Is your software a Medical Device?
Decision steps to assist qualification of Medical Device Software (MDSW)

### A

**Is your software a Medical Device Software?**
- **Yes**
  - 1. Is the product a 'Software' according to the definition of MDCG 2019-11?
  - **Yes**
    - 2. Is the software an 'MDR Annex XVI device', an 'Accessory' for a medical device according to Art. 2(2) of the MDR or IVDR or 'software driving or influencing the use of a (hardware) medical device'?
    - **No**
      - **NOT COVERED BY MDCG 2019-11**
    - **Yes**
      - 3. Is the software performing an action on data different from storage, archival, communication or simple search?
      - **No**
        - **Yes**
          - 4. Is the action for the benefit of individual patients?
          - **No**
            - **Yes**
              - 5. Is the software a Medical Device Software (MDSW) according to the definition of MDCG 2019-11?
              - **No**
                - **Yes**
                  - COVERED BY THE MEDICAL DEVICES REGULATIONS*
                  - NOT COVERED BY THE MEDICAL DEVICES REGULATIONS*

**Medical devices Regulations* refers to the two applicable regulations:**
- Regulation (EU) 2017/745 on Medical Devices (MDR)
- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)

### B

**Is your MDSW an In Vitro Diagnostic Medical Device Software (IVD MDSW) or a Medical Device Software (MD MDSW)?**
- **Yes**
  - 1. MDSW according to the definition of MDCG 2019-11
    - **Yes**
      - 2. Does the MDSW provide information within the scope of the IVD definition?
      - **No**
        - **Yes**
          - 3. Does the MDSW provide information based on data obtained by IVD medical devices only?
          - **No**
            - **Yes**
              - COVERED BY REGULATION (EU) 2017/746 (IVDR)
              - COVERED BY REGULATION (EU) 2017/745 (MDR)

**Does the MDSW provide information based on data obtained by IVD medical devices only?**
- **Yes**
  - COVERED BY REGULATION (EU) 2017/746 (IVDR)
  - COVERED BY REGULATION (EU) 2017/745 (MDR)
- **No**