

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِيَّاسَةُ عُمَانِ
وَزَارَةُ الصِّحَّةِ
وَالرِّيَّاسَةِ الْعَامَّةِ لِلصِّدْقِ
وَالرَّفَاقَةِ الدَّوْلِيَّةِ
مَسْقَط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 08..... dated 17/10/21 Regarding NCMDR Recall of Isolation Gowns, Lab Coats, and Kendall Gowns from (mfr: Cardinal Health).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للأجهزة
والأدوية الصيدلانية
والتحكم في الأدوية
مسقط

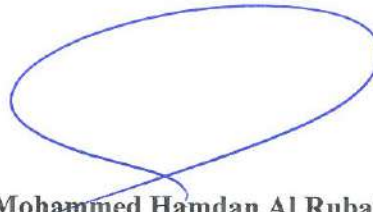
Circular No. ٥٨ / 2021

٥٣ -06-1442 H

١٧ -01-2021

Recall of Isolation Gowns, Lab Coats, and Kendall Gowns from Cardinal Health.

Source	NCMDR- National Centre for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15512
Product	Isolation Gowns, Lab Coats, and Kendall Gowns.
Description	Consumables.
Manufacturer	Cardinal Health.
The affected products	Attached.
Reason	Potential rips, holes, tears, incomplete and/or open seams, staining, foreign material or debris on the gowns and lab coats.
Action	1. Identify and quarantine affected devices. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through an E-mail: Med-device@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie

Director General





Attachment 1 – Affected Product List

Product	SKU	Lot
Gown Isolation W/Ties Univ Ylw	1100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	V1100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties XI Ylw	1101PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Blu	1200PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	2100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	V2100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	2150PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Blue	2200PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties XI Blue	2201PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS Large Blue	2202LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS X-Large Blue	2203LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS 2X-Large Blue	2204LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS Medium White	2301LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS Large White	2302LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS 2X-Large White	2304LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	V2100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Blue	552200PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	NON24258N	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Kendall Blue RG	CT5000	All lot numbers from 1901XXK to 2010XXK
Gown Kendall Blue L	CT5100	All lot numbers from 1901XXK to 2010XXK
Gown Kendall Blue L	CT5101	All lot numbers from 1901XXK to 2010XXK
Gown Kendall Blue XXL	CT5102	All lot numbers from 1901XXK to 2010XXK