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Class 2 Device Recall Custom Made Tracheostomy Device

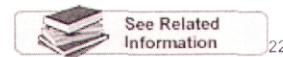


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Class 2 Device Recall Custom Made Tracheostomy Device



Date Initiated by Firm	July 15, 2016
Create Date	February 09, 2018
Recall Status ¹	Open ³ , Classified
Recall Number	Z-0577-2018
Recall Event ID	79045 ²³
Product Classification	Tube tracheostomy and tube cuff ²⁴ - Product Code JOH ²⁵
Product	Custom Made Tracheostomy Device The CADD Administration Sets with Flow Stop are designed to be used with a variety of CADD ambulatory infusion pumps to allow fluid delivery from an IV bag.
Code Information	GS025081
Recalling Firm/Manufacturer	Smiths Medical ASD, Inc. 5700 W 23rd Ave Gary IN 46406-2617
For Additional Information Contact	219-989-9150
Manufacturer Reason for Recall	Smiths Medical determined that a single custom Tracheostomy device had been shipped to the customer without required sterilization.
FDA Determined Cause ²	Under Investigation by firm
Action	The firm, Smith Medical, notified the consignee by phone on July 29, 2017 of the Field <i>Corrective Action Report</i> . The consignee was instructed to return the devices for destruction and replacement. If you have any questions, contact VP, Global Quality and Regulatory at 219-989-9150.
Quantity in Commerce	1
Distribution	International Distribution to:Germany
Total Product Life Cycle	TPLC Device Report ²⁶

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁷.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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