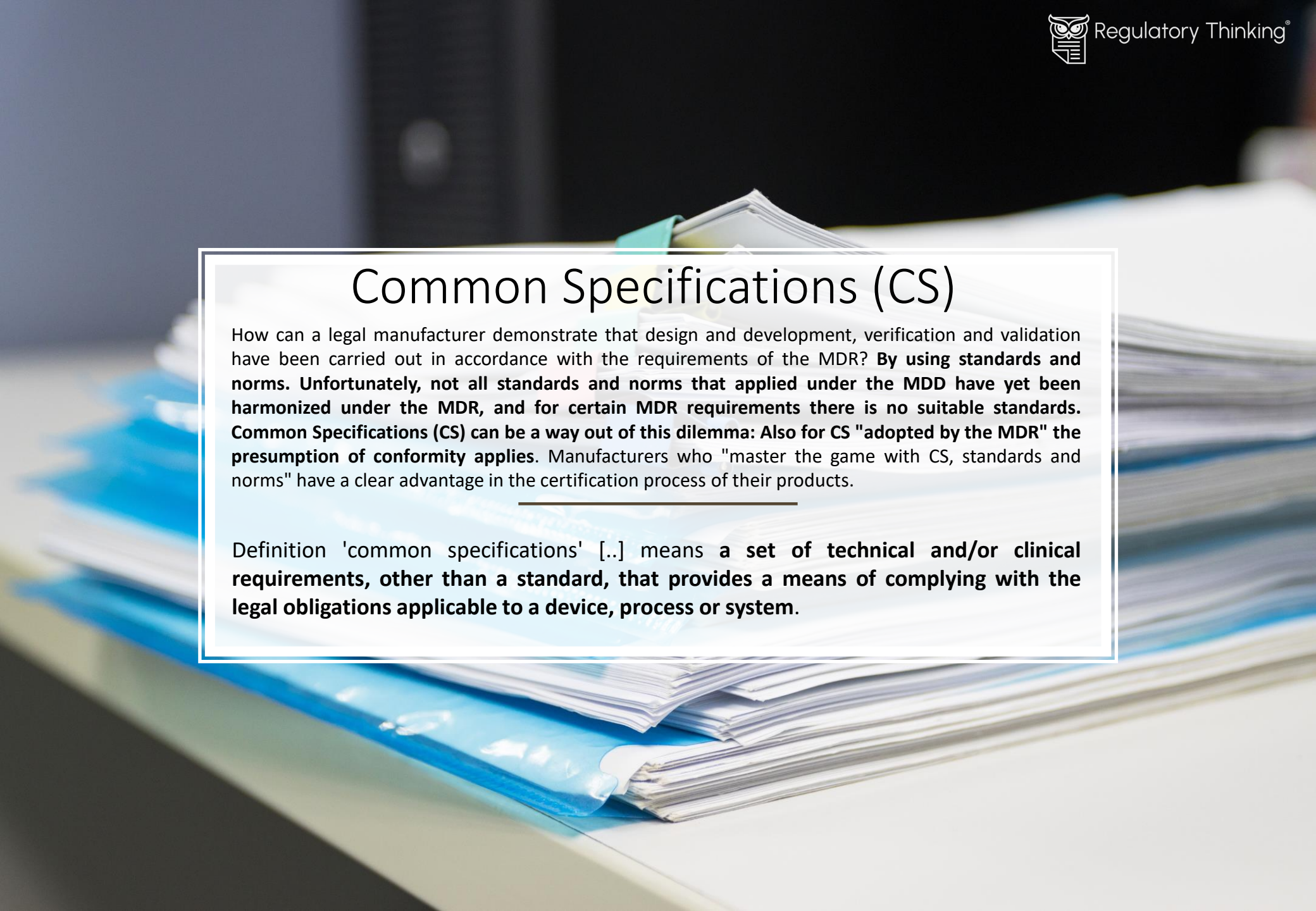

Common Specifications (CS)

How can a legal manufacturer demonstrate that design and development, verification and validation have been carried out in accordance with the requirements of the MDR? **By using standards and norms. Unfortunately, not all standards and norms that applied under the MDD have yet been harmonized under the MDR, and for certain MDR requirements there is no suitable standards. Common Specifications (CS) can be a way out of this dilemma: Also for CS "adopted by the MDR" the presumption of conformity applies**. Manufacturers who "master the game with CS, standards and norms" have a clear advantage in the certification process of their products.

Definition 'common specifications' [..] means **a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system**.

Common Specification (CS)

Without prejudice *(comment: or without influence/change/harm)* to Article 1(2) and 17(5) and the deadline laid down in those provisions, where:

- no harmonised standards exist or
- relevant harmonised standards are not sufficient, or
- there is a need to address public health concerns,

the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt **common specifications** (CS) in respect of:

- the general safety and performance requirements set out in Annex I,
- the technical documentation set out in Annexes II and III,
- the clinical evaluation and post-market clinical follow-up set out in Annex XIV or
- the requirements regarding clinical investigation set out in Annex XV.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Devices that are **in conformity** with the CS (…) shall be presumed to be **in conformity** with the requirements of this Regulation covered by those CS or the relevant parts of those CS.
Manufacturers **shall comply** with the CS (…) unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.
Manufacturers of products listed in **Annex XVI** shall comply with the relevant CS for those products.

For more information, please review:

Article 9: Common Specification (regulation (EU) 2017/745 on medical devices (MDR))

REGULATORY THINKING COMMENT:
Without touching articles 1 and 17, this article says, that the the commission can adopt **common specifications** where:

- no harmonised standards exist or
- relevant harmonised standards are not sufficient, or
- there is a need to address public health concerns.

Manufacturers (also manufacturers of products listed in Annex XVI) **shall comply** with these standards, unless they can duly justify that they have a solution that ensures a level of **safety** and **performance** that is **at least equivalent**.

If devices are in conformity with the CS, they shall be presumed to be **in conformity** with the requirements of the MDR covered by these CS.

If you have questions related to Common Specifications
or want an updated list of
[X] current CS, [X] Standards and [X] Norms:
Please Contact us!


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