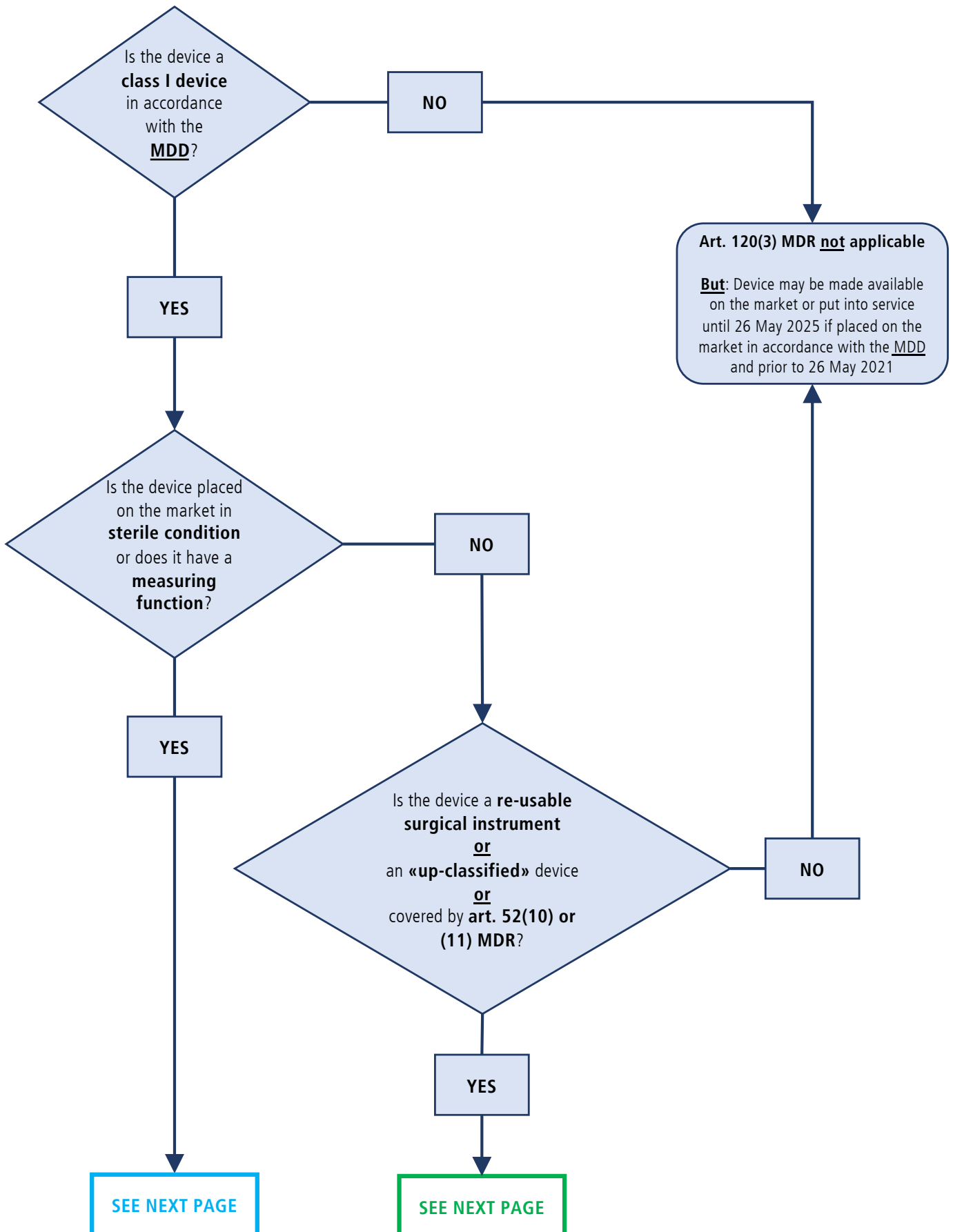
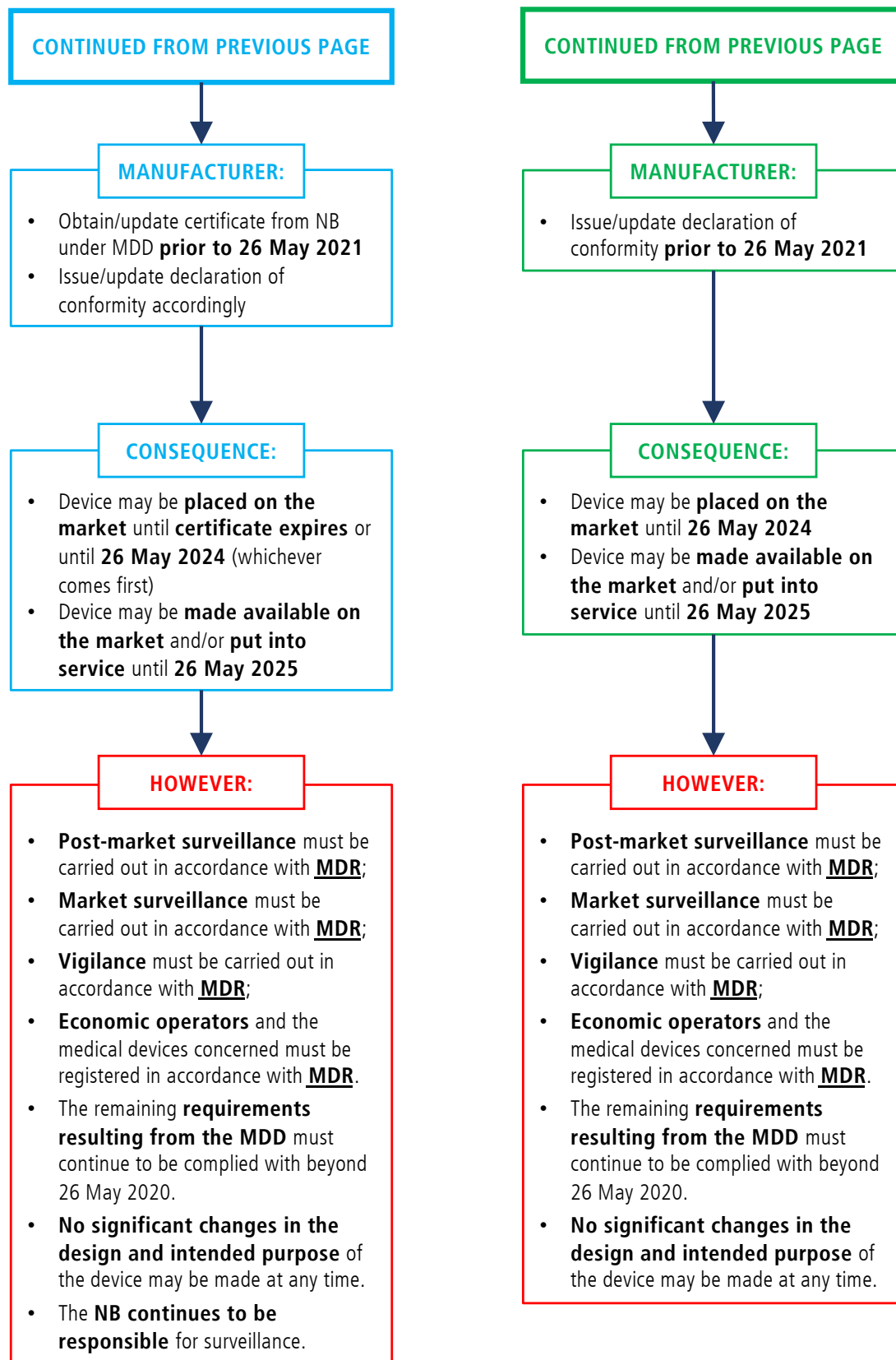


Step 1: Identifying whether the device falls within the scope of art. 120(3) MDR



Step 2: Action to be taken, effects, and additional requirements to be observed



Note: As to the background of, and details on, the matters outlined above, see the corresponding paper available at: www.muresan.legal/ENGLISH/PUBLICATIONS/OP-MDR-120/