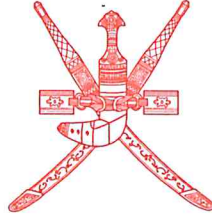


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَة عُمان
وَزارة الصِّحة
الديرة العامة للصحة
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. 5/2020 dated 1/1/2020 Regarding TGA Recall of QUADROX-iD Paediatric with BIOLINE Coating (Mfr: MAQUET Cardiopulmonary GmbH)

Copy to:

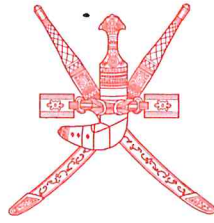
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central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

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سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
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مسقط

Circular No. 5 / 2020

5-05-1441 H

1 - 1 - 2020

Recall of QUADROX-iD Paediatric with BIOLINE Coating from MAQUET Cardiopulmonary

Source of Recall	TGA Recall		
Product	QUADROX-iD Paediatric oxygenator with BIOLINE Coating		
Manufacturer	MAQUET Cardiopulmonary GmbH		
The affected products	Model Number	Part Number	Lot No
	BE-HMOD 30000	701047041	70124702, 70120467, 70121343, 70122531, 70125287, 70130805, 70124701, 70119853, 70123312, 70122267, 70123904, 70121443, 70119850, 70121443, 70119850 and 70123493
Reason for Recall	During design verification tests Maquet Cardiopulmonary has determined that the sterile barrier system of the QUADROX-iD may be compromised during transportation. Under unfavorable transport conditions, excessive movement of the device and its accessories in the carton can lead to stress points that could compromise the sterile barrier of the packaging pouches. Additional tests on products returned from Getinge's Sales and Service Units revealed that the primary packaging might be breached. The size of the breach is small, which may be difficult for the user to detect.		
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Users are advised to immediately quarantine the affected product.		
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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om		

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al-Rubaie

DIRECTOR GENERAL

