Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	IV cannula
Device Model	22G
Lot No.	71022 71023 71022 71018 71020
Manufacturer	Saudi Mais Co. for medical (SMMP)
Country of Origin	Saudi Arabia
Reference	attached
Reason of Alert	NHRA initiates this FSN due to a Breakage of Catheter (FEP tube) and Leakage in Catheter (FEP tube).
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Universal Medical Equipments at dhanya@ume-bh.com

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

FSCA 2023 0025

15/May/2023

Saudi mais Co.
for Medical Products
C.R. 1010112398 A Limited Liability Co.
Capital S.R. (34,500,000) Fully Paid
VAT No. : 3000 5661 72000 03

SMMP
رقم العضوية ٥٥٣٥٨

شركة مايس
السعودية للمنتجات الطبية
س.ت ١٠١٠١١٢٣٩٨ شركة ذات مسؤولية محدودة
رأس المال المدفوع (٣٤,٥٠٠,٠٠٠ريال) مدفوع بالكامل
الرقم الضريبي: ٣٠٠٠٥٦٦١٧٢٠٠٠٠٣

29/03/2023

To whom it may concern…

We Saudi Mais Co. for Medical Products would like to inform you that the Safety Alerts of Medical Device Products announced by SFDA is a safety communication letter about recommendation to achieve the safe usage of IV Cannula,

kindly read it carefully.

The product is safe to use, Saudi Mais values its customers and always looking to supply good quality products.

Saudi Mais Co. for Medical Products

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المصنع : المملكة العربية السعودية – الرياض – المنطقة الصناعية الثالثة
طريق الخرج شارع رقم ٢٥٦ ص.ب ٣٩٠٠- الرياض ١٤٣٣٥-٧٥٩٩
هاتف : ٠٠٩٦٦١١٢٦٥٠١٨٤ – فاكس : ٢٦٥٠١٣٩
فرع الرياض هاتف ٢٦٥٠١٨٤ (٠١١)
فرع جدة هاتف ٦٨٩٧٢٦٢ (٠١٢)
فرع الدمام هاتف ٨٤٣٥٠٨٨ (٠١٣)
فرع المدينة (تيلفاكس) ٨٤٨٦٨٩٤ (٠١٤)