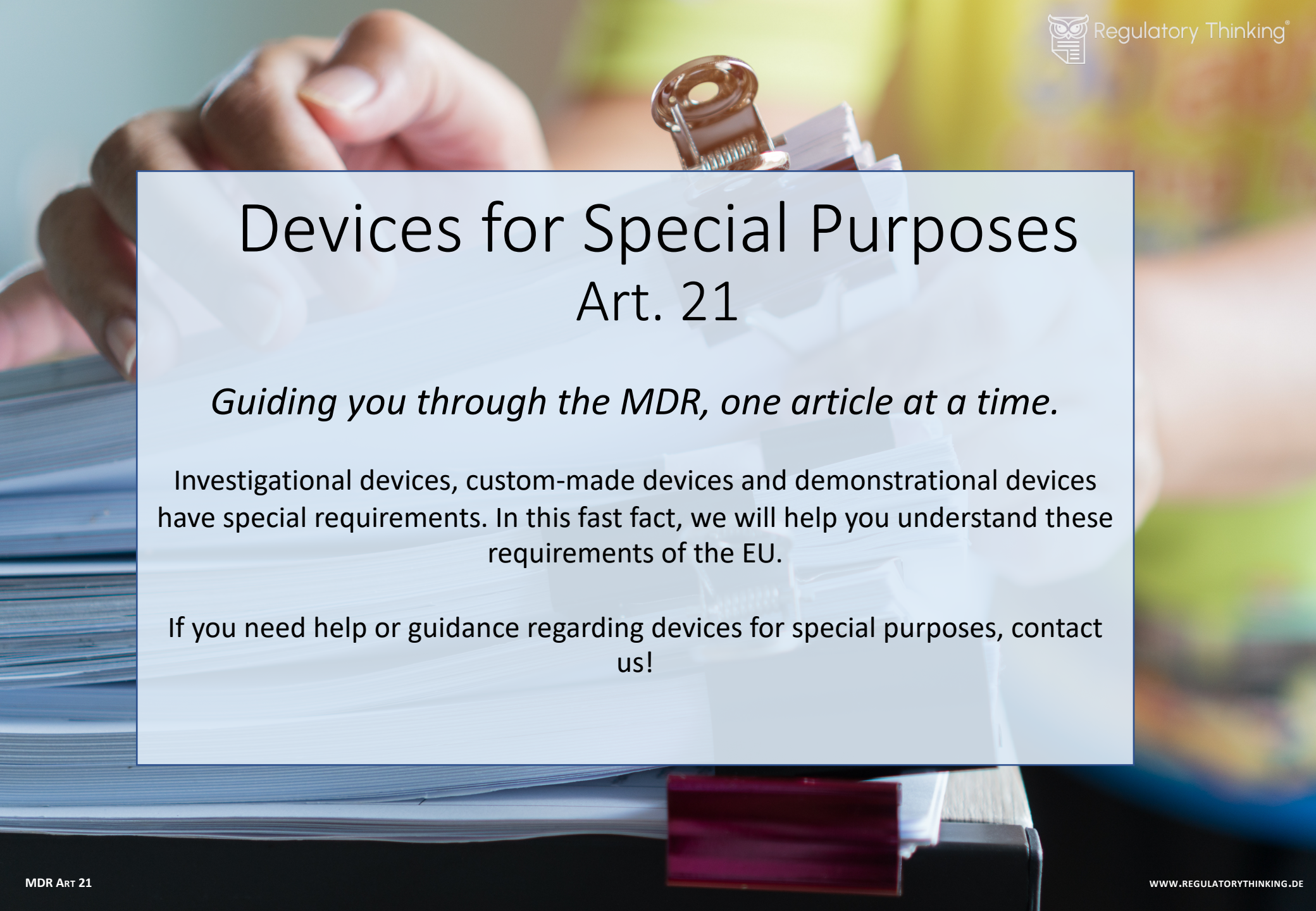

Regulatory Thinking®

Devices for Special Purposes
Art. 21

Guiding you through the MDR, one article at a time.

Investigational devices, custom-made devices and demonstrational devices have special requirements. In this fast fact, we will help you understand these requirements of the EU.

If you need help or guidance regarding devices for special purposes, contact us!

Devices for special purposes

1. Member States shall **not** create **obstacles** to:

a) **investigational devices** being supplied to an investigator for the purpose of a **clinical investigation** if they meet the conditions laid down in Articles 62 to 80 and Article 82, in the implementing acts adopted pursuant to Article 81 and in Annex XV;

b) **custom-made devices** being made available on the market if Article 52(8) and Annex XIII have been complied with.

The devices referred to in the first subparagraph shall **not** bear the **CE marking**, with the exception of the devices referred to in Article 74.

For more information, please review:

Article 21: Devices for special purposes

CE Marking of Conformity

2. **Custom-made devices** shall be accompanied by the statement referred to in Section 1 of Annex XIII, which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.
Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.
3. At **trade fairs**, **exhibitions**, **demonstrations** or **similar events**, Member States shall **not create obstacles** to the showing of devices which **do not comply** with this Regulation, provided a **visible sign** clearly indicates that such devices are **intended for presentation** or **demonstration** purposes only and cannot be made available until they have been brought into compliance with this Regulation.

For more information, please review:

Article 21: Devices for special purposes

Takeaway

Investigational devices, custom-made devices and demonstrational devices have special requirements.

- **They cannot bear the CE-mark**
- **They need to bear a statement, that they are custom-made/investigational or demonstrational devices, so the user/patient can differentiate them.**

For more information, please review:

Article 21: Devices for special purposes


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