

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدل
والرقابة الدوائية
مسقط

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. ٥٠٠٠٠٠٠٠ dated ١٥/٥/٢٠١٢ Regarding NCMDR Recall of Pediatric Venous Hardshell Cardiomy Reservoir from (MAQUET Cardiopulmonary GmbH).

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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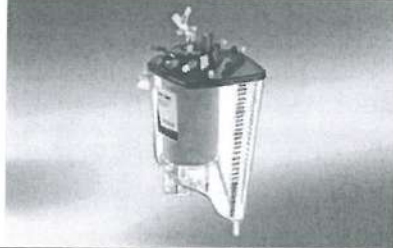
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Circular No. 04 / 2021

27 -05 -1442 H

10 -01-2021

Recall of Pediatric Venous Hardshell Cardiomy Reservoir from MAQUET Cardiopulmonary Gm.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15478
Product	Pediatric Venous Hardshell Cardiomy Reservoir.
Description	Cardiopulmonary bypass blood Reservoir,.Oxygenator.
Manufacturer	MAQUET Cardiopulmonary GmbH.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	1- Ref No.: VKMO 30000 Article No.: 701050111 Product Description: Quadrox-I Pediatric Oxygenator HMO 30000 with Pediatric Venous Hardshell Cardiomy Reservoir VHK 31000. Lot No.: 92282864 2- Ref No.: VKMO 31000 Article No.: 701049185 Product Description: Quadrox-I Pediatric Oxygenator HMO 31000 with Pediatric Venous Hardshell Cardiomy Reservoir VHK 31000 Lot No.: 92270128 - Affected Lots: PLN036F - Expiry Date: 01 Jun 2021.
Reason	A potential impairment of the sterile packaging barrier system was identified.
Action	1. Please return immediately all affected products in your stock. 2. Contact the local agent for remedial action.
Product image	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL



ص . ب : ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني: dg-padc@moh.gov.om

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