulation, or includes a feature to compare images to specify the **progression of a disease**



Smartwatch application, which is intended to **send alarm notifications** to the user and/or **healthcare professional** when it recognises irregular heartbeats in order to detect **cardiac arrhythmias**



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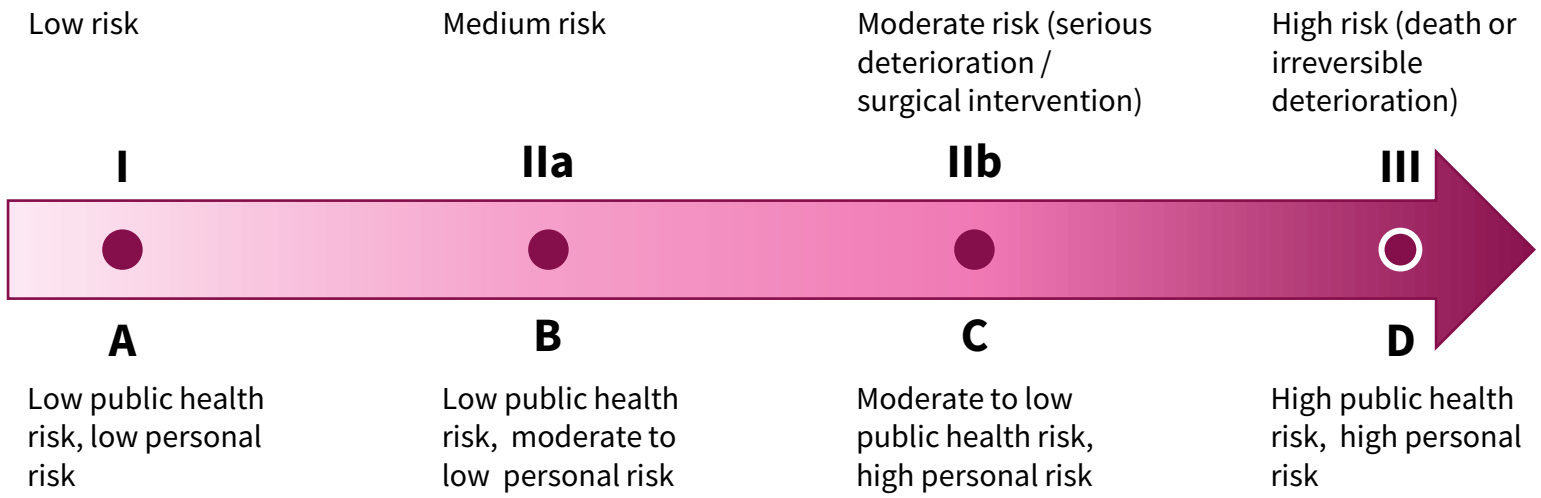
Risk Classification

MDR (EU) 2017/745

Annex VIII – MDR: Rule 11

IVDR (EU) 2017/746

Annex VIII – IVDR: Rules 1-6



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Roadmap for Regulatory Approval

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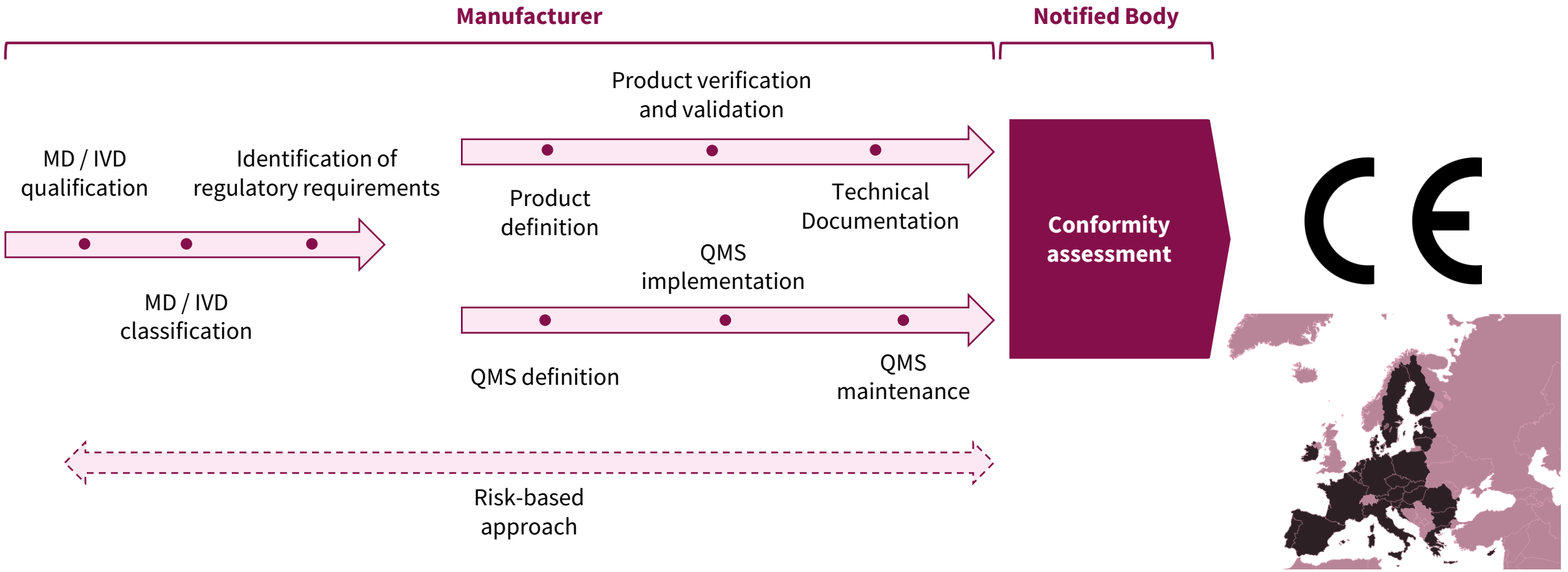
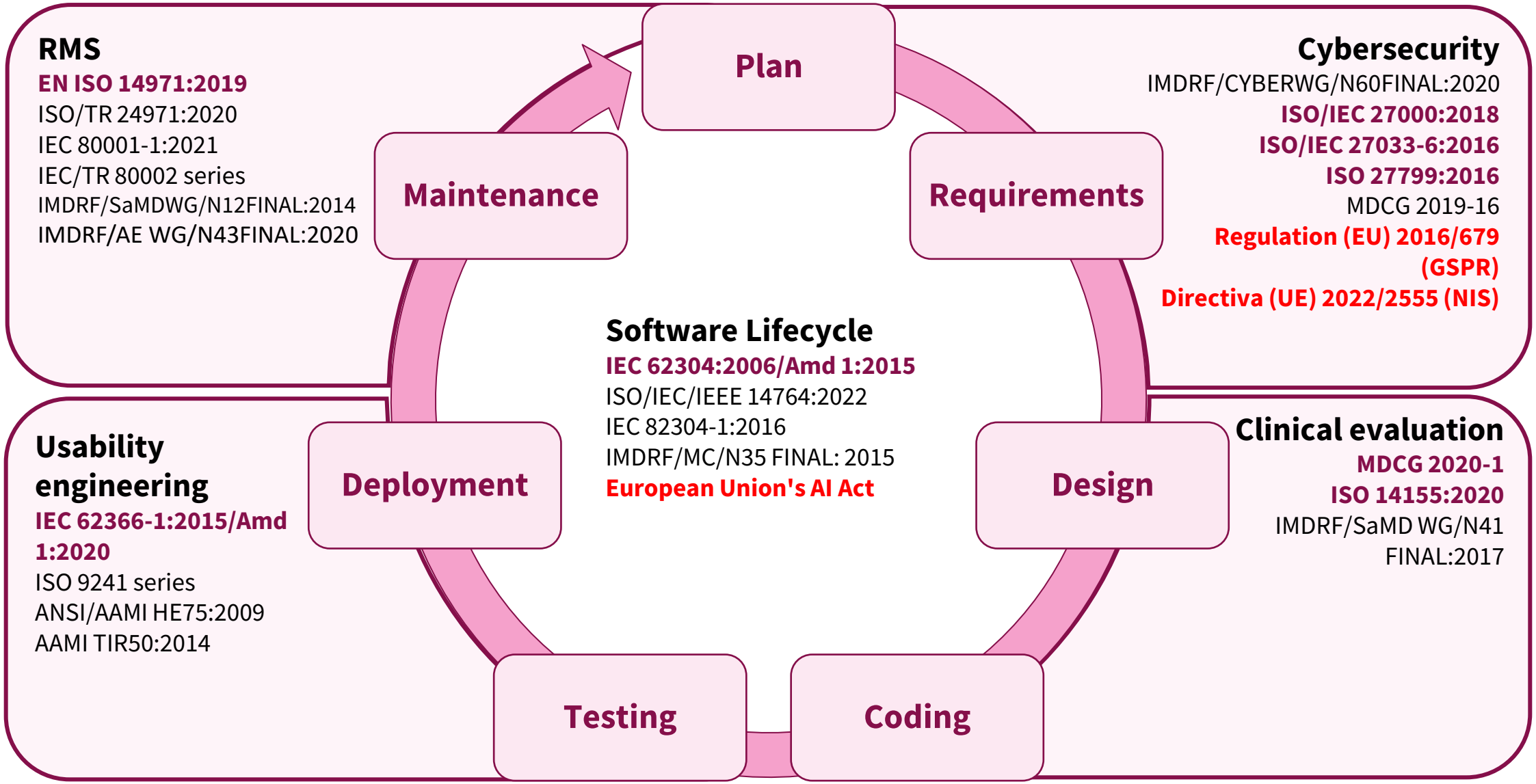


Technical Documentation



Key points

- It is crucial to review the **intended purpose** and the **handling of input data** by our software to conclude whether we have a **medical device or not**.
- The first step in the development of an MDSW is the identification of the **risk class and the applicable regulatory requirements**.
- Identifying the **regulatory state of the art** applicable to our product (**guidelines and standards**) will facilitate development until **CE marking** is achieved.

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Thank you!

Are there any questions?

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