California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Draeger, Inc. Recalls Bidirectionally breathing system filter.

Recall Date	Product Description	Recalling Firm	Recall Reason
7/31/25	SafeStar 90 Plus Filter. Bidirectionally breathing system filter.	Draeger, Inc.	Reports of slow increase of CO2-curve when gas sample is taken from the gas sampling port of filters.
7/31/25	SafeStar 55 Plus Filter. Bidirectionally breathing system filter.	Draeger, Inc.	Reports of slow increase of CO2-curve when gas sample is taken from the gas sampling port of filters.
7/31/25	SafeStar 60A Plus Filter. Bidirectionally breathing system filter.	Draeger, Inc.	Reports of slow increase of CO2-curve when gas sample is taken from the gas sampling port of filters.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model No. MP05785; UDI: 04048675665762; All Lots.	Worldwide - US Nationwide distribution including in the states of AK, AZ, CA, CO, CT, FL, ID, IL, IN, KAS, LA, MA, ME, MI, MN, MO, NC, NE, NM, NV, NY, OH, PA, SD, TN, TX, UT, WA, WI, WY and the countries of Angola, Argentina, Australia, Austria, Belarus, Belgium, Bolivia, Bosnia-Herz., Brazil, Bulgaria, Burkina-Faso, Canada, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Dominican Rep., El Salvador, Faeroe,	June 2025 and prior

		France, French Guiana, Gabon, Germany, Greece, Honduras, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Ivory Coast, Japan, Jordan, Kosovo, Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Malaysia, Mali, Mexico, Moldavia, Mongolia, Morocco, Netherlands, New Zealand, Nigeria, North Macedonia, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Senegal, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Trinidad, Tobago, Turkey, Ukraine, United Kingdom, United Arab Emirates, Uzbekistan, Vietnam.	
I	Mode No. MP05790; UDI: 04048675558736; All Lots.	Worldwide - US Nationwide distribution including in the states of AK, AZ, CA, CO, CT, FL, ID, IL, IN, KAS, LA, MA, ME, MI, MN, MO, NC, NE, NM, NV, NY, OH, PA, SD, TN, TX, UT, WA, WI, WY and the countries of Angola, Argentina, Australia, Austria, Belarus, Belgium, Bolivia, Bosnia-Herz., Brazil, Bulgaria, Burkina-Faso, Canada, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Dominican Rep., El Salvador, Faeroe, France, French Guiana, Gabon, Germany, Greece, Honduras, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Ivory Coast, Japan, Jordan, Kosovo, Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Malaysia, Mali, Mexico, Moldavia, Mongolia, Morocco, Netherlands, New Zealand, Nigeria, North Macedonia, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Senegal, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Trinidad, Tobago, Turkey, Ukraine, United Kingdom, United Arab Emirates, Uzbekistan, Vietnam.	June 2025 and prior.
I	Model No. MP05795; UDI: 04048675665786; All Lots.	Worldwide - US Nationwide distribution including in the states of AK, AZ, CA, CO, CT, FL, ID, IL, IN, KAS, LA, MA, ME, MI, MN, MO, NC, NE, NM, NV, NY, OH, PA, SD, TN, TX, UT, WA, WI, WY and the	June 2025 and prior.

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		countries of Angola, Argentina, Australia, Austria, Belarus, Belgium, Bolivia, Bosnia-Herz., Brazil, Bulgaria, Burkina-Faso, Canada, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Dominican Rep., El Salvador, Faeroe, France, French Guiana, Gabon, Germany, Greece, Honduras, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Ivory Coast, Japan, Jordan, Kosovo, Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Malaysia, Mali, Mexico, Moldavia, Mongolia, Morocco, Netherlands, New Zealand, Nigeria, North Macedonia, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Senegal, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Trinidad, Tobago, Turkey, Ukraine, United Kingdom, United Arab Emirates, Uzbekistan, Vietnam.	

For additional information, please visit the Z-2158-2025, Z-2159-2025, Z-2161-2025

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