



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	CARDIOHELP-i
Serial Number	All cardiohelps until 2021-03
Manufacturer	Getinge
Country of Origin	Germany
Reference	<u>Link</u>
Reason of Alert	NHRA initiates this FSN due to a noticeable high number of breaks in the insulation sheath and a shielding breach of the venous prob connection cable, which can lead to incorrect or missing data transmission.
Action should be	Please refer to "Actions to be taken by Customer/ User" in the attached FSN
taken	And for more information please contact the authorized representative Gulf Corporation for Technology W.L.L at quality@gctbahrain.com

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

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