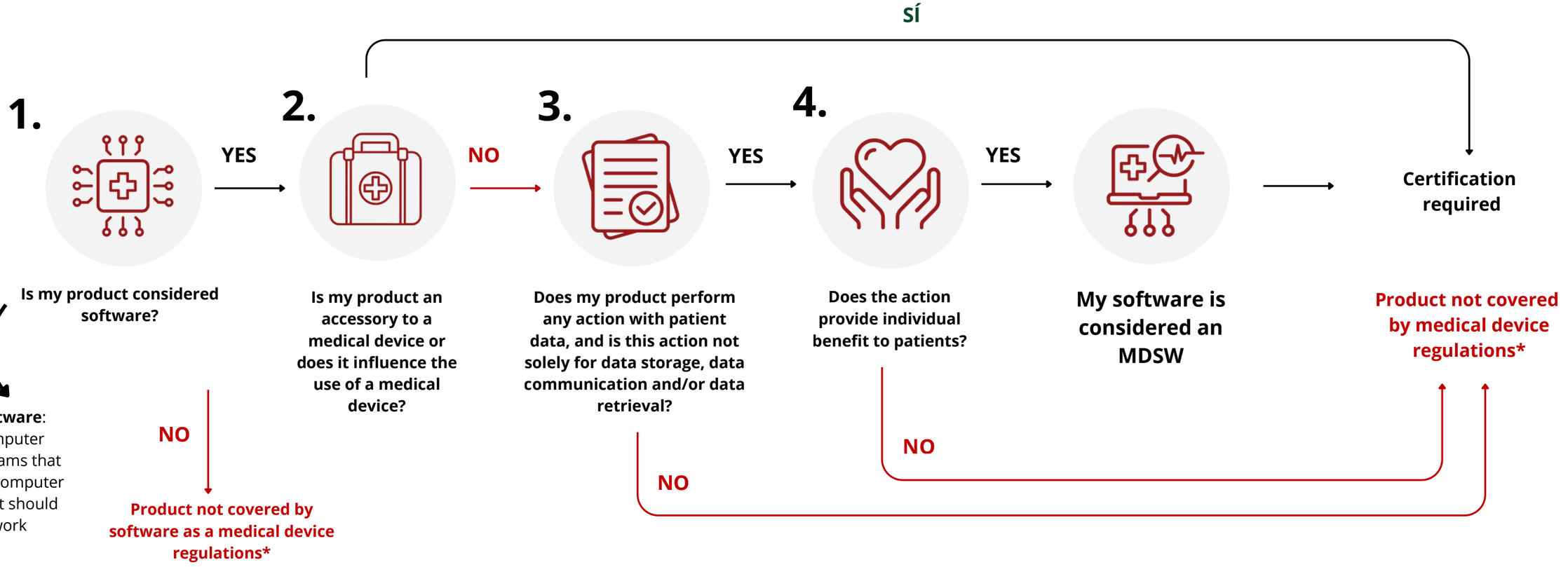
Am I required to certify my software as a Medical Device (MDSW)?



What is a medical device? Device intended for healthcare purposes such as diagnosis, treatment, prevention, or monitoring, without a primary pharmacological action, including contraception control and equipment disinfection.

What is an MDSW? Software intended to be used, alone or in combination, for a purpose as specified in the definition of a medical device in the regulations*.

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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