



To:

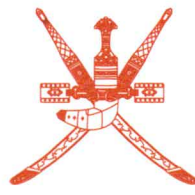
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of 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...153. dated 23/8/22. Regarding NCMDR Recall of Absorbable Gelatin Hemostat from (mfr: Gelita Medical 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



Circular No. 153 / 2022

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23 -08-2022

بمقدم بثقة
Moving Forward
with Confidence



Recall of Absorbable Gelatin Hemostat from Gelita Medical GmbH.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17245
Product	GELITA-SPON® STANDARD, GELITA-SPON® RAPID3, GELITA® ENT X-BLOD, GELITA® ENT X-DENSE, GELITA® ENT X-PAND, GELITA® ENT X-PASTE, GELITA-SPON® POWDER
Description	Absorbable Gelatin Hemostat.
Manufacturer	Gelita Medical GmbH.
The affected products	All products described above, still within shelf-life are being recalled. The shelf-life of these products is 5 years.
Reason	The endotoxin concentration of the product in some samples has been measured above the limit.
Action	1. Quarantine, return the affected device 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

Ph. Ahmed Saif AL Harbi

Acting Director General

