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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

نمضي بثقة
Moving Forward
with Confidence
رؤية عُمان
2040

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 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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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سلطنة عُمان
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مسقط

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 https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17275
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	1. Quarantine and return the affected devices for destruction. 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

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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Annex 1

Product Categorie	Article number	Unit of Use (Primary/ Secondary sterile packaging) UDI-DI (GTIN)	Sales Unit (Suture box) UDI-DI (GTIN)	Transport Unit (Standard transport box) UDI-DI (GTIN)
GELITA TUFT-IT®	GF-7365	4260293133717	4260293130716	4260293137715
GELITA TUFT-IT®	GF-7336	4260293133793	4260293130792	4260293137791