



To:

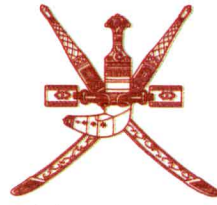
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (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 132 dated 21/6/2023 Regarding NCMDR Field Safety Corrective Action of DERMLITE DL4W from (mfr: DermLite LLC).

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



Circular No. 132/2023

نتقدم بـ  
Moving Forward  
with Confidence



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21 -06-2023

**Field Safety Corrective Action of DERMLITE DL4W from DermLite LLC.**

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=19548">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=19548</a>
Product	DERMLITE DL4W.
Description	Automated sample handling system.
Manufacturer	DermLite LLC.
The affected products	REF: DL4W, Rx Only MD, CE Code Information: Lot # 7654, serial numbers DL4WGXXXX & DL4WBXXXX (1304-1353 and 1504); UDI-DI: (01) 0 8559970
Reason	Incorrect labelling; Package labelling contains a different serial number than the serial number on the product labelling.
Action	1. A corrected box label(s) will be issued by the manufacturer to the affected customer to correct their boxes labels. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General

