



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**

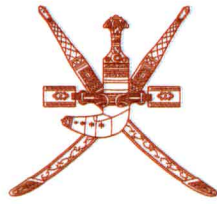
After Compliments,

Please find attached our Circular No 143 dated 18/7/23 Regarding NCMDR  
FSN of Rotaflow II drive closing cover 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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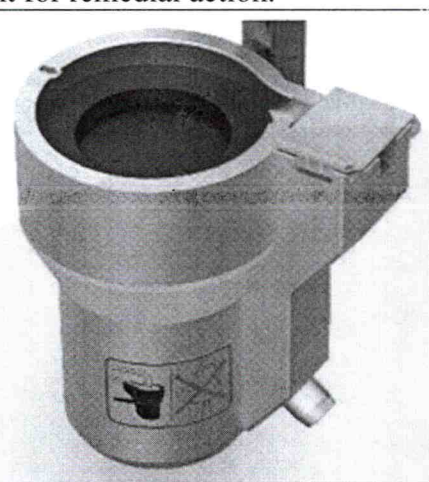
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18 -07-2023

نتقدم بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Oman Vision

**Field Safety Notice of Rotaflow II drive closing cover from MAQUET Cardiopulmonary GmbH.**

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19612">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19612</a>
Product	Rotaflow II drive closing cover.
Description	Heart-lung support system.
Manufacturer	MAQUET Cardiopulmonary GmbH.
Local agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	701074622 Rotaflow II drive (flex) (UDI: 04058863229263) 701074623 Rotaflow II drive (compact) (UDI: 04058863229256) All Serial Numbers.
Reason	Material behavior (strain, rigidity, etc.) of above products is subject to change over time and a reduction of unlocking force over multiple use cycles occurs.
Action	1. As this error can end treatment and is a potential risk for patients, please do not use this product until corrective servicing is performed. 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 the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General

