



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Smiths Medical ASD Recalls Devices Employing Fast Flow Fluid Warming and Irrigation System Disposables for leaching of Aluminum from Heat Exchangers**

Recall Date	Product Description	Recalling Firm	Recall Reason
8/17/2021	<b>Level 1 Fluid Warmer</b> Model H-1000, H-500, H-1025	<b>Smiths Medical ASD Inc.</b> Minneapolis, Minnesota	Fast Flow Fluid Warming and Irrigation System Disposables, contain aluminum heat exchangers which have the potential to leach high levels of aluminum during the infusion of blood products, were distributed.
8/17/2021	<b>Level 1 Fluid Warming System</b> Model H-1028, H-1200	<b>Smiths Medical ASD Inc.</b> Minneapolis, Minnesota	Aluminum leaching
8/17/2021	<b>Level 1 Normothermic I.V. Fluid Administration Set</b> Model D-100, D-300, D-50, D-60HL, D-70, DI-100, DI-300, DI-50, DI-60HL, DI-70	<b>Smiths Medical ASD Inc.</b> Minneapolis, Minnesota	Aluminum leaching

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Level 1 Fluid Warmer</b> H1000	268 Devices in California	August 2021 and prior
I	<b>Level 1 Fluid Warmer</b> H-1000-INT-230	1 Device in California	August 2021 and prior
I	<b>Level 1 Fluid Warmer</b> H-500	12 Devices in California	August 2021 and prior

I	<b>Level 1 Normothermic I.V. Fluid Administration Set</b> Model D-100	51,221 Devices in California	August 2021 and prior
I	<b>Level 1 Normothermic I.V. Fluid Administration Set</b> Model D-300	4,900 Devices in California	August 2021 and prior
I	<b>Level 1 Normothermic I.V. Fluid Administration Set</b> Model D-70	49,020 Devices in California	August 2021 and prior
I	<b>Level 1 Normothermic I.V. Fluid Administration Set</b> Model DI-70	200 Devices in California	August 2021 and prior
I	<b>Level 1 Normothermic I.V. Fluid Administration Set</b> Model D-60HL	3,750 Devices in California	August 2021 and prior
I	<b>NORMOFLO Irrigation Fluid Warmer</b> Model H-1129	46 Devices in California	August 2021 and prior

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