

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 following medical device:

Device Details	
Device Name	Bio-Oss Pen
Device Model	30661.1 / 30662.1 & 30671.1
Lot No.	81700707
Manufacturer	Geistlich
Country of Origin	Switzerland
Reference	https://fsca.swissmedic.ch/mep/#/ https://fsca.swissmedic.ch/mep/api/publications/Vk_20190320_01/documents/7 https://fsca.swissmedic.ch/mep/api/publications/Vk_20190320_01/documents/6
Device picture	
Reason of Recall	NHRA initiated this safety notice due to the appearance of a green visible particle on the outer barrel of the pen when unscrewing the green filter cap from the Bio-Oss pen.

For more information please contact Medical_Devices@nhra.bh

Action should be taken	When unscrewing the Bio-Oss Pen filter cap, if a loose green/red particle from the filter cap are present, do not use the Bio-Oss Pen and return it to the local agent Gulf Pharmacy .
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Note: In case of having the defected device model in your stock, kindly contact **Gulf Pharmacy** at regulatory@gctbahrain.com to take the necessary action.

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

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