



European  
Commission

# Is your software a Medical Device?



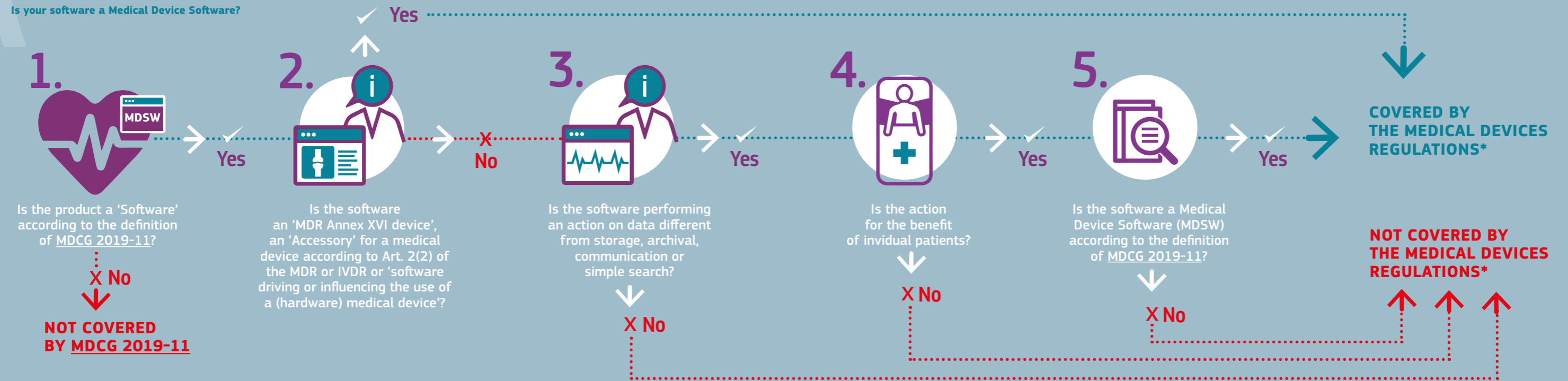
Health



# Decision steps to assist qualification of **Medical Device Software (MDSW)**

**Medical Device Software (MDSW):** Software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the Medical Devices Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR).

Is your software a Medical Device Software?



**Medical devices Regulations\*** refers 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)

Is your MDSW an *In Vitro* Diagnostic Medical Device Software (IVD MDSW) or a Medical Device Software (MD MDSW)

