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

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 84 **dated** 30/4/2023 **Regarding NCMDR Recall of QUADROX / VHK / VKMO 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

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
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سلطنة عُمان
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مسقط

Circular No. 84 **/ 2023**

09 -10-1444 H
30 -04-2023

Recall of QUADROX / VHK / VKMO from MAQUET Cardiopulmonary GmbH

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19492
Product	QUADROX / VHK / VKMO.
Description	Surgical equipment/ Anaesthesia - surgical equipment.
Manufacturer	MAQUET Cardiopulmonary GmbH.
Local agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Refer to Annex I in the attached FSN.
Reason	Potentially compromised sterile barrier.
Action	1. Recall of all affected products according to Annex I. 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

URGENT FIELD SAFETY NOTICE

Subject: FSCA 781869 - QUADROX / VHK / VKMO – potentially compromised sterile barrier

Affected Product: Refer to Annex I

Affected Batch No.: All

Unique Device Identifier: Refer to Annex I

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) became aware of various failure modes in regard to the QUADROX-i/ -iD, VHK 11000 and VKMO 10000/ 11000 products in the course of six non-conformity reports. The identified failure modes can be divided into two categories: a potentially compromised sterile barrier and a deviation from the coating specifications.

Health-Hazard-Evaluations (HHEs) were performed to assess the risk of the non-conformities. The outcome of the HHEs states, that the residual risk which results from the non-conformities is not justifiable according to the current product Risk Management.

The HHEs documented potential hazardous situations and harmful events related to the non-conformities. These are shown in the table below.

Failure	Potential hazardous situation	Potential harm
1	• Failure of sterile packaging • Contamination of device • Application of contaminated device • Product exchange/ replacement • Patient is exposed to pathogenic agents • Delay in the procedure: Patient is exposed to inappropriately low blood flow	• Inflammation • Infection • Sepsis • Ischemia • User inconvenience
2	• Insufficient gas exchange • Systemic thrombotic event • Final product with degraded coating properties is used • Replacement/ exchange of product	• Hypoxemia • Ischemia (Thromboembolism) • Haemolysis • Inflammation • User inconvenience

2023-03-23

Maquet Cardiopulmonary GmbH is working with all possible urgency on investigating the root causes for the various failure modes. In the meantime, Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries or deaths due to failure modes described above.

Corrective actions:	• Recall of all affected products according to Annex I
Action to be taken by the customer:	• Please identify all affected products according to Annex I in your stock and **return product which is not in use immediately to your local Getinge representative** for credit. • Please contact your local Getinge representative for potential alternative products. • Please always report any adverse events, e.g. infections potentially related to the affected products, to your Getinge representative. • Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative by **May 15, 2023 the latest**. Please mention FSCA-781869 as reference in the subject line of your email.
Actions to be taken by the manufacturer	• Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers. • Identify the root cause for the various failure modes.
Enclosed documents:	• Letter of Acknowledgement

Transmission of the Field Safety Notice:

- Please ensure that within your organization, all users of the above-mentioned products, as well as others who need to be informed, are made aware of this urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause you and will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative, or send an e-mail to FSCA.cp@getinge.com.

2023-03-23

Sincerely,

Managing Director

Signature: Dieter Engel *Electronically signed by: Dieter Engel Reason: I approve this document. Date: Mar 24, 2023 09:42 GMT+1*

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Timur Güvercinci *Electronically signed by: Timur Güvercinci Reason: I approve this document. Date: Mar 23. 2023 18:21 GMT+1*

Email: timur.guevercinci@getinge.com

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 – 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

Subject: 781869 – QUADROX / VHK / VKMO – potentially compromised sterile barrier

Affected Product: Refer to Annex I

Affected Batch No.: all

Please send this form to your local Getinge representative at the latest by **May 15, 2023**.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for products listed in Annex I. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personnel.

☐ I do not have any affected products in my inventory.
☐ I have the following affected products in my inventory:

REF	Article Number	Description	Batch Number	Quantity

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email

Annex I List of affected products

This Annex I List of affected products is considered as a supplementary attachment to the 781869 Field Safety Notice.

Below are listed all products which are affected.

Table 1 QUADROX-i Small Adult (Screw variant)

REF	Article	Batch range	UDI
HMO 50000	701067890	All batches affected	04037691984995
HMO 51000	701067894	All batches affected	04037691997070
HMO 50000-J	701067914	All batches affected	04037691997520
HMO 51000-J	701067917	All batches affected	04037691990804
HMO 50000-USA	701067891	All batches affected	04058863019055
HMO 51000-USA	701067895	All batches affected	04058863019185
BE-HMO 50000	701067904	All batches affected	04058863011967
BE-HMO 51000	701067910	All batches affected	04058863060811
BEQ-HMO 50000-USA	701067905	All batches affected	04058863019079
BEQ-HMO 51000	701067911	All batches affected	04058863019178

Table 2 QUADROX-i Adult (Screw variant)

REF	Article	Batch range	UDI
HMO 70000	701067818	All batches affected	04037691971032
HMO 71000	701067821	All batches affected	04037691972374
HMO 70000-J	701067830	All batches affected	04037691990781
HMO 71000-J	701067832	All batches affected	04037691996059
HMO 70000-USA	701067820	All batches affected	04058863019147
HMO 71000-USA	701067823	All batches affected	04058863017341
BE-HMO 70000	701067825	All batches affected	04058863004099
BE-HMO 71000	701067827	All batches affected	04058863002125
BEQ-HMO 70000	701067826	All batches affected	04058863159645
BEQ-HMO 71000	701067828	All batches affected	04058863159669
BEQ-HMO 71000-USA	701067829	All batches affected	04058863017372

Table 3 QUADROX-iD Adult (Screw variant)

REF	Article	Batch range	UDI
HMOD 70000	701067836	All batches affected	04058863079509
HMOD 71000	701067845	All batches affected	04058863159546
HMOD 70000-USA	701067840	All batches affected	04058863019000
BE-HMOD 70000	701067857	All batches affected	04058863015361
BE-HMOD 71000	701067860	All batches affected	04058863159584
BEQ-HMOD 70000	701067858	All batches affected	04058863159560
BEQ-HMOD 70000-USA	701067859	All batches affected	04058863019024

Table 4 QUADROX -i Neonatal (Screw variant)

REF	Article	Batch range	UDI
HMO 10000	701070411	All batches affected	04058863154459
HMO 10000-USA	701070412	All batches affected	04058863154473
HMO 10000-J	701070413	All batches affected	04058863154497
BE-HMO 10000	701070419	All batches affected	04058863154619
HMO 11000	701070415	All batches affected	04058863154534
HMO 11000-USA	701070416	All batches affected	04058863154558
HMO 11000-J	701070417	All batches affected	04058863154572
BE-HMO 11000	701070420	All batches affected	04058863154633

Table 5 QUADROX-i Pediatric (Screw variant)

REF	Article	Batch range	UDI
HMO 30000	701070383	All batches affected	04058863153650
HMO 30000-USA	701070384	All batches affected	04058863153681
HMO 30000-J	701070385	All batches affected	04058863154213
BE-HMO 30000	701070392	All batches affected	04058863154398
HMO 31000	701070387	All batches affected	04058863154244
HMO 31000-USA	701070388	All batches affected	04058863154299
HMO 31000-J	701070389	All batches affected	04058863154329
BE-HMO 31000	701070395	All batches affected	04058863154411

Table 6 QUADROX-iD Pediatric (Glue Variant)

REF	Article	Batch range	UDI
BE-HMOD 30000	701047041	All batches affected	04037691516233
BEQ-HMOD 30000-USA	701050330	All batches affected	04037691670164

Table 7 QUADROX-iD Pediatric (Screw Variant)

REF	Article	Batch range	UDI
BE-HMOD 30000	701070396	All batches affected	04058863078519
BEQ-HMOD 30000-USA	701070397	All batches affected	04058863154435
BE-HMOD 30000-Aus	701073348	All batches affected	04058863305639

Table 8 Venous Hardshell Cardiotomy Reservoir (VHK 11000)

REF	Article	Batch range	UDI
VHK 11000	701073019	All batches affected	04058863153735
VHK 11000-J	701073017	All batches affected	04058863153711
BO-VHK 11000	701073015	All batches affected	04058863153599
BO-VHK 11000-J	701073018	All batches affected	04058863153728
BE-VHK 11000	701073014	All batches affected	04058863153582

Table 9 Combination of Venous Hardshell Cardiotomy Reservoir with Oxygenator (VKMO 10000, VKMO 11000)

REF	Article	Batch range	UDI
VKMO 10000	701070440	All batches affected	04058863153896
VKMO 10000 -J	701070442	All batches affected	04058863153803
VKMO 10000-USA	701070441	All batches affected	04058863153841
BO-VKMO 10000	701071074	All batches affected	04058863153834
BO-VKMO 10000 -J	701071075	All batches affected	04058863153766
BE-VKMO 10000	701070448	All batches affected	04058863153759
VKMO 11000	701070444	All batches affected	04058863153742
VKMO 11000-J	701070446	All batches affected	04058863153827
VKMO 11000-USA	701070445	All batches affected	04058863153889
BO-VKMO 11000	701071077	All batches affected	04058863153865
BO-VKMO 11000 -J	701071078	All batches affected	04058863153780
BE-VKMO 11000	701070449	All batches affected	04058863153797