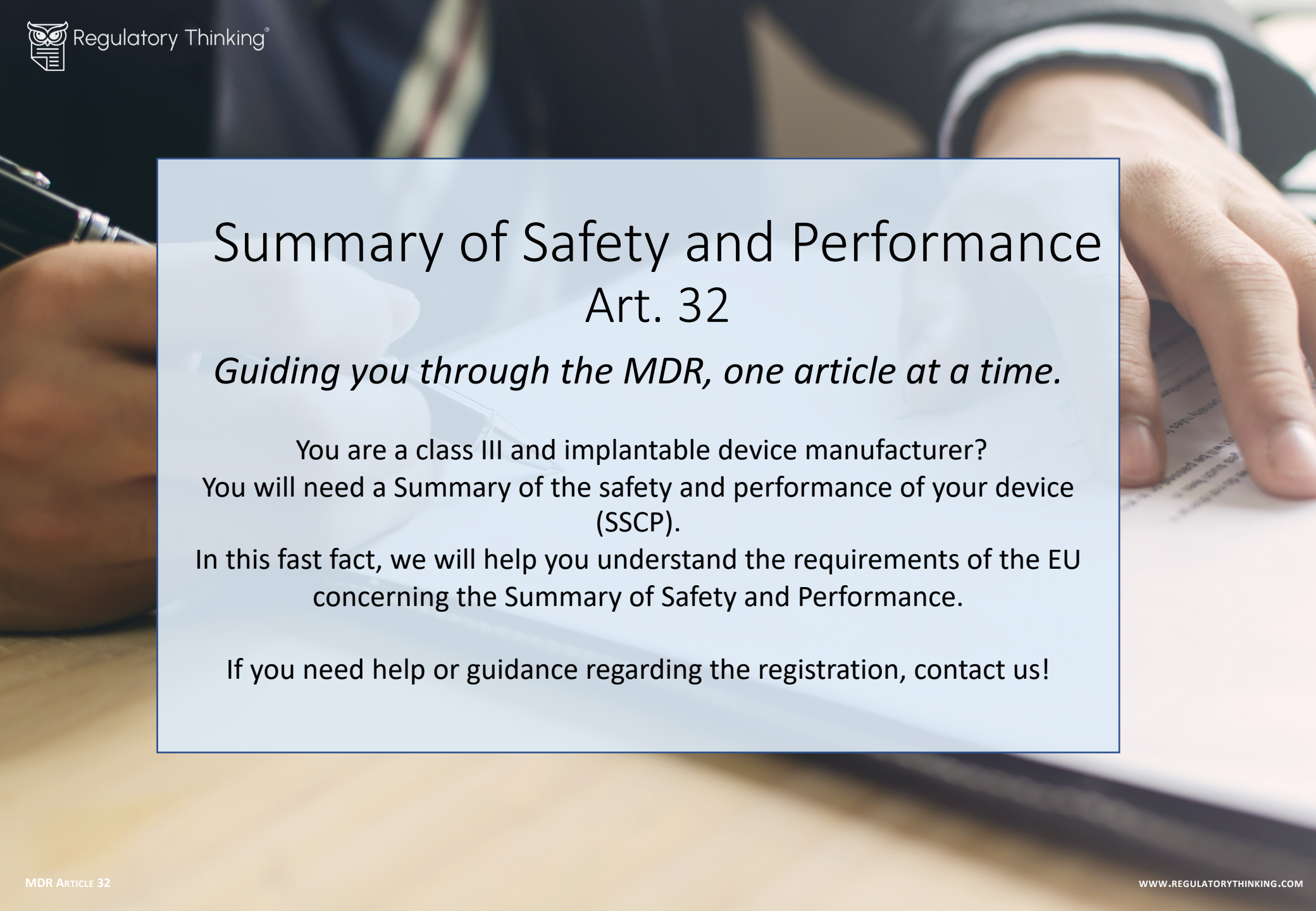

Regulatory Thinking®

Summary of Safety and Performance Art. 32

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

You are a class III and implantable device manufacturer?
You will need a Summary of the safety and performance of your device (SSCP).
In this fast fact, we will help you understand the requirements of the EU concerning the Summary of Safety and Performance.

If you need help or guidance regarding the registration, contact us!

Summary of Safety and Performance

1. For **implantable** devices **and** for **class III** devices, other than custom-made or investigational devices, the manufacturer shall draw up a **summary of safety and clinical performance**.
   The summary of safety and clinical performance shall be written in a way that is **clear** to the **intended user** and, if relevant, to the patient and shall be **made available** to the public via **Eudamed**.

For more information, please review:

Article 32 MDR

Summary of Safety and Performance

1. (continued) The **draft** of the summary of safety and clinical performance shall be part of the **documentation** to be **submitted** to the **notified body** involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the **notified body** shall **upload** the summary to Eudamed. The manufacturer shall mention on the label or instructions for use **where the summary is available**.

For more information, please review:

Article 32 MDR

Summary of Safety and Performance

2. The summary of safety and clinical performance shall include at least the following aspects:
   a) the **identification of the device** and the **manufacturer**, including the **Basic UDI-DI** and, if already issued, the **SRN**;
   b) the **intended purpose** of the device and any **indications**, **contraindications** and **target populations**;
   c) a **description** of the device, including a **reference** to **previous generation(s)** or **variants** if such exist, and a description of the **differences**, as well as, where relevant, a description of any **accessories**, **other devices** and **products**, which are **intended** to be **used** in **combination** with the device;

For more information, please review:

Article 32 MDR

Summary of Safety and Performance

2. (continued)
   d) possible **diagnostic** or **therapeutic** alternatives;
   e) reference to any **harmonised standards** and **CS** applied;
   f) the **summary of clinical evaluation** as referred to in Annex XIV, and relevant information on **post-market clinical follow-up**;
   g) suggested **profile** and **training** for **users**;
   h) information on any **residual risks** and any **undesirable effects**, **warnings** and **precautions**.

For more information, please review:

Article 32 MDR

Summary of Safety and Performance

3. The **Commission** may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

For more information, please review:

Article 32 MDR

Takeaway

In Article 32, the requirements for the Summary of Safety and Performance are clear:

- Has to be written in a **clear** way – for the intended **user** and if applicable for the **patient**.
- It is part of the documentation for the **conformity assessment**, and the notified body concerned makes it **publicly available** on Eudamed after its validated.
- It has to contain **all requirements** of subsection 2 of this article *(get ready for next week's worksheet – we will provide a checklist so you think of everything!)*.

For more information, please review:

Article 32 MDR


Regulatory Thinking®
www.regulatorythinking.com