Medical Devices

SECTION EDITOR

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Useful links for medical device writing

Want to learn more about medical device regulations? Then read some of the presentations held at EMWA's medical device symposium this year: https://www.emwa.org/conferences/emwa-symposia/.

There are also several webinars on medical devices stored on EMWA's webinar archive https://www.emwa.org/training/emwa-webinars-programme-archive/.

For those who want to dig deep into the new regulations, the landing page of the **European Commission (EC)** Medical Devices Unit is a must: https://ec.europa.eu/growth/sectors/medical-devices_en

From there, you can access all relevant information https://tinyurl.com/mlhrsxs
The current regulation are :

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD),
- Council Directive 93/42/EEC on Medical Devices (MDD), and
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD)

These can be found, as well as the new medical device regulations replacing them:

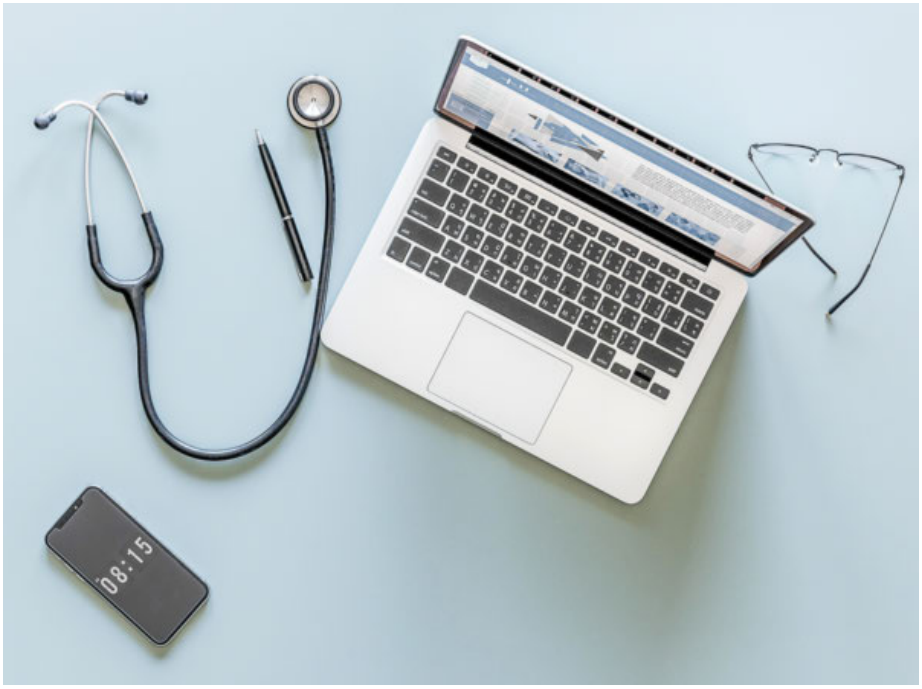
- Medical Device Regulation 2017/745 (MDR)
- In vitro Device Regulation 2017/746 (IVDR)

Both were entered into force on May 25, 2017, but will only apply after a transitional period (MDR in spring 2020 and IVDR in spring 2022).

Relevant for medical writers, these guidelines describe the content requirements of study documents such as clinical study protocol (clinical investigation plan), patient informed consent, etc. They also describe new documents to be created in the future, e.g., the periodic safety update report.

The regulations are supplemented by guidance documents, the MEDDEV guidelines, which can also be accessed via this page (tab Guidance MEDDEV). Relevant for medical writers are:

- MEDDEV 2.1 guidance documents that relate to the scope, field of application and definition of medical devices
- MEDDEV 2.7/1 rev 4 specifies the content requirements of a Clinical Evaluation Report (CER)



The **European Competent Authorities for Medical Devices** https://www.camd-europe.eu/ is an umbrella group of national competent authorities. The group currently works on providing guidance and generating templates to facilitate the implementation of the new regulations.

See for instance:

- MDR and IVDR Transitional FAQs: https://tinyurl.com/ya245elb
- MDR/IVDR Roadmap: https://tinyurl. com/zyckuv9wt

Joint Action on Market Surveillance of Medical Devices (JAMS): https://tinyurl.com/y8mwl5du

The **Notified Bodies** are also quite active in providing support for the implementation of the new regulations, see the following links:

- https://www.bsigroup.com/en-GB/medical-devices/resources/ From here, you can also access the guide "Want to know more about the Notified Body?" This guide helps you understand terms like Notified Body, Competent Authority and CE-mark.
- https://www.tuv-sud.com/industries/medical-devices-healthcare From here, you can find information and webinars related to the new MDR https://tinyurl.com/y8babpjf.
- https://industries.ul.com/healthcare From here, you can, e.g., access the IVDR webisode series https://tinyurl.com/y8y97tdw.

You can also check out the page of EMWA's Medical Device Special Interest Group at https://www.emwa.org/members/special-interest-groups/medical-devices-sig/

Happy reading!

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