

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	KN 95
Lot No.	All lots mentioned in below links
Manufacturer	Manufacturers mentioned in below links
Country of Origin	China
Reference	https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#nolongerauth
Device picture	
Reason of Notice	NHRA initiates this urgent FSN to all healthcare professions using the medical masks mentioned in the above links, as it has been proven that these medical masks are in Bahrain market and are not in compliance with the standards and not effective based on additional filtration performance testing conducted by the National Institute for Occupational Safety and Health (NIOSH).
Action should be taken	The masks mentioned in the above links are restricted to be used in non-medical field and it is prohibited to be used in medical field.

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

For more information please contact Medical_Devices@nhra.bh