



European
Commission

Is your software a Medical Device?



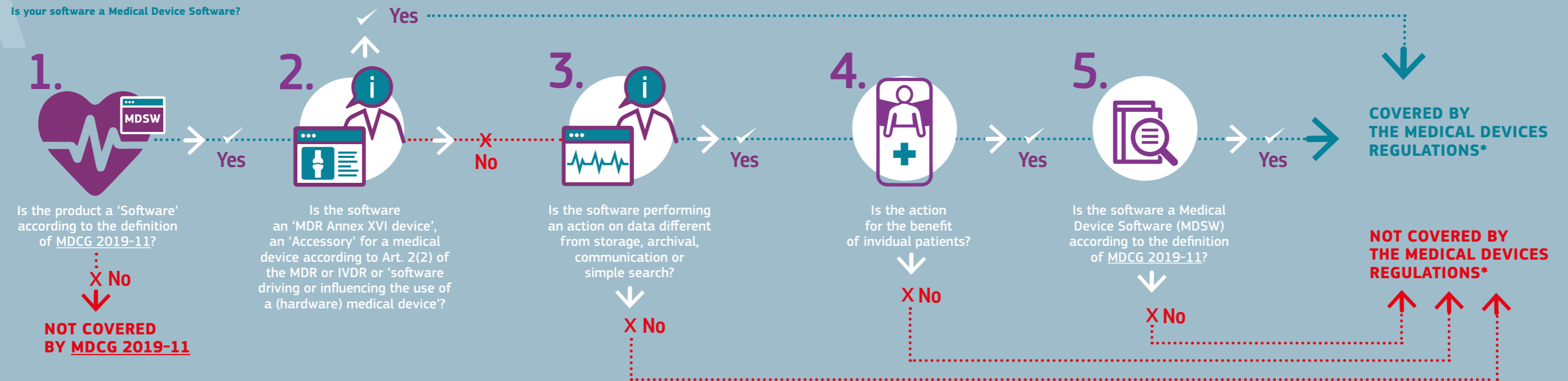
Health



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)*?



MDSW according to the definition of MDCG 2019-11



Does the MDSW provide information within the scope of the IVD definition?



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BY REGULATION (EU) 2017/746 (IVDR)

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