

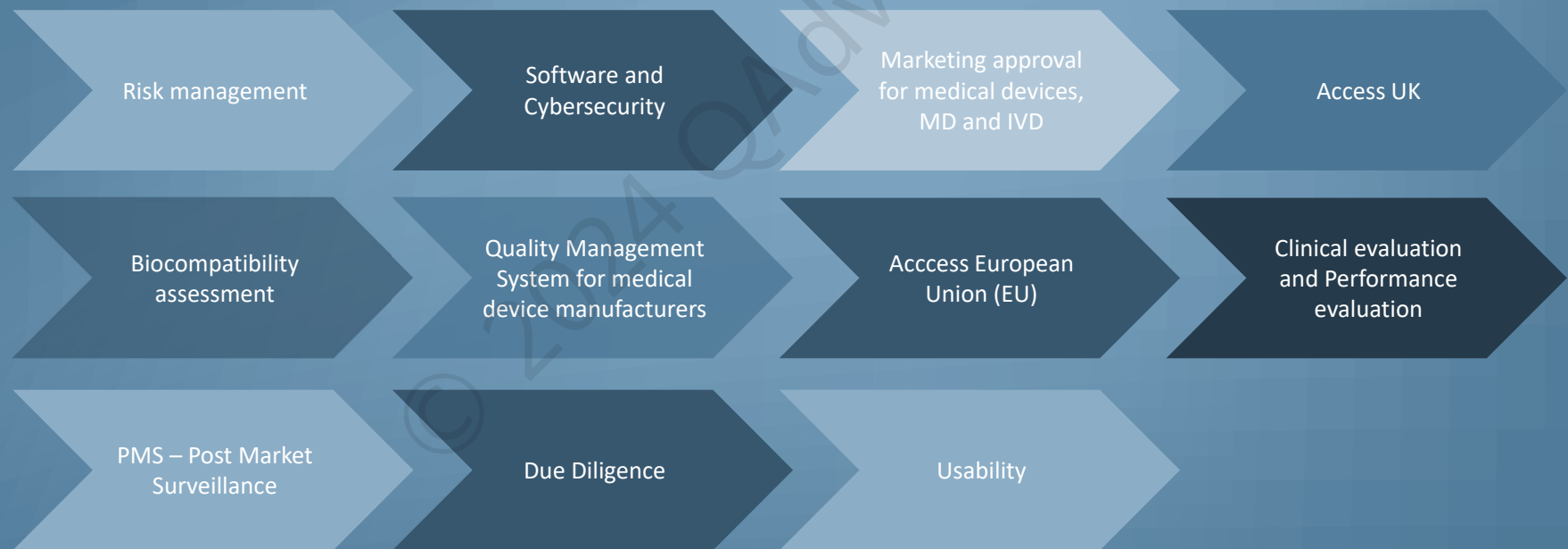
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# Well positioned for the future?

Minimize the risk of any missteps with our areas of expertise!



# Combination Products

*Caroline Ehrenborg, 2024-10-09*

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What is a combination  
product?





Primary mode of action

## Physical effect:

- Mechanical action
- Physical barrier
- Lubrication
- Heat transfer
- Radiation
- Ultrasound
- Replacement

## Physical effect:

- Mechanical action
- **Physical barrier**
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## Pharmacological: Interaction between

- Ligand and receptor
- Substance and membrane lipids
- Substance and components of the cytoskeleton

## Pharmacological: Interaction between

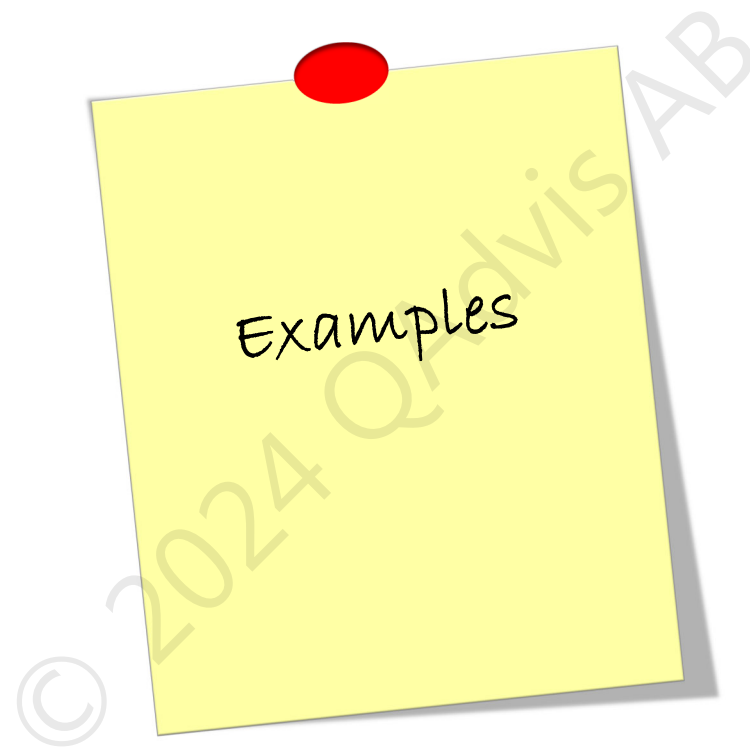
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## MDCG 2022-5

Guidance on borderline between medical  
devices and medicinal products

















MDR 2017/745

MPD 2001/83/EC

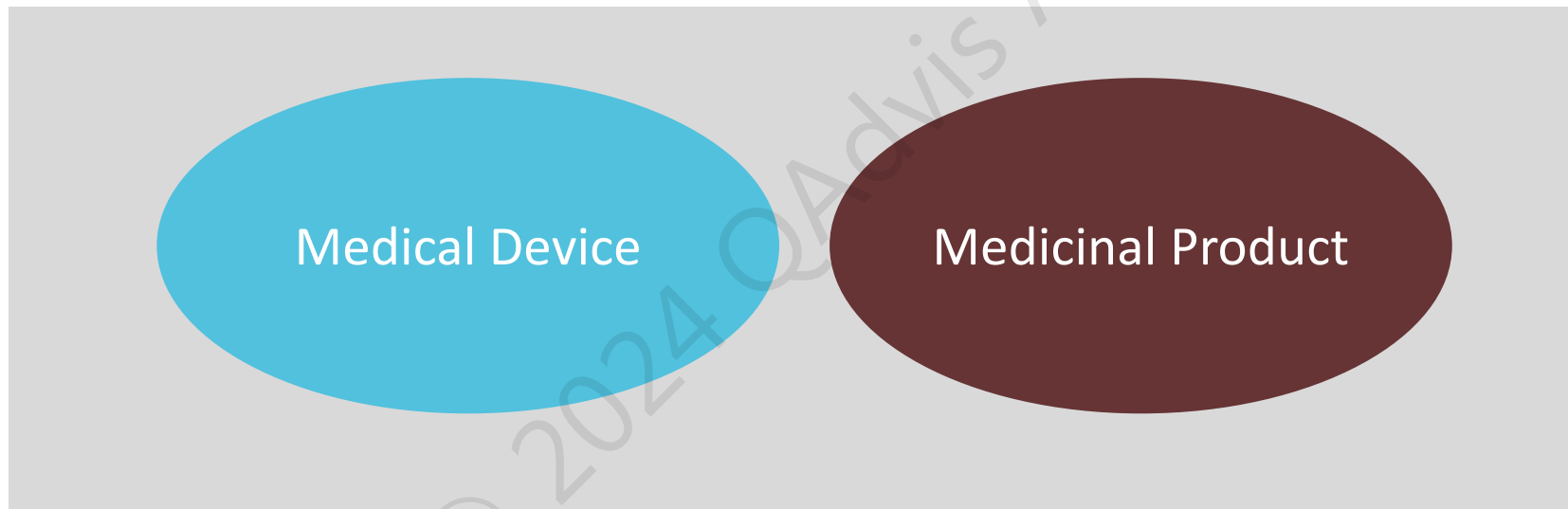
MDR 2017/745

MPD 2001/83/EC

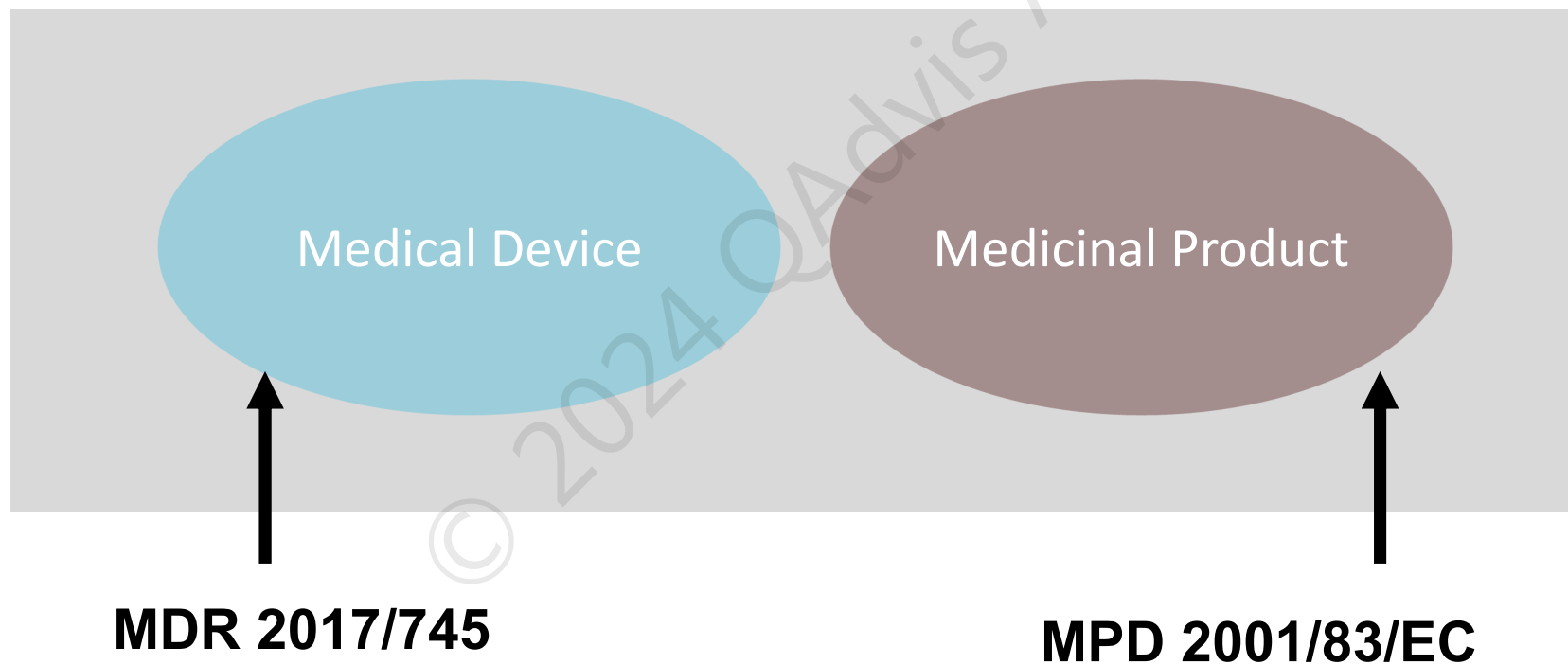
Integrated product



## Co-packed product



Co-packed product








MDCG 2022-5 Guidance on borderline

Manual on borderline and classification

MDCG 2022-5 Guidance on borderline

Manual on borderline and classification

## Helsinki Procedure



Summary  
combination  
products

1) Integrated or co-packed?

2) Primary mode of action?

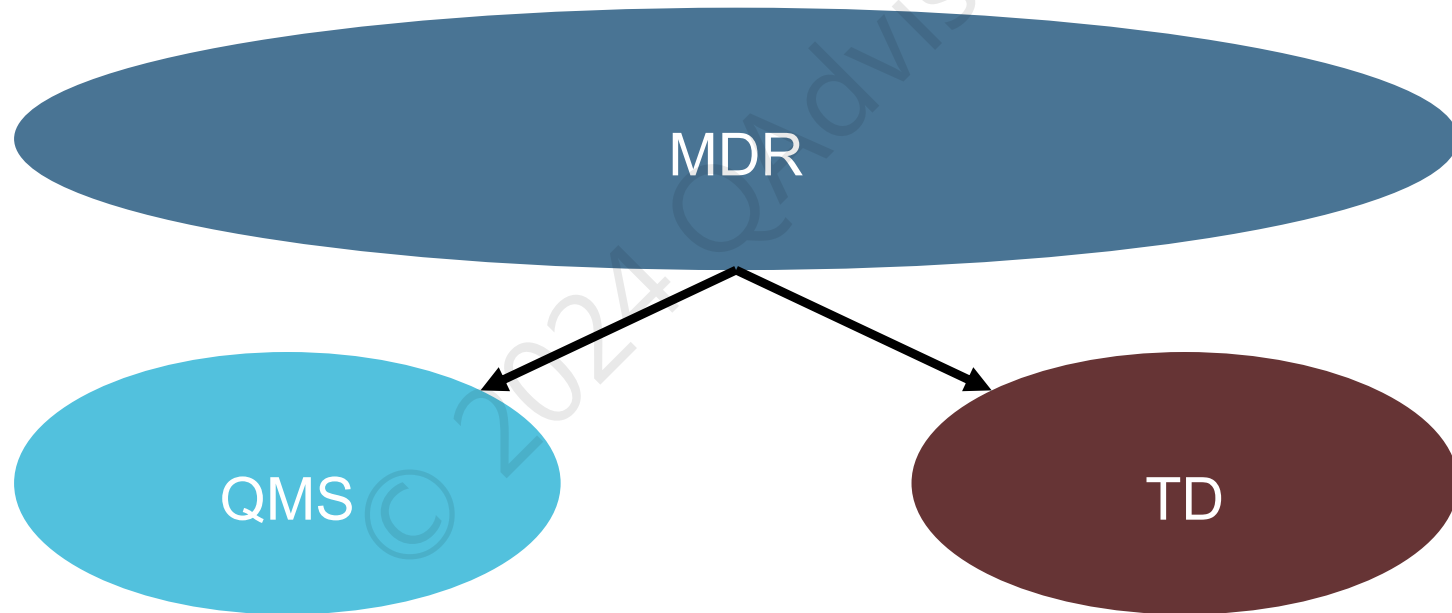
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- 1) Integrated or co-packed?
- 2) Primary mode of action?

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device / drug





## Rule 14 – Class III

Technical documentation

Medicinal substance

EMA /CHMP/578661/2010

- The ancillary substance
- Its manufacturing process
- The way the substance is incorporated into the device
- Design, manufacturing of the device which could influence the quality, safety or usefulness of the ancillary substance

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CEP

Certification of suitability



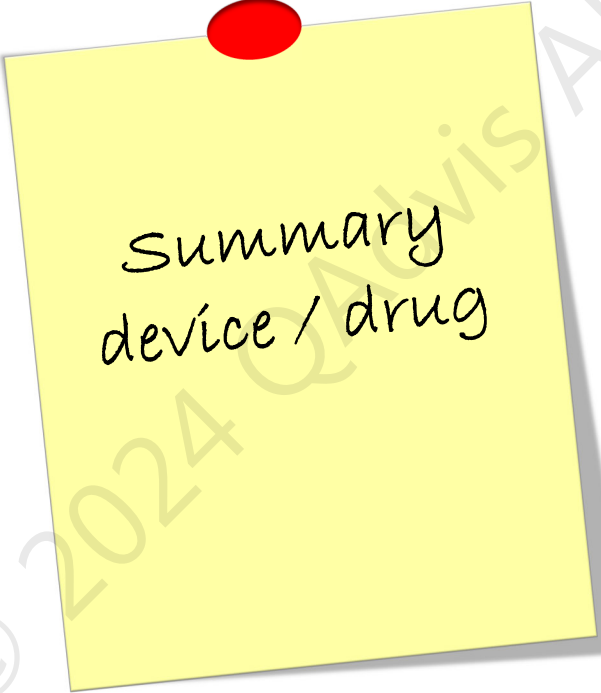
CA consultation

< 210 days

MDCG-2020-12

Risk assessment

PMS



summary  
device / drug

drug / device

the impact of the device (part) on:

- the Quality Target Product Profile (QTPP),
- Critical Quality Attributes (CQA) and
- overall control strategy of the medicinal product

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GSPR

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## MDR § 117

Class I:  
DoC

Class Is, Im, Ir, IIa, IIb, III:  
EU certificate or  
Notified Body opinion

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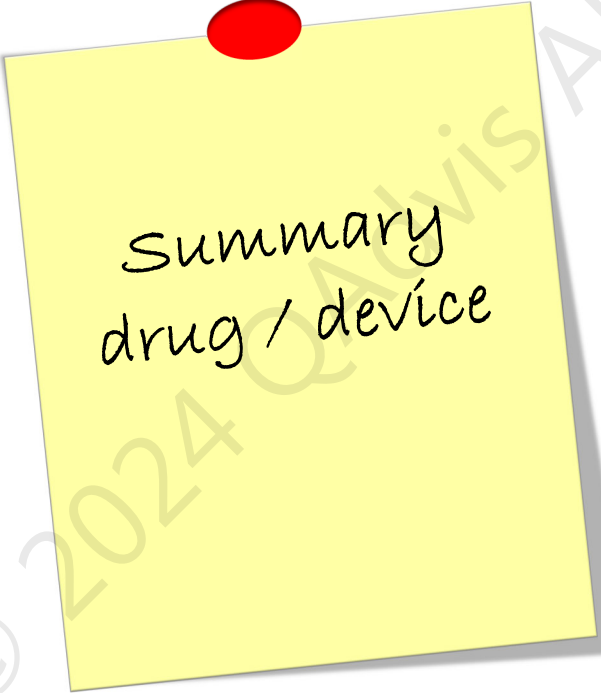
Guideline on quality  
documentation when used with a  
medical device

Q&A for applicants, marketing  
holders of medicinal products and  
notified bodies with respect to the  
implementation of MDR and IVDR

EMA:

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summary  
drug / device

Q & A

# Summary

## Regulatory strategy

- Integrated or co-packed?
- Primary mode of action?

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Remember...

- Both components are reviewed
- Consult guidance

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