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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