



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Maquet Medical Systems USA Recalls Bubble Sensor due to Labeling Issues and BO-RF-32-USA Rotaflow Centrifugal Pump due to nonconformities on the seal of the device.

Recall Date	Product Description	Recalling Firm	Recall Reason
2/14/2024	Bubble Sensor REF: 70105.5720	MAQUET MEDICAL SYSTEMS USA Wayne, New Jersey	This product is being recalled due to a labeling issue. The device contains an incorrect UDI on the label attached to it.
2/14/2024	BO-RF-32-USA Rotaflow Centrifugal Pump with SOFTLINE Coating, Product Code 701047553. For use with an extracorporeal cardiovascular or cardiopulmonary bypass circuit.	MAQUET MEDICAL SYSTEMS USA Wayne, New Jersey	This product is being recalled due to nonconformities on the seal of the device. This compromises the sterile barrier, potentially exposing patients to pathogenic agents, which can cause inflammation, infection, and sepsis.

Recall Class	Product Identification	Distribution	Affected Dates
II	Bubble Sensor Model: BS 3/8x3/32 L1.7; Correct UDI DI: 04037691816432; Incorrect UDI DI (as labeled): 04058863025148; SNs: 90041799 90041816 90041938 90042009 90042069 90041802 90041817 90041939 90042011 90042070 90041804 90041818 90041940 90042036 90042071 90041805 90041821 90041943	13 Units in California California	February, 2024 and prior

	90042037 90042074 90041806 90041822 90041957 90042038 90042076 90041807 90041823 90041963 90042042 90042079 90041808 90041826 90041966 90042049 90042083 90041809 90041836 90041974 90042050 90042085 90041810 90041898 90041983 90042054 90042089 90041811 90041905 90041993 90042056 90042090 90041812 90041907 90041994 90042058 90042092 90041813 90041921 90041995 90042060 90042093 90041814 90041925 90041997 90042063 90042094 90041815 90041930 90042005 90042066 90042097;		
II	BO-RF-32-USA Rotaflow Centrifugal Pump UDI-DI 4037691650326 Lots 3000283239 and 3000330438	70 Units in California California	February, 2024 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE [Bubble Sensor](#), [BO-RF-32-USA RotaFlow Centrifugal Pump](#)

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