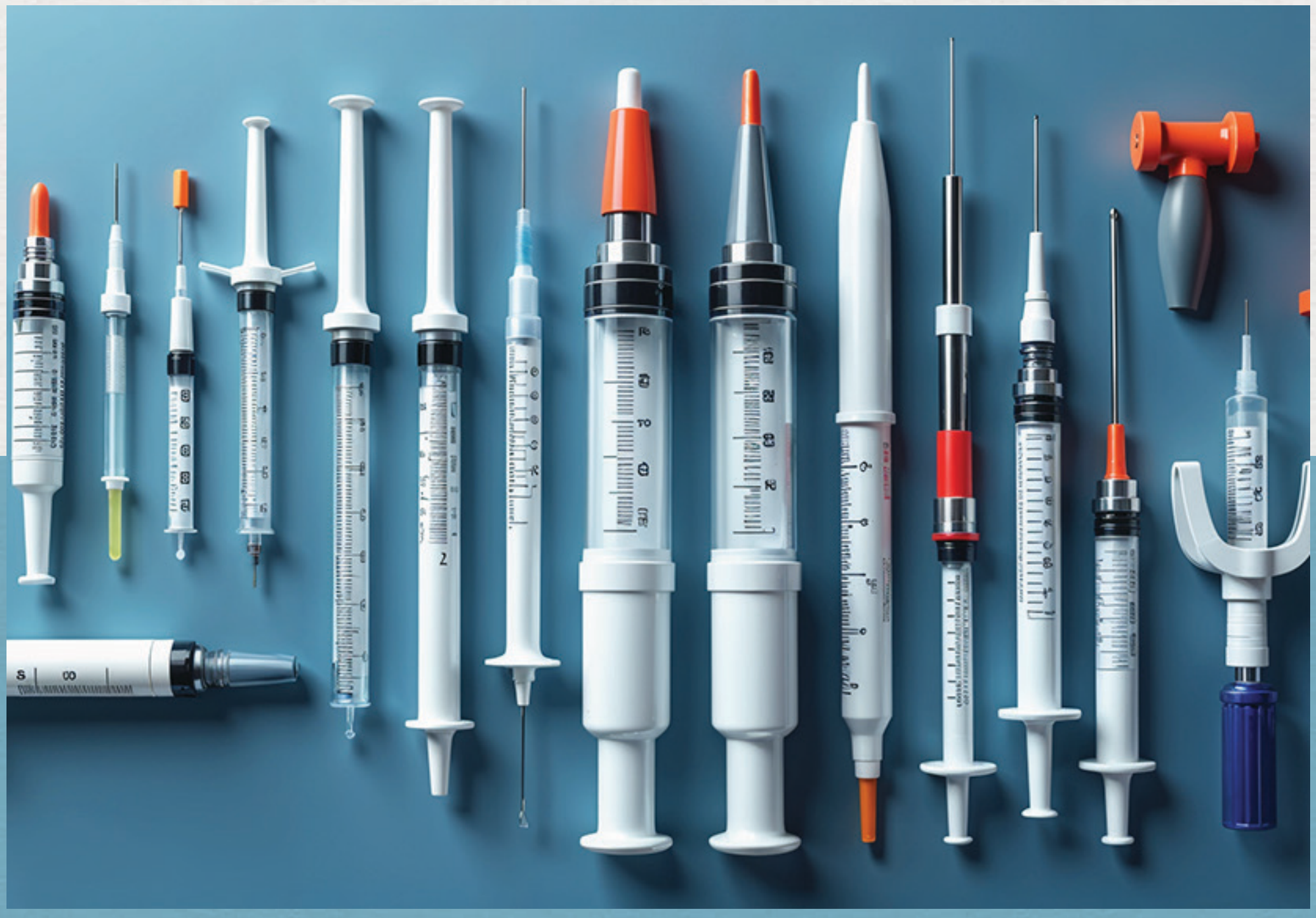
regenold

What You Need to Know About

Drug-Device Combination Product Classification in the EU

Felix Metzner, **regenold GmbH**



What You Need to Know About

Drug-Device Combination Product Classification in the EU

The European Union (EU) regulations concerning drug-device combination products (DDCPs) have established specific classifications to ensure these products are properly evaluated for safety, efficacy, and quality. The classifications for these products under the EU Medical Device Regulation (MDR) 2017/745 and the In Vitro Diagnostic Medical Devices Regulation (IVDR) 2017/746 are as follows:

1. Integral Drug-Device Combination Products:

Description: These are products where the medical device and the medicinal product are physically or chemically combined to form a single product. The device is intended to deliver the medicinal product and is not reusable.

Examples: Prefilled syringes, transdermal patches, inhalers, and drug-eluting stents.

Regulatory Pathway: These products are primarily regulated as medicinal products under Directive 2001/83/EC or Regulation (EC) No 726/2004. The medical device component must meet relevant requirements of the MDR. A Notified Body must be involved in assessing the device part's conformity.

2. Co-Packaged Drug-Device Combination Products:

Description: These are products where the medicinal product and the medical device are packaged together but not physically or chemically combined. They are intended to be used together.

Examples: Insulin vials sold with syringes, blister packs containing a drug and a dosing device.

Regulatory Pathway: Each component (the medicinal product and the medical device) must comply with its respective regulations (medicinal product regulations and MDR).

3. Cross-Labelled Drug-Device Combination Products:

Description: These are products where the medicinal product and the medical device are separately marketed but are intended to be used together and specified as such in their labelling and instructions for use.

Examples: Separate drug vials and reusable injector devices.

Regulatory Pathway: Similar to co-packaged products, each component must meet its respective regulatory requirements.

Key Points of the Regulatory Framework:

- **Integral Products:** Require a single marketing authorization as a medicinal product, including conformity assessment of the device part.

- **Co-Packaged and Cross-Labelled Products:** Each component is independently regulated, but combined use must be justified and documented.

These classifications ensure that all aspects of safety, performance, and quality are thoroughly evaluated, providing a comprehensive regulatory framework for DDCPs within the EU.

Have a Question?

Need assistance in determining the classification of your product? Our team of experts is here to guide you, whether you have general inquiries or require product-specific support. Contact us today for more information or book a free consultation here.

regenold GmbH
Zöllinplatz 4, 79410 Badenweiler, Germany
Email: info@regenold.com
Phone: +49 7632 82 26-0

regenold

www.regenold.com