Class 2 Device Recall DuoDERM

See Related Information[22]

Date Initiated by Firm	August 09, 2021
Create Date	September 23, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-2519-2021
Recall Event ID	88460[23]
Product Classification	Dressing, wound, occlusive[24] - **Product Code** NAD[25]
Product	DuoDERM CGF Dressing 10x10CM (1x5PK) (ICC 187660) DuoDERM Extra Thin Dressing 15X15CM (1X10PK) (ICC 187957) DuoDERM Extra Thin Dressing 10X10CM (1X10PK) (ICC 187955)
Code Information	ICC 187660 - Lots 9B02984Y, 9G04308, 9K05775, 9L00556, 0A03460, and 9A04124Y ICC 187957 - Lots 9J02859, 9H02226, 9H04865, 9L02456 ICC 187955 - Lots 9L01731, 9L04890, 9K02656, 9H01234, 9M01779, and 9H00183
Recalling Firm/ Manufacturer	ConvaTec, Inc 7815 National Service Rd Ste 600 Greensboro NC 27409-9403
For Additional Information Contact	336-547-3730
Manufacturer Reason for Recall	There is a potential for open seals which can compromise sterility.
FDA Determined Cause [2]	Process control
Action	Customer notification was made via email and via UPS letter. Distributors are asked to stop distributing and quarantine all recalled lots. All customers are notified that a Recall Response Form is to be completed and returned to the recalling firm. All impacted product is to be returned via third party Sedgwick, Indianapolis, IN. If product was further distributed, the customer shall forward the recall notification letter and ask subaccounts to follow the recall instructions.

Quantity in Commerce	2,734,830 units
Distribution	International distribution to the countries of Argentina, Aruba, Australia, Bonaire, Brazil, Canada, Chile, , Colombia, Costa Rica, Curaco, Dominican Republic, Ecuador, Egypt, El Salvador, Guatemala, Hong Kong, Indonesia, Iran, Malaysia, Mexico, Myanmar, Nicaragua, New Zealand, Panama, Peru, , Pakistan, Paraguay, Qatar, Singapore, South Korea, Switzerland, Taiwan, Thailand, UAE, Uruguay, USA and Vietnam.
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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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=88460
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NAD
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NAD
26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NAD
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm