

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Merit Medical Systems, Inc. Recalls Custom Inflation Kit

Recall Date	Product Description	Recalling Firm	Recall Reason
10/11/2024	Custom Inflation Kit, REF: K05-00052M, K05-00053H, K05-00109G, K05-00137K, K05-00296L, K05-00399D, K05-00404C, K05-00410G, K05-00438G, K05-00502F, K05-00564L, K05-00587D, K05-00612Q, K05-00704F, K05-00724F, K05-00793B, K05-00798, K05-00890D, K05-00890D, K05-00944D, K05-00956D, K05-01018C, K05-01051, K05-01104G, K05-01140D, K05-01194G, K05-01274D, K05-01304A, K05-01756B, K05-01820B, K05-01853A, K05-01855L, K05-01895A, K05-01933A, K05-02161, K05-02431A, K05-02487A, K05-02489C, K05-02495B, K05-02554, K05-02573, K05-02575, K05-02595, K05-02595, K05-02657A, K05-02810, K05-02887, K05-03069A, K05-03095B, K05-03112, K05-03124, K05-03150, K05-50037G	Merit Medical Systems, Inc.	Inflation devices may have a small hole in the sterile barrier of the device and use of affected devices may result in exposure to pathogens/pyrogens which could lead to infection.

Recall Class	Product Identification	Distribution	Affected Dates
	REF/UDI-DI/Lot(Expiration):	4995 in California	August 2024 and

II	K05-00052M/00884450138120/H29 34735(5/5/2027), H2943603(5/19/2027). K05-00053H/00884450052921/H29 18538(4/22/2027), H2934736(5/5/2027). K05-00109G/00884450464533/H29 18443(4/15/2027), H2925236(4/22/2027), H2943604(5/19/2027). K05-00137K/00884450290316/H29 25237(12/31/2026), H2934737(5/12/2027). K05-00296L/00884450467824/H29 18499(4/29/2027), H2925271(4/29/2027). K05-00399D/00884450138298/H29 29510(4/29/2027), H2934739(5/12/2027). K05-00404C/00884450138304/H29 18500(4/29/2027). K05-00410G/00884450142295/H29 18501(4/15/2027), H2934833(5/12/2027). K05-00438G/00884450142301/H29 18502(4/15/2027), H2934834(5/5/2027), H2978145(6/3/2027). K05-00502F/00884450138427/H29 18505(4/15/2027), H2934837(5/5/2027). K05-00564L/00884450257166/H29 34839(5/5/2027). K05-00587D/00884450052952/H29 18446(4/22/2027), H2934744(5/5/2027), H2938620(5/12/2027). K05-00612Q/00884450138519/H29 25240(4/22/2027), H2934746(5/5/2027), H2943608(5/26/2027). K05-00704F/00884450138588/H29 18508(4/15/2027), H2938622(5/12/2027). K05-00724F/00884450146538/H29 18509(4/15/2027). K05-00793B/00884450236987/H29 18448(4/15/2027),		Prior
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H2929514(4/29/2027), H2938623(5/12/2027). K05-00798/00884450046951/H292 5242(4/22/2027), H2943609(5/19/2027). K05-00890D/00884450453629/H29 18449(4/15/2027), H2929515(4/29/2027). K05-00890D/00884450453629/H29 34749(5/5/2027), H2943610(5/19/2027). K05-00944D/00884450151631/H29 18450(4/15/2027), H2929516(4/29/2027). K05-00956D/00884450142448/H29 18511(4/15/2027), H2925278(4/22/2027), H2938625(5/12/2027). K05-01018C/00884450152324/H29 25244(4/22/2027), H2938626(5/12/2027). K05-01051/00884450047057/H292 5280(4/22/2027). K05-01104G/00884450145401/H29 25285(4/22/2027), H2929540(4/29/2027), H2934846(5/5/2027). K05-01140D/00884450147931/H29 25286(4/22/2027), H2934847(5/5/2027), H2972616(5/26/2027). K05-01194G/00884450409091/H29 25288(4/22/2027). K05-01274D/00884450160596/H29 18453(4/22/2027), H2934750(5/12/2027), H2938628(5/12/2027). K05-01304A/00884450279014/H29 72617(5/26/2027). K05-01756B/00884450145449/H29 29520(4/29/2027). K05-01820B/00884450639115/H29 29521(4/29/2027), H2943614(5/19/2027). K05-01853A/00884450153864/H29 18460(4/15/2027), H2934761(5/12/2027), H2943615(5/19/2027).		
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K05-01855L/00884450453667/H29 18518(4/15/2027), H2978189(6/3/2027). K05-01895A/00884450141458/H29 29522(5/26/2027). K05-01933A/00884450462768/H29 18519(4/15/2027), H2934855(5/5/2027). K05-02161/00884450139738/H291 8522(4/15/2027), H2925298(4/29/2027), H2943617(5/19/2027), H2978192(6/3/2027). K05-02431A/00884450150191/H29 29525(4/29/2027). K05-02487A/00884450140468/H29 18472(4/15/2027). K05-02489C/00884450639177/H29 38638(5/12/2027). K05-02495B/00884450257326/H29 25259(4/22/2027), H2934775(5/5/2027). K05-02554/00884450148372/H293 4780(5/5/2027). K05-02573/00884450148884/H291 8476(4/15/2027). K05-02575/00884450158500/H293 8639(5/12/2027). K05-02595/00884450165881/H291 8525(4/15/2027), H2929547(4/29/2027), H2938640(5/12/2027). K05-02595/00884450165881/H297 2630(5/26/2027), H2982566(6/10/2027). K05-02657A/00884450639214/H29 18480(4/15/2027), H2925265(4/29/2027), H2934784(5/5/2027), H2938643(5/12/2027), H2982568(6/10/2027). K05-02810/00884450253083/H292 9528(4/29/2027), H2938646(5/12/2027). K05-02887/00884450285923/H291 8527(4/29/2027), H2925313(4/29/2027), H2934862(5/12/2027).		
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K05-03069A/00884450461440/H29 38301(3/31/2027). K05-03095B/00884450639429/H29 25319(4/22/2027), H2938649(5/12/2027). K05-03112/00884450404492/H293 8650(5/12/2027). K05-03124/00884450432631/H293 4820(5/5/2027), H2938651(5/12/2027), H2978212(6/3/2027). K05-03150/00884450480045/H292 5320(4/22/2027). K05-50037G/0088445045609/H292 5266(4/29/2027), H2934824(5/5/2027), H2938652(5/12/2027).		
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For additional information, please visit the [FDA Website](#).