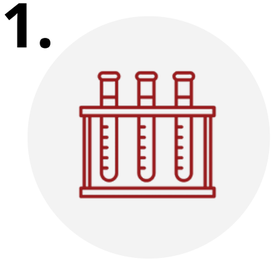
Is my MDSW an in vitro diagnostic (IVD) medical device?

For software considered a medical device (MDSW)

1.



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

YES

2.

Does the MDSW provide information exclusively or primarily based on data obtained from the IVD?

YES

YES

IVDR 2017/46 CERTIFICATION REQUIRED

NO

MDR 2017/45 CERTIFICATION REQUIRED

NO

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*.

What is a IVD? In vitro diagnostic medical device intended to analyse biological samples for purposes such as diagnosis, prediction, monitoring, or information about physiological or pathological conditions or therapies, including specimen receptacles.

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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