Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	DuoDERM Extra Thin and DuoDERM CGF adhesive wound dressings
Affected Devices	187957, 187955 and 187660
Batch No.	9J02859, 9H02226, 9H04865, 9L02456, 9L01731, 9L04890, 9K02656, 9H01234, 9M01779, 9H00183, 9B02984Y and 0A03460
Manufacturer	ConvaTec Australia Pty Ltd
Country of Origin	Australia
Reference	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188719
Device picture	
Reason of Recall	NHRA initiates this FSN due to The packaging of the adhesive wound dressings is not sealed together completely, leaving partial or fully open seals, this may result in infection and health complications
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2021 0047