



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 218 dated 23/10/2023 Regarding NCMDR Field Safety Corrective Action of BD Alaris™ Syringe Module, BD Alaris™ PCU Module and Alaris™ PCA Module from (mfr: Becton Dickinson & Co. (BD)).

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





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2040
Oman Vision

Circular No. 218/2023

08 -04-1445 H

23 -10-2023

FSCA of BD Alaris™ Syringe Module, BD Alaris™ PCU Module and Alaris™ PCA Module from BD.

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| Source | NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19745 |
| Product | BD Alaris™ Syringe Module, BD Alaris™ PCU Module and Alaris™ PCA Module. |
| Description | Infusion Pump. |
| Manufacturer | Becton Dickinson & Co. (BD). |
| Local agent | Muscat Pharmacy & Stores LLC. |
| The affected products | Product Name (Product Code (REF/SKU)): Alaris™ PCA Module (8120); BD Alaris™ Syringe Module (8110); BD Alaris™ PCU Module (8015) Please refer to attachment for UDI. Serial Numbers: All |
| Reason | Cardinal Health branded Monoject™ syringes have not been validated for use with the BD Alaris™ Syringe and PCA modules. BD has validated Covidien branded Monoject™ syringes for use with the BD Alaris™ Syringe and PCA modules. |
| Action | 1. You should cease use of Cardinal Health branded Monoject™ syringes with the BD Alaris™ PCU, Syringe and PCA Modules; except for SKU 8881135609, which is not impacted. 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 the E-mail: Med-device@moh.gov.om |

Dr. Mohammed Hamdan Al Rubaie

Director General



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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