

# California Device Recall Information Sheet

## Food and Drug Branch – Device Recalls

Datex-Ohmeda, Inc. Aisys CS2 with Et Control

Recall Date	Product Description	Recalling Firm	Recall Reason
10/18/2024	Aisys CS2 with Et Control. This anesthesia gas machine is intended to provide general inhalation anesthesia and ventilatory support to patients and are to be used only by medical professionals trained and qualified in the administration of general anesthesia.	Datex-Ohmeda, Inc.	Potential issue that may arise if the limb of a patient breathing circuit is mistakenly connected to the Auxiliary Common Gas Outlet (ACGO) port.

Recall Class	Product Identification	Distribution	Affected Dates
I	GTIN: 00195278588128. Model Number: 1011-9055-000. All Serial Numbers. Not model or lot specific. All devices of the indicated products configured with the AGCO option are potentially affected.	92 units globally.	July 12 <sup>th</sup> and onwards.

For additional information, please visit the [FDA Website](#).