

Software as a medical device

The MDR defines a medical device as follows:

Any instrument, apparatus, appliance, software, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

Software incorporated into a product falls in above definition e.g. app registering blood glucose levels, measured by a Bluetooth connected glucometer. Wearables or mobile apps that transfer measurement data from the human body such as temperature, weight, pulse, etc. are considered a medical device, irrespectively if the data has been entered by a sensor with body contact, an implant or manually. **Software connected to the wearable is determined by the same classification as the wearable.**

Software in its own right (standalone) that falls in above definition is also a medical device. E.g. an app to determine melanoma or not via capture of an image.

Software that is an accessory to a medical device is also treated as a medical device in its own right. An accessory is defined as

Software which, whilst not being itself a medical device, is intended to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

The qualification of software, either as a medical device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

Software for general purposes, even when used in a healthcare setting and software intended for life-style and well-being purposes is n ot a medical device.

Examples:

- Data in databases, registers and forms
- Digital transmission of manual counselling services
- Collect and maintain administrative patient details