



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Therapeutic Goods Act 1989**

**Notification under section 42DG of approval of use of restricted representations by Bayer Australia Ltd**

I, Leanne McCauley, Delegate of the Secretary to the Department of Health for the purposes of section 42DG of the *Therapeutic Goods Act 1989* (the Act), advise that following receipt of an application from Bayer Australia Ltd, the restricted representations described in paragraph (a) (i) – (ii) below for use in advertisements directed to consumers, for the product identified in paragraph (b) were approved on 20 October 2019:

(a)

(i) 'Bacterial infections' or 'bacterial vaginosis' in the context of providing information about the purpose and correct use of the Device;

(ii) 'Bacterial infections' or 'bacterial vaginosis' in the context of providing information about the diseases the Device is intended to diagnose.

(b) "Clinical chemistry biological screening IVDs" (ARTG No 294252)

Dated this 29th day of November 2019

*Signed electronically*

Leanne McCauley  
Delegate of the Secretary to the Department of Health  
Advertising Education and Assurance Section  
Regulatory Education and Compliance Branch