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# The Essence of **EU SSCP** and EU PSUR ?

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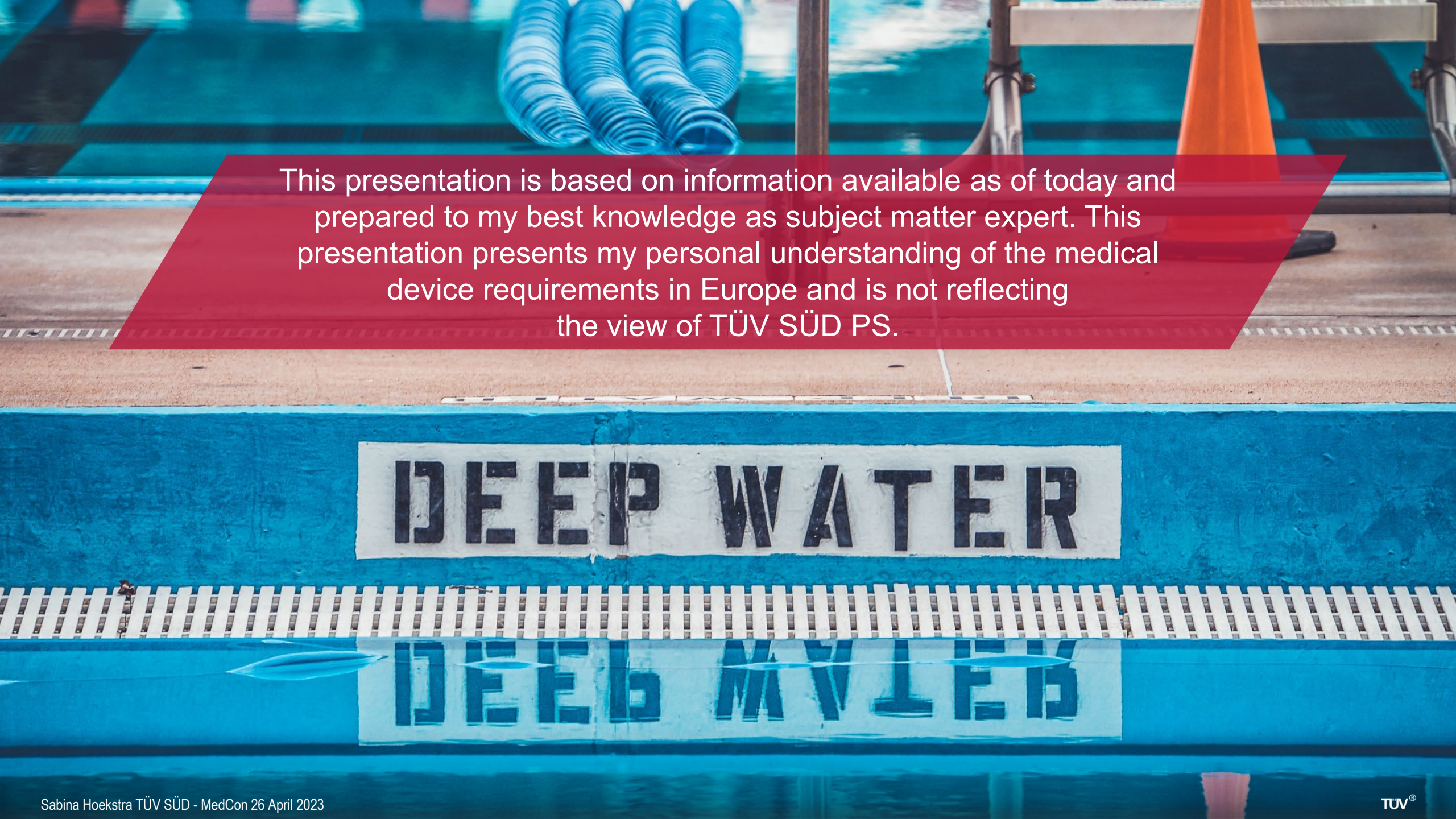



This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert. This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.

# Summary

- What is an SSCP and why does MDR require it?
- Main items in SSCP
- Common mistakes in SSCP

Official Journal of the European Union

L 117

Volume 60

5 May 2017

Legislation

English edition

*Article 32*

**Summary of safety and clinical 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.

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.

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;

(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.

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).

# Article 32: Summary of safety & clinical performance (SSCP)

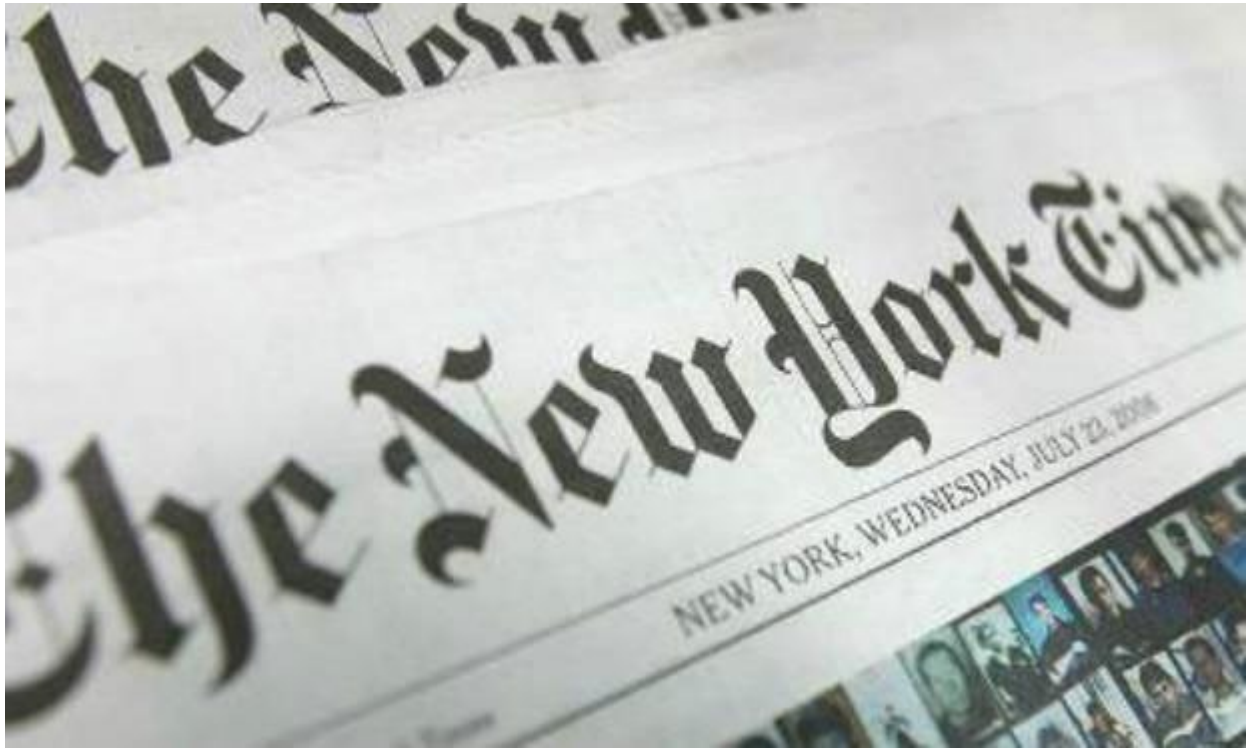
In case of **class III & implantable devices (including all classes),** other than custom-made or investigational devices, manufacturer shall draw up a SSCP

Manufacturer shall mention on **label or IFU** where the SSCP is*

*will be up-loaded to EUDAMED

# Concept of SSCP

- Why do we need SSCP?
  - We have IFU & labelling…
  - With EUDAMED, a lot of information will be available…



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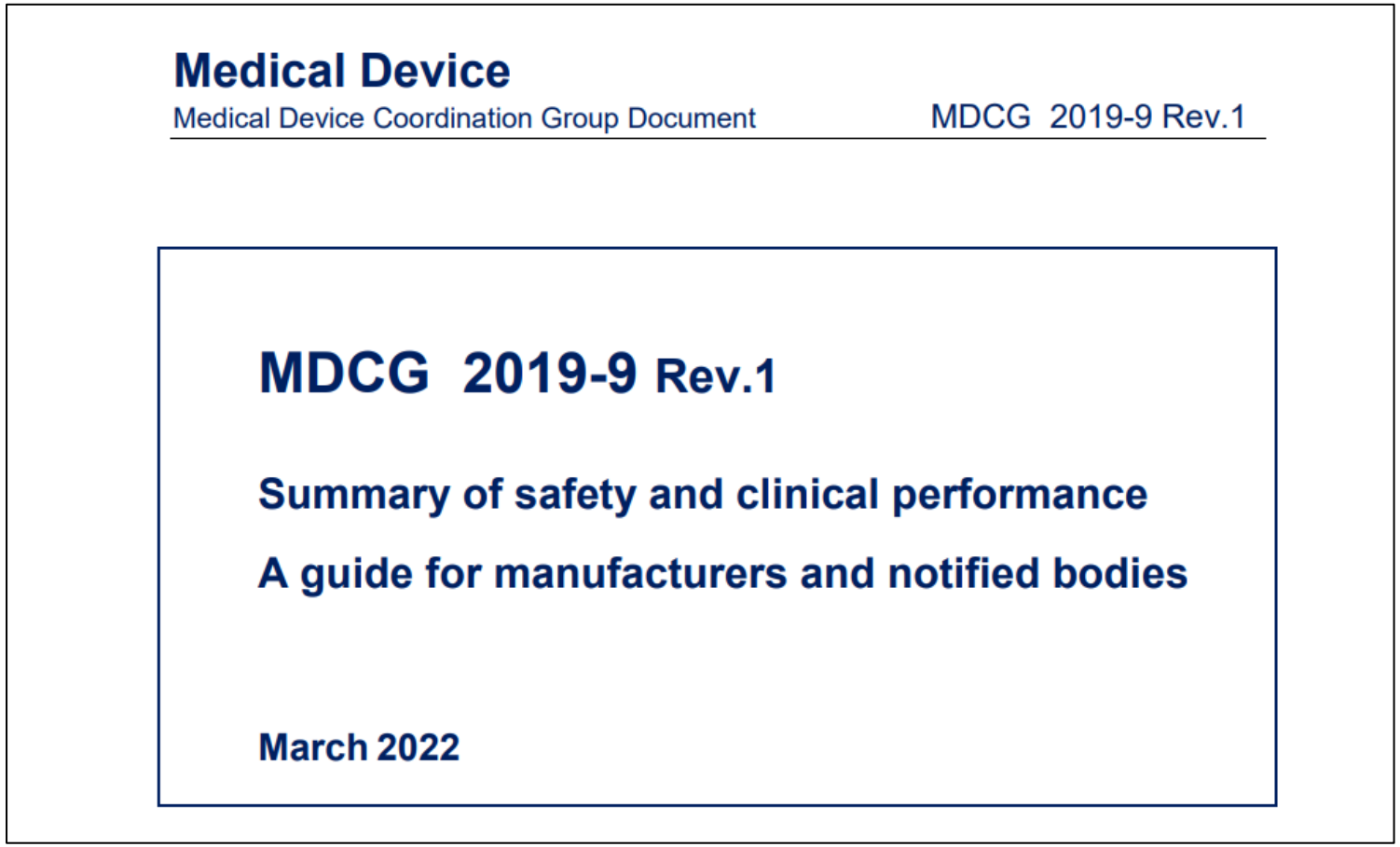


- Very detailed guidance
- Currently Rev.1 under revision in MDCG WG on Clinical Investigations and Evaluation (CIE of 19 April 2023 in Brussels)
  - Upload SSCP translations in EUDAMED will transfer from NB to manufacturer
  - Other changes (?)

# Common issues with SSCPs identified by NBs

- “Quick wins”
  - Failure to include all relevant device model numbers;
  - Failure to include clear pictures of the medical devices;
  - No link to SSCP in the instructions for use (IFU) on manufacturer’s website (requirement in the absence of EUDAMED)

- “Really amazing”
  - marketing materials are copy pasted in SSCP;

# Common issues with SSCPs identified by NBs

- Others
  - Clinical Evaluation Reports (CER) and SSCP inconsistent;
    - *incompliance with MDCG 2019-9 rev1 section 5.3 and 5.4*
  - Information for Use (IFU) and SSCP inconsistent
  - Quantification of risks not adequate or completely left out;
    - *incompliance with MDCG 2019-9 rev1 section 4.1 and specifically all that is described under "Quantitative data"*
  - PMCF-activities only listed, not summarized;
    - *incompliance with MDCG 2019-9 rev1 section 5.5*
  - Section on possible diagnostic or therapeutic alternatives in most cases very short; just listing the options without any additional data or information
    - *incompliance with MDCG 2019-9 rev1 section 6*
  - Detail on relation between risk and product´s lifecycle is missing
  - Uncertainty which devices require a SSCP version in lay language
  - Detailed review of the State of the Art (SOTA) missing
    - "summary" ≠ "copy-paste".
  - Only 'positive' literature is summarized

- Thanks for your attention!

- Questions and Answers