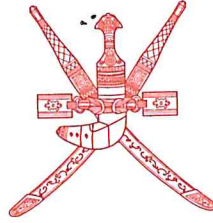


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سلطنة عُمان  
وزارة الصحة  
الديرة العامة للأدوية  
والرعاية الصيدلانية  
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...15.6... dated 30/08/20 Regarding NCMDR Recall of Single holder for oxygenator Neonatal/Pediatric from (mfr: Maquet Cardiopulmonary GmbH).

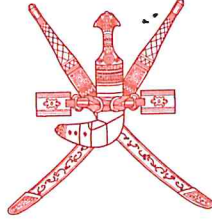
Copy to:

- 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

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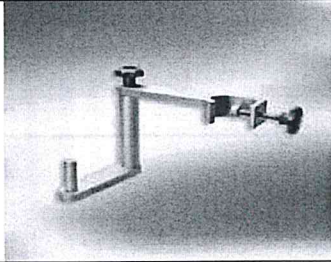
سلطنة عمان  
وزارة الصحة  
الديرة العامة للأدوية  
والرقابة الدوائية  
مسقط

Circular No. 156/2020

10 -01-1442 H

30 -08-2020

## Recall of Single Holder for Oxygenator Neonatal/Pediatric from Maquet Cardiopulmonary GmbH.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=15294">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=15294</a>
Product	Single holder for oxygenator Neonatal/Pediatric
Description	Holder
Manufacturer	MAQUET Cardiopulmonary GmbH
Local agent	Mustafa Sultan Science & Industry Co.L.L.C
The affected products	Single holder for oxygenator neo./ped. as a supplement to holder arm (QUADROX-i, QUADROX) (Article No. 70104.7495, REF No. HKHZ 19) Batch No.: 70128207
Reason	Maquet Cardiopulmonary GmbH became aware that the snapping function between holder and oxygenator was not given.
Action	1. Quarantine the 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 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

