

رؤية عمان 2040  
ننقدم بثقة  
Moving Forward  
With Confidence

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 235 dated 20/12/2022 Regarding NCMDR recall of Accu-Chek Solo cannula assembly & pump holder from (mfr: Roche Diabetes Care 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



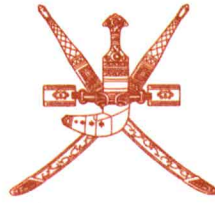
**PADC**  
المديرية العامة للصيدلة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

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Circular No. 235/2022


26 -05-1444 H

20 -12-2022

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Recall of Accu-Chek Solo cannula assembly & pump holder from Roche Diabetes Care 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=18366">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18366</a>
Product	Accu-Chek Solo cannula assembly & pump holder.
Description	Cannula assembly & pump holder for Accu-Chek Solo Micropump System.
Manufacturer	Roche Diabetes Care GmbH.
Local agent	National Pharmacy LLC.
The affected products	Accu-Chek Solo cannula assembly & pump holder (9 mm; 10+3): REF Number: 07858833001; Device Identifier: 04015630881659; Impacted LOT Numbers in Saudi Arabia: 846752003, 847055258, 847201899, 847201943, 847241925 Accu-Chek Solo cannula assembly & pump holder (6 mm; 10+3): REF Number: 07858841001; Device Identifier 04015630881642; Impacted LOT Numbers in Saudi Arabia: 846913965, 846994477, 847055257, 847201895, 847266884
Reason	Insulin leakage that might not be noticed immediately when using the Accu-Chek Solo system.
Action	1. Please ask your patients using the Accu-Chek Solo system to check the Accu-Chek Solo cannula assembly & pump holders they have stored at home if these show Lot Number 847468303 and lower. 2. Discontinue using cannulas included in this voluntary recall immediately. 3. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General

