

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Illumina recalls NextSeq 550 DX for Potential Short Circuit during reconnection of Circuit Board

Recall Date	Product Description	Recalling Firm	Recall Reason
02/22/2022	Illumina NextSeq 550Dx REF: 20005715, CE, IVD	Illumina Inc. San Diego, California	There is a potential that the DNA sequence analyzer may short circuit shortly after disconnection and reconnection of circuit board or imaging module due to an insufficient reconection of the ribbon cable. The short circuit results in the device being inoperable.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot #s NDX550110 – NDX 550843; UDI: (01)008162700 20125	46 Instruments in California	February 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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