

Background note on the use of the Manual on borderline and classification for medical devices under the Directives

Starting from September 2022, a new series of the Manual on borderline and classification was initiated under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices. The previous Manual issued under Directive 93/42/EC on medical devices, Directive 90/385/EEC on active implantable medical devices and Directive 98/79/EC on *in vitro* diagnostic medical devices will not be updated anymore.

The MDCG Working Group on Borderline and Classification decided to keep the [Manual under the Directives](#) available for reference and use as long as devices with CE-marking issued under the Directives remain available on the market.

The latest and last version of the Manual under the Directives is embedded below.



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