

### **Australian Government**

## Department of Health and Aged Care

Therapeutic Goods Administration

### Therapeutic Goods Act 1989

# Approval under section 42DF for use of restricted representations by

### Roche Diabetes Care Australia Ptv Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health and Aged Care, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraphs 1-4, for use in advertisements directed to consumers, for the products identified in paragraphs 1-4:

1.

- representations that refer to "diabetes" in the trading name or copyright notice of the applicant
- "for people living with diabetes"

in advertisements for:

- o ARTG 190251 Clinical chemistry substrate IVDs (all Accu-Chek blood glucose strips included in this ARTG entry)
- o ARTG 167228 Manual blood lancing device, single-use
- o ARTG 167227 Lancet automatic
- o ARTG 100623 Lancet automatic
- o ARTG 190250 Instrument/analyser IVDs (all Accu-Chek blood glucose meters included in this ARTG entry)

2.

• "the Accu-Chek system for use with people with diabetes"

in advertisements for:

- o ARTG 190251 Clinical chemistry substrate IVDs (all Accu-Chek blood glucose strips included in this ARTG entry)
- o ARTG 190250 Instrument/analyser IVDs (all Accu-Chek blood glucose meters included in this ARTG entry)

3.

- representations that refer to "diabetes" in the trading name or copyright notice of the applicant
- representations that refer to "diabetes" in the product name "Roche Diabetes Care Platform"

in advertisements for:

o ARTG 316258 - Accu-Chek SmartPix Online - Clinical data collection/ management information application software

Email: info@tga.gov.au https://www.tga.gov.au

4.

- Representations that refer to "diabetes" in the trading name or copyright notice of the applicant
- For people living with diabetes
- mySugr is created by people with diabetes for people with diabetes
- Our mySugr app allows your patients to share their diabetes data with you at any time.
- mySugr includes a digital diabetes logbook for recording blood sugar readings, which can help with the management of diabetes
- mySugr App: your diabetes data in one place.
- How can mySugr support my diabetes management?
- With the mySugr app, it's quick and easy to collect important diabetes therapy data in one place.

in advertisements for:

o ARTG 392894 - Self-care monitoring web-based application software (mySugr logbook)

Dated this 10th day of May 2023

Signed electronically

#### **Michael Shum**

Delegate of the Secretary to the Department of Health and Aged Care Advertising and Compliance Education and Policy Section Regulatory Compliance Branch