Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 10 / 2022

21 -06-1443 H

24 -01-2022

Recall of Tubing sets from MAQUET Cardiopulmonary GmbH.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15986
Product	Tubing sets.
Description	Tubing sets.
Manufacturer	MAQUET Cardiopulmonary GmbH.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Refer to "Annex I List of affected products" in the attached FSN.
Reason	Incomplete system verification of sets with integrated 3rd party arterial filters.
Action	1. Please segregate and return immediately all affected products in your stock to your local agent for Getinge. 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

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
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والرقابة الدوائية
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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.10/2022. dated 24/11/2022. Regarding NCMDR Recall of Tubing sets from (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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED QUALITY MANAGEMENT SYSTEMS

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2021-07-23

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2021-07-19 Tubing sets – incomplete system verification of sets with integrated 3rd party arterial filters

Affected Product: Tubing sets

REF	Product Description	Article number
BE-H 30803	Filtro Arterial Neonatos	701018952
BE-HQV 34708-1	Adult Closed System with	701064517
BE-HQV 34708-2	Adult Closed System with	701069147
BE-HQV 51608	Adult Perfusion Set	701073988
BE-HQV 64704	MECC system	701074327
BE-HQV 89202	XVIVO Disposable Lung Circu	701069387
BE-MECC 101403	MECC system w/o Reservoir	701075208
BE-MECC 50310	National UK NRP Pack	701071853
BE-MECC 50310u	National UK NRP Pack	701075048
BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592
BO-H 81202	Neonate Perfusion Pack	701050629
BO-H 81203	Pediatric Perfusion Pack	701051078
BO-H 81204	Infant Perfusion Pack	701051079
BO-HQV 104100	EVLP Circuit	701066978
H 109401	Pediatric Tubing Pack	701070305
H 109402	Infant Pack	701070307
H 12217	Standard Pediatric Set w. Filter	701063544
H 32605	Set Pequeno	701066054
H 32606	Ped./Mediano Pack	701066055
H 37803	Clydebank Perfusion Pack	701045747
H 61900	Lineas 1/4x1/4	701043741
H 61902	Lineas 1/4x3/8	701056918
H 99100	Tubing Set for HMO 30000	701063568
HQV 89200	XVIVO Disposable Lung Circuit	701052184

Affected Batch No.: See Annex I List of affected products

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الاجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

BfArM Recall

Reference Number: mdprc 005 01 22 000
Date submitted: 1/4/2022

Back

Manufacturer:	MAQUET Cardiopulmonary GmbH
Device Type:	Tubing sets
Description:	Tubing sets
Medical Device Identifier:	Refer to "Annex I List of affected products" in the attached FSN
Reason of Field Safety Corrective Action:	Incomplete system verification of sets with integrated 3rd party arterial filters
Remedy Action:	- Please do not use the affected products listed In the attached FSN. - Please segregate and return immediately all affected products in your stock to your local Getinge Representative for credit notes.
Athorized Representative/Importer/Distributor:	Medical Elements
Report Source:	BfArM
Source Ref. Number:	15493/21
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Maquet Cardiopulmonary GmbH.pdf

View History