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



Circular No. 5

/ 2022

21 -06-1443 H

24-01-2022

Recall of VACUTAINER BLOOD COLLECTION TUBE from Becton Dickinson.

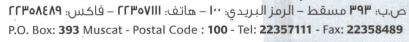
Source	GHC-Gulf Health Council.
Product	VACUTAINER BLOOD COLLECTION TUBE.
Manufacturer	Becton Dickinson.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	0316293.
Reason	Apotential to underfill or exhibit draw volumes below labeled product claims. Underfilling of tubes could result an incorrect additive-to-blood ratio, which could cause erroneous test results that potentially could lead to improper diagnosis or treatment.
Action	 Kindly take the necessary action to recall the above-mentioned models of the medical device if available in your facility. Contact the local agent for remedial action.
Product Picture	
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 contact E-mail: Med-device@moh.gov.om

/ Dr. Mohammed Hamdan Al Rubaie DIRECTOR GENERAL



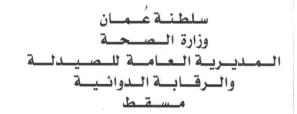






Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

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. 5. 1222. dated 24/11/20. Regarding GHC recall of VACUTAINER BLOOD COLLECTION TUBE from (mrf: Becton Dickinson).

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







تقارير السلامة للأجهزة والمستلزمات الطبية Safety Alerts of Medical Device Products

To: HE / Members of the Executive Committee of	مجلس	بدول	التنفيذية	الهيئة	أعضاء	سعادة/	إلى:
the Cooperation Council States Members						ن.	التعاو

the Cooperation Cou	ncil States Members	التعاون.
Subject:	تحذير سلامة عن سحب منتج طبي VACUTAINER BLOOD) (Becton Dickinson) من أنتاج شركة	الموضوع:
Product Name:	VACUTAINER BLOOD COLLECTION TUBE	اسم المنتج:
Company:	Becton Dickinson	الشركة :
Affected product:	0316293	المنتجات المتأثرة:
Reg. Status in GHC:	Not registered	وضع المنتج في مجلس الصحة:
Source of Warning:	Health Canada – MOHAP UAE	مصدر التحذير:
Reason for Recall:	أفادت وزارة الصحة ووقاية المجتمع أن سبب التحذير هو بسبب أحتمالية نقص ملء الأنابيب إلى نسبة غير صحيحة من المواد المضافة إلى الدم، مما قد يؤدي إلى نتائج اختبار خاطئة قد تؤدي إلى التشخيص أو العلاج غير الصحيح.	سبب السحب:
Recommendation:	أوصت وزارة الصحة ووقاية المجتمع: باتخاذ الإجراءات اللازمة حيال سحب التشغيلة المذكورة للمنتج أعلاه، حال توفرها لديكم.	التوصيات:
Link of Circular	For more information, please click here	رابط التعميم:
or inquiries and pms@ghc.sa		للاستفسارات والإبلاغ: