

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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With the exemptions defined in Article 4 of the Regulation (EU) 2017/745 on medical devices¹, the Member States have the competence and responsibility to take decisions on the qualification of medical devices.

The Helsinki procedure² is a voluntary cooperation system enabling the consultation among EU competent authorities on borderline and classification issues concerning medical devices and ensuring that appropriate guidance is published in the Manual on Borderline and Classification³. This voluntary cooperation mechanism does not have any suspensive or binding effect on the decisions adopted by the competent authorities of Member States.

The entries in the Manual represent the agreements reached by the EU competent authorities that are members of the Borderline and Classification Working Group of the Medical Device Coordination Group⁴. The recommendations contained in the Manual are not legally binding.

The qualification of the same technology as a medical device always requires a case-by-case assessment on the technical characteristics and the indications for use of a given device.

¹ ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

² Helsinki Procedure: https://health.ec.europa.eu/document/download/2e667094-2eaf-4370-9861-d1a283210da7_en?filename=md_border-class_helsinki-proc-mdr-ivdr_en.pdf.

³ Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 v4 https://health.ec.europa.eu/document/download/71a87df8-5ca1-4555-b453-b65bdf8de909_en?filename=md_borderline_manual_en.pdf.

⁴ https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en#six.