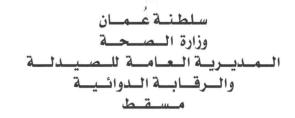
# Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

روية **عيمان** 

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 176 dated 26/9/2022 Regarding NCMDR Recall of GELITA TUFT-IT® from (mfr: Gelita Medical GmbH).

## Copy to:

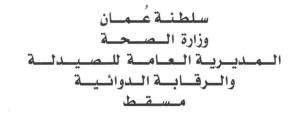
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





Circular No. 176/2022

29 -02-1444 H

26 -09-2022

## Recall of GELITA TUFT-IT® from Gelita Medical GmbH.

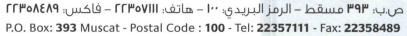
Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17275">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17275</a>			
Product	GELITA TUFT-IT®.			
Description	Absorbable hemostat.			
Manufacturer	Gelita Medical GmbH.			
The affected products	Refer to "Appended in Annex I" in the attachment.			
Reason	In re-testing, undertaken as part of an effort to optimize the production process in regard to the elimination/reduction of Endotoxins in GELITA MEDICAL's gelatin-based devices, higher than the "acceptance" levels of Endotoxins were found in product already admitted to the market.			
Action	<ol> <li>Quarantine and return the affected devices for destruction.</li> <li>Contact the local agent for remedial action.</li> </ol>			
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="Med-device@moh.gov.om">Med-device@moh.gov.om</a>			

Dr. Mohammed Hamdan Al Rubaie **Director General** 









# Annex 1

**Unit of Use** 

(Primary/

Sales Unit

**Transport** Unit

Secondary sterile

(Suture box)

(Standard

nac	Laging		
Date	Naeille		
Puc	kaging		

transport box)

Product Categorie	Article number	UDI-DI (GTIN)	UDI-DI (GTIN)	UDI-DI (GTIN)
GELITA TUFT-IT®	GF-7365	4260293133717	4260293130716	4260293137715
GELITA TUFT-IT®	GF-7336	4260293133793	4260293130792	4260293137791