



**Australian Government**

**Department of Health and Aged Care**  
Therapeutic Goods Administration

**URGENT MEDICAL DEVICE RECALL\***

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2022-RN-01541-1

DATE AGREED: 19/12/2022

**PRODUCT:** **Accu-Chek Solo cannula assembly & pump holder (9 mm; 10+3 & 6 mm; 10+3) and Accu-Chek Solo supply kit (9 mm) & (6 mm)**

Cannula lot numbers: 847468303 and lower

Reference numbers: 07858833001, 07858841001, 07858817001 & 07858825001

ARTG 308704

(Roche Diabetes Care Australia Pty Ltd - Insulin infusion patch pump administration set)

ARTG 311432

(Roche Diabetes Care Australia Pty Ltd - Ambulatory insulin infusion administration set/reservoir kit)

**SPONSOR:** Roche Diabetes Care Australia Pty Ltd

**CONTACT INFORMATION:** 1800 251 516 - Diabetes customer care - Roche

**REASON:** Roche Diabetes Care has identified that insulin leakage has occurred in a low number of cases with the Accu-Chek Solo cannula assembly & pump holder. As such insulin leakage might not be noticed immediately when using the Accu-Chek Solo system which could potentially lead to an under-delivery of insulin.

The possible consequences could range from no clinical impact to adverse health events including severe hyperglycaemia or diabetic ketoacidosis (DKA).

There have no reports of adverse events been reported in Australia to date.

**PROPOSED CUSTOMER ACTIONS:** Roche are advising consumers, healthcare professionals and distributors to identify impacted products and discontinue using them. Customers are also advised to contact Roche customer care to receive the information on how to send the impacted stock back and receive the replacement.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 31 hospitals and health clinics nationally excluding NT and TAS

Product export status: N/A

This issue was first identified by the Sponsor

This information has been published in the TGA's searchable database, the System for Australian Recall Actions (SARA) –

<https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-01541-1>

\*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>