California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Baxter Healthcare Corporation Welch Allyn Life2000 Compressor and Welch Allyn Life2000 Ventilation system

Recall Date	Product Description	Recalling Firm	Recall Reason
05/09/2025	Welch Allyn Life2000 Compressor, Product Codes: BT-80-0004; BT-80-0004A; BT-80-0008; BT-80-0008A; RMS010093CP.	Baxter Healthcare Corporation	A cybersecurity vulnerability was discovered through internal testing.
05/09/2025	Welch Allyn Life2000 Ventilation system, Product Codes: BT-20-0002; BT-20-0002A; BT-20-0002AP; BT200007; BT-20-0007; BT200011; BT-20-0011; RMS010118CP.	Baxter Healthcare Corporation	A cybersecurity vulnerability was discovered through internal testing.

Recall Class	Product Identification	Distribution	Affected Dates
I	All Serial Numbers: 1) BT-80-0004, UDI/DI 00887761978041 or 00815410020292 or 00887761978072; 2) BT-80-0004A, UDI/DI 00887761978041 or 00815410020292 or 00887761978072; 3) BT-80-0008, UDI/DI 00887761976283; 4) BT-80-0008A, UDI/DI 00887761976283; 5) RMS010093CP, UDI/DI 00887761978041 or 00815410020537 or 00815410020292.	4,174 units Worldwide	April 2025 and Prior
I	All Serial Numbers: 1) BT-20-0002, UDI/DI 00815410020537 or	4,881 units Worldwide	April 2025 and Prior

	00887761978089; 2) BT-20-0002A, UDI/DI 00815410020537 of 00887761978089; 3) BT-20-0002AP, UDI/DI 00815410020537 or 00887761978089; 4) BT200007, UDI/DI 00815410020278 or 00887761978089; 5) BT-20-0007, UDI/DI 00815410020278 or 00887761978089; 6) BT200011, UDI/DI 00815410020537 or 00887761978089; 7) BT-20-0011, UDI/DI 00815410020537 or 00887761978089; 8) RMS010118CP, UDI/DI 00815410020537 or 00887761978089.		

For additional information, please visit this FDA Website Welch Allyn Life2000 Compressor and this FDA Website Welch Allyn Life2000 Ventilation system.