



Appendix 3 – ‘drives or influences the use of a device’

The term “*drives a device or influences the use of a device*” can include anything from direct control of a device to just selecting a device. This must be an intended action by the manufacturer of the software and not just an accidental influence on use of a device.

Examples:

Third party software that uses patient CT images and stent sizes from published data to help a clinician select the best implant for a patient. It is a new product.

The stent manufacturers do not specifically recommend stent sizing by this method (the use was not prohibited as they didn't know about this product)

Software is influencing the use of a device outside its intended purpose. Software will take the classification of the device.

Third party software that sends insulin dose values via Bluetooth connection to any compatible insulin pump.

The pump manufacturer allows Bluetooth communication but **ONLY** from its dedicated software.

Software is influencing the use of a device outside that mentioned in the IFU. Software will take the classification of the device.

Third party dental image PACS that can be connected to a digital detector to acquire images. It doesn't control/drive/influence the performance of the x-ray source but does influence the use of the detector.

Some digital detectors allow connection to third party systems but only if the listed standards are met. Others specify OEM connection only.

This software states that it can be used with **ALL** detectors.

Software is influencing the use of those devices that do not mention this use in their IFUs. Software will take the classification of the detector.

Third party software that makes recommendations about choices of contraceptive devices/medications.

The app decision process follows national prescribing recommendations and not the contraceptive device's IFU (some contraindications are not considered by the app).

Software is influencing the use of a device outside that mentioned in the IFU. Software will take the classification of the device.

Annex IX, implementing rules:

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

Any interactions should be considered under the post-market surveillance plans of the software and device manufacturers.

