



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

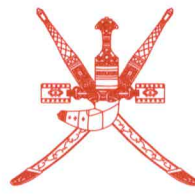
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 201 dated 14/11/2022 Regarding NCMDR Recall of Gelita Tampon from (mfr: B Braun Surgical SA).

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. 201/2022


20-04-1444 H

14-11-2022

تقدم بثقة
Moving Forward
with Confidence



Recall of Gelita Tampon from B Braun Surgical SA.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=17291
Product	Gelita Tampon.
Description	Spongy Hemostat.
Manufacturer	B Braun Surgical SA.
The affected products	Reference name GELITA-TAMPON 1 X 1 X 1 CM, GELITA-TAMPON 1 X 1 X 1 CM 045, GELITA-TAMPON 1,5 X 1,5 X 1 CM 045, GELITA-TAMPON 8 X 5 X 1 CM, GELITA-TAMPON 8 X 2 X 1 CM Reference number: 2070014, 2070103, 2070154, 2070600, 2070707
Reason	The endotoxin concentration of the product in some samples has been measured above the limit.
Action	1. Identify, quarantine, and return back the affected products. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

