



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Fresenius Medical Care Holdings Recalls 2008t Hemodialysis System For Potential Pcba Leaching From Tubing Of Hemodialysis Machines**

Recall Date	Product Description	Recalling Firm	Recall Reason
10/18/2023	<b>Fresenius Medical Care</b> 2008T HD SYS. CDX BLUESTAR	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential PCBA leaching from tubing of hemodialysis machines.
10/18/2023	<b>Fresenius Medical Care</b> 2008T HD SYS. CDX W/BIBAG BLUESTAR	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential PCBA leaching from tubing of hemodialysis machines.
10/18/2023	<b>Fresenius Medical Care</b> 2008T HD SYS. W/O CDX BLUESTAR	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential PCBA leaching from tubing of hemodialysis machines.
10/18/2023	<b>Fresenius Medical Care</b> 2008T HD SYS. W/O CDX W/BIBAG BLUESTAR	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential PCBA leaching from tubing of hemodialysis machines.
10/18/2023	<b>Fresenius Medical Care</b> 2008T Hemodialysis SYS, with CDX	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential PCBA leaching from tubing of hemodialysis machines.
10/18/2023	<b>Fresenius Medical Care</b> 2008T Hemodialysis System without CDX	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential PCBA leaching from tubing of hemodialysis machines.

10/18/2023	<b>Fresenius Medical Care</b> 2008T Hemodialysis System w/Bibag	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential leaching from tubing of hemodialysis machines. PCBA
10/18/2023	<b>Fresenius Medical Care</b> 2008T GEN 2 Bibag without CDX	<b>Fresenius Medical Care Holdings</b> Waltham, Massachusetts	Potential leaching from tubing of hemodialysis machines. PCBA

<b>Recall Class</b>	<b>Product Identification</b>	<b>Distribution</b>	<b>Affected Dates</b>
I	<b>Fresenius Medical Care</b> Model No: 191124; UDI-DI: 00840861102082	733 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 191126; UDI-DI: 00840861102099	733 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 191128; UDI-DI: 00840861102105	733 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 191130; UDI-DI: 00840861102112	733 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 190713; UDI-DI: 00840861100897	703 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 190858; UDI-DI: 00840861100903	733 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 190766; UDI-DI: 00840861100910	733 Unit Nationwide	September 2023 and prior
I	<b>Fresenius Medical Care</b> Model No: 190895; UDI-DI: 00840861100927	733 Unit Nationwide	September 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

---

CDPH Food and Drug Branch  
MS 7602 • P.O. Box 997435 • Sacramento, CA 95899-7435  
(916) 650-6500 • (916) 650-6650 FAX  
Internet Address: [www.cdph.ca.gov](http://www.cdph.ca.gov)

