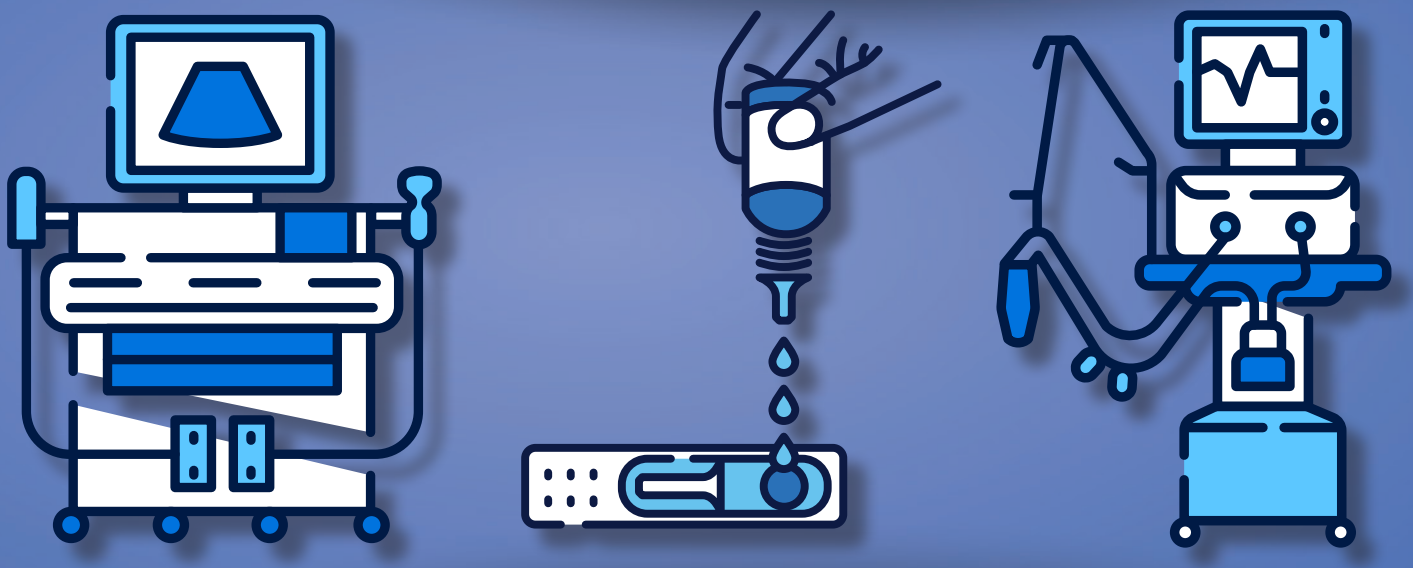
World Health Organization

Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics



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This guidance will be reviewed in 2025, unless substantive technological advancements are made that would require an earlier review. This guidance will be used as the basis for a series of training materials to be presented via the WHO Academy. Its impact on regulatory practice will be monitored through the WHO Global Benchmarking Tool for regulatory system strengthening once it has been rolled out for medical devices. Its impact on post-market surveillance obligations will be monitored through review of annual reports for WHO-recommended medical devices. This guidance will be made available in the six languages of the United Nations.

[1] English version (https://apps.who.int/iris/bitstream/handle/10665/255576/9789241509213-eng.pdf?sequence=1)
Version française (https://apps.who.int/iris/bitstream/handle/10665/258534/9789242509212-fre.pdf?sequence=1)
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