PLANTVISION
BEYOND TOMORROW

COMBINATION PRODUCTS

Management of Complaints, Withdrawal & Recall

Belma Hot

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SENIOR CONSULTANT & ACADEMY LEADER

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VÄRA EXPERTOMRÄDEN

QUALITY & COMPLIANCE

LABORATORY

MANUFACTURING

DIGITAL TRANSFORMATION

TECH CONSULTING

MANAGEMENT

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PLANTVISION ACADEMY

- Introduktion till kvalitetsledningssystem
- MDR
- IVDR
- Dataintegritet och Cyber Security
- Medicinteknisk mjukvara
- Kombinationsprodukter
- Validering & kvalificering
- GMP
- Dataintegritet
- GAMP 5
- GDP
- Systemförvaltning
- GxP for Management

Öppna kurser i samarbete med Swedish Medtech, Swedish Labtech och Läkemedelsakademin,

Alla aktuella utbildningar finns på plantvision.se

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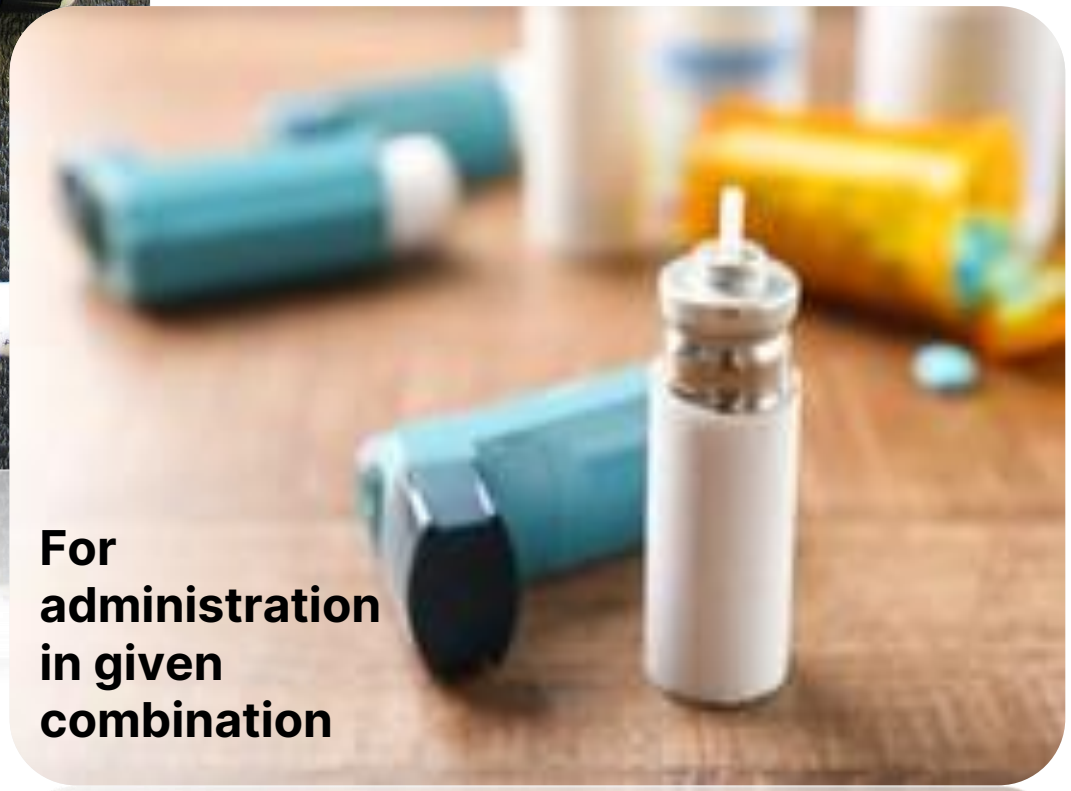
WHAT IS A COMBINATION PRODUCT?

- Regulation 2017/745 (EU)
- Article 117 Amendment to Directive 2001/83/EC
- Guideline on quality documentation for medicinal products when used with a medical device


Integral
Important:
For demonstration only
Not to be injected
Not for treatment of diabetes
The product does not contain insulin
Novo Nordisk A/S


For administration in given combination

Governed by:

Directive 2001/83/EC or

Regulation (EC) No 726/2004

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COMPLAINT, WITHDRAWAL & RECALL

HOW SHOULD IT BE MANAGED?

Governed by:

Directive 2001/83/EC or

Regulation (EC) No 726/2004

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Directive 2001/83/EC or

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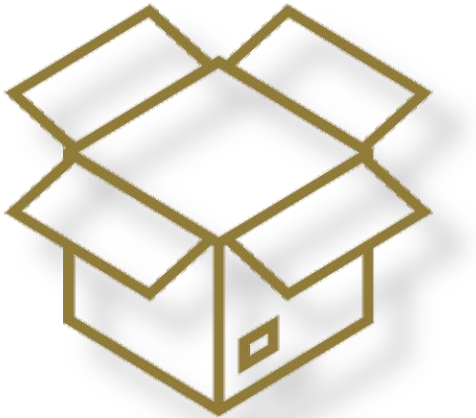
Combination product

Pharmaceutical

Medical device



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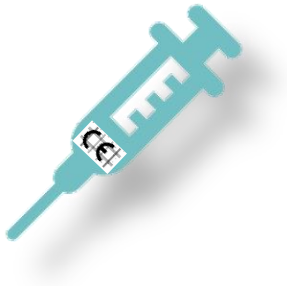
Medical device

CE-mark attached



No CE-mark attached

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WHAT IS CE MARKING

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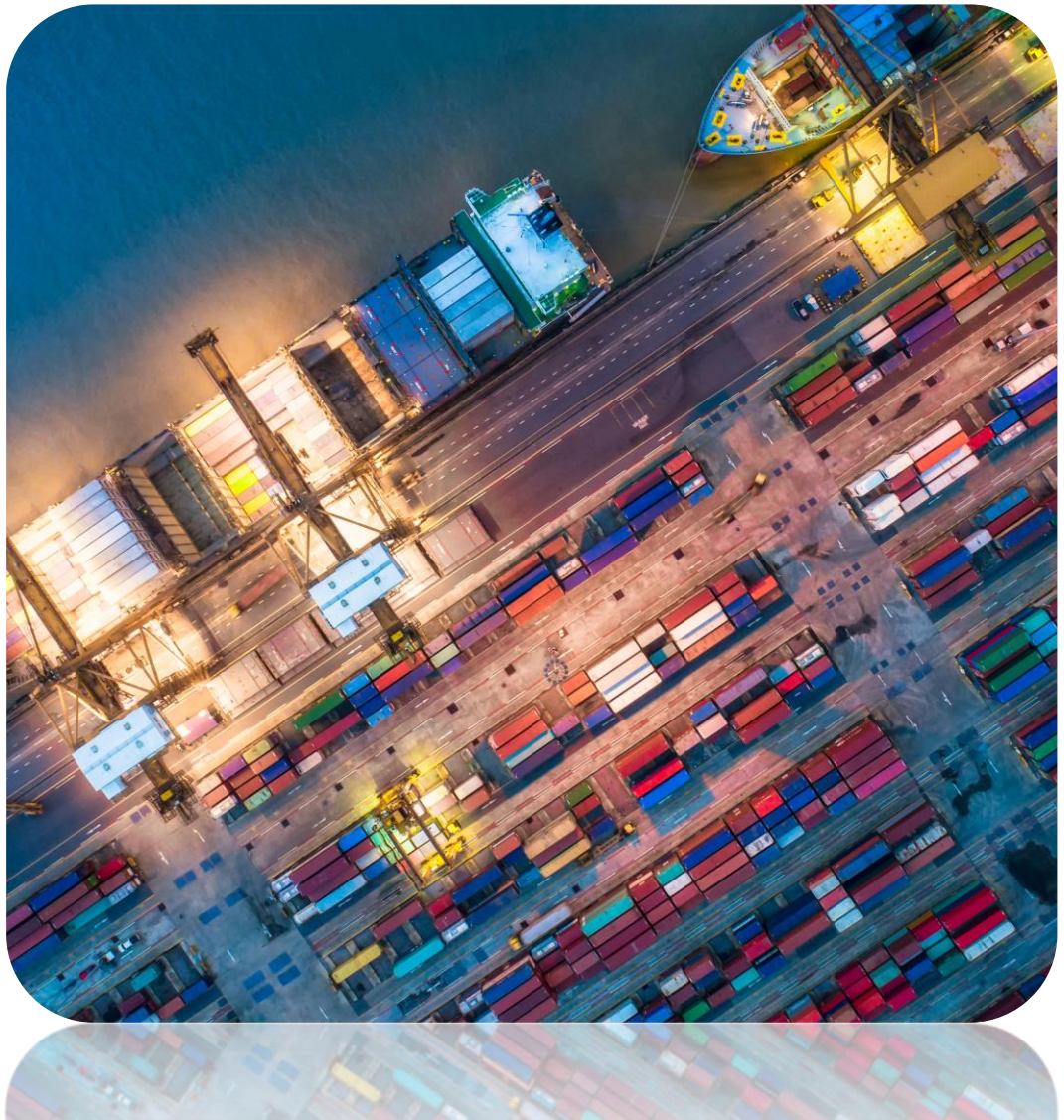

- Importer
- Distributor
- Authorised representative

- As part of a combination product:

- Making a device available on the market, up until the point of putting into service

- CE-marked devices

- Primarily applicable for co-packaged devices but can also apply to integral medicinal product

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DISTRIBUTOR OBLIGATIONS

- MD not in conformity
  - Inform
  - Do not place on the market
  - Co-operate in corrective actions, withdrawal or recall
- Inform Competent authority if serios risk/falsified MD
- Forward complaints and reports to manufacturer
- Keep register of complaints, non-conforming devices, recalls and withdrawals
- Inform Manufacturer, AR and Importer of register

- CE mark and DoC
- Information supplied by the manufacturer
- For imported MD, importer complies with requirements
- UDI
- Storage and Transport conditions
- Cooperate with Competent authority

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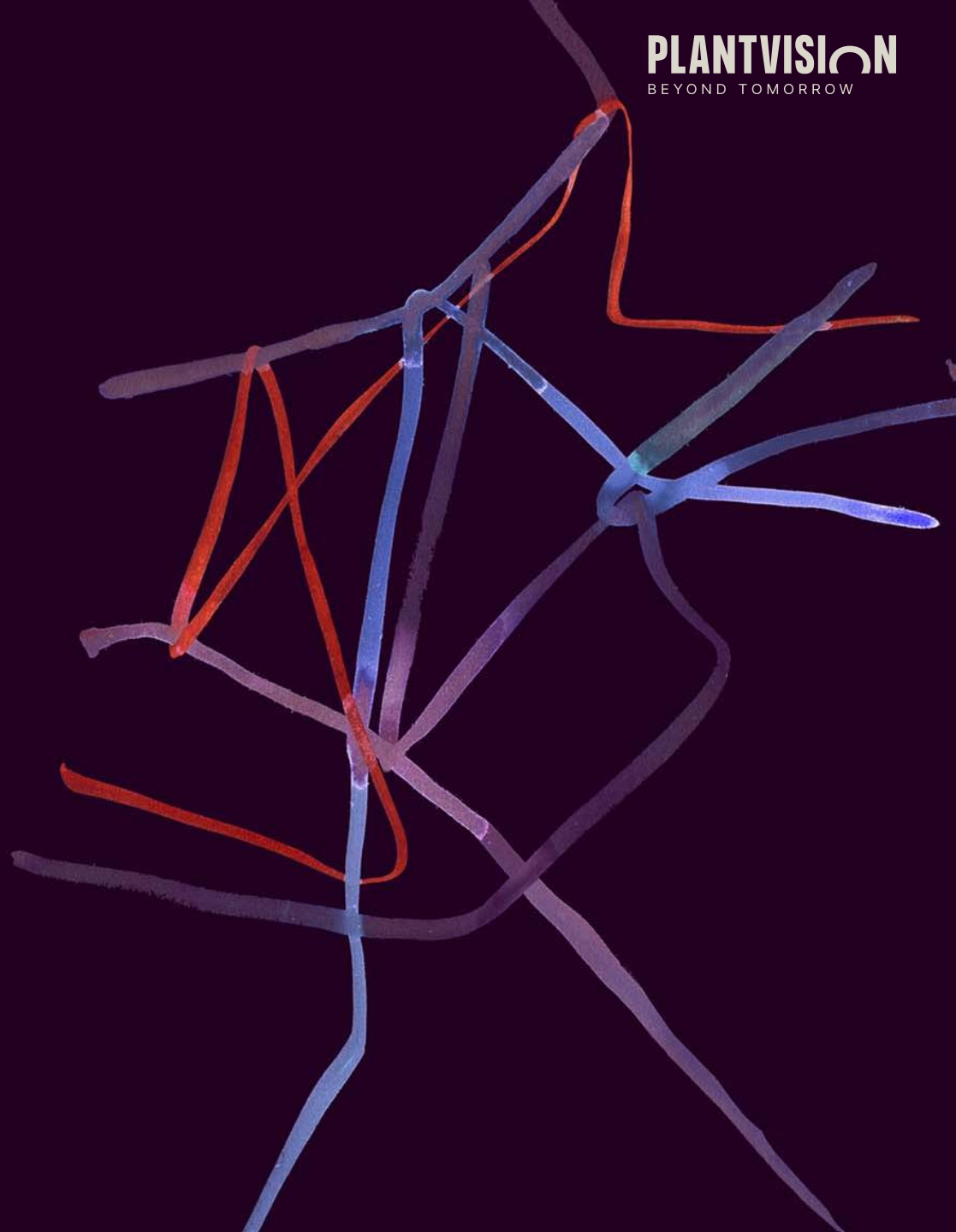
WHAT IF THE DEVICE IS NOT CE MARKED



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new®

- Only available in this combination
- Medicinal product

Managed as a medicinal product in regard to complaints, recall and withdrawal

- New products
- Significant change to the product

Additional requirements on the manufacturer of a combination product on safety and performance to fulfill.

Morning,

Thanks for reaching out to the Office of Combination Products (OCP). Regarding your question below, there are several resources at this site to address your questions, Postmarketing Safety Reporting for Combination Products | FDA.

Thanks,
Adeola


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TACK!