SOFTWARE AS A MEDICAL DEVICE (MDSW)

What is an MDSW?

Software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a medical device according to the Medical Device Regulations*. A medical device is a device intended for healthcare uses such as diagnosis, treatment, prevention, or monitoring, without a primary pharmacological action, including contraception control and equipment disinfection.

SOFTWARE LOCATION

Software can qualify as MDSW regardless of its location (in the cloud, on a mobile phone, etc.).

INTENDED USERS

It may be intended for healthcare professionals as well as lay users.

EXAMPLES

- Software that analyses MRI images to detect brain tumors.
- Smartwatch app that detects cardiac arrhythmias and sends alarm notifications to the user or the healthcare professional.

Dependence on HARDWARE that is a medical device

INDEPENDENT MEDICAL DEVICE

If software has its own medical purpose, regardless of whether it is integrated into or associated with a medical device, it must obtain independent MDSW certification.

Examples:

- App that calculates the insulin dose based on glucose automatically read by a continuous glucose monitor.
- Application that receives ECG data and analyses whether atrial fibrillation or arrhythmias are present, and displays diagnostic alerts.

INTEGRAL PART OF A MEDICAL DEVICE

Component that does not have its own medical purpose independently and only works in the context of another medical device, so that it forms part of its overall functioning.

Examples:

- Software inside an insulin pump that controls the motor and administration but does not decide the dose.
- Software of a portable ECG device that displays the signal on a screen or transmits it without interpretation.

Software = software
Hardware = hardware

The Medical Device Regulations refer to the two applicable regulations: Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR).

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