

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سِلْطَنَة عُومَان  
وَزَارَة الصِّحَّة  
وَالرِّقَابَة الدَّوْلِيَّة  
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. 18.2 dated 29.10.12 Regarding NCMDR Recall of Neonatal Cots (Trendelenburg Mechanism) from (mfr: K Care Pty Ltd).

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 للأدوية  
والرقابة الدوائية  
مسقط

Circular No. 182/2020

11 -02-1442 H

29 -09-2020

## Recall of Neonatal Cots (Trendelenburg Mechanism) from K Care Pty Ltd.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. <a href="http://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2020-RN-00732-1">http://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2020-RN-00732-1</a>
Product	Neonatal Cots (Trendelenburg Mechanism).
Manufacturer	K Care Pty Ltd.
The affected products	Model Number: KH944SP Serial Numbers: OX10371 - OX10382
Reason	When the red release lever is lifted on the KH944-SP01 neo-natal cot, the mattress base will drop in freefall unless supported by the other hand on the handle attached to the mattress base. This causes a pinch point between the mattress base and cot frame. If the mattress base drops in freefall on fingers or hands, it may cause serious damage.
Action	1. K care will recall all affected cots. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

