

18/02/2026

## Summary view of ARTG# 231433

 **ARTG Name:** MyHealthTest Pty Ltd - Home blood collection kit ( 231433 Class IIa )


Sponsor Name: **MyHealthTest Pty Ltd - 66245**

Therapeutic type: **Medical Device**

Licence product category: **Included**

Class: **Class IIa**

### Active Manufacturers

 **Manufacturer:** ITL Asia Pacific Sdn Bhd Active (33732)

Country: **Malaysia**

Step:

### Ceased Manufacturers

 **Manufacturer:** ITL Asia Pacific Sdn Bhd Ceased (33732)

Country: **Malaysia**

Step:

 **Manufacturer:** ITL Asia Pacific Sdn Bhd Ceased (33732)

Country: **Malaysia**

Step:

### Product

 **Product:** Home blood collection kit (441442)

Product type: **Procedure Pack**

*Intended purpose: A collection of sterile and non-sterile devices and materials intended to be used by a layperson to collect and mail a blood sample to a clinical laboratory for diagnostic testing or screening purposes. The kit includes a lancet, blood collection card and other standard items (e.g. alcohol prep pad, gauze pad, bandage strip ). The blood sample is taken from the finger after being pricked by the lancet and is stored in the form of two or more spots on a collection card (not vial or syringe), which can be mailed to a clinical laboratory for diagnostic testing of a range of different blood attributes. It is normally available (non-prescription ) over-the-counter (OTC) for home-use. This is a single-use device.*

*Functional description: No data found*

*Variant information:*

*GMDN: Capillary blood collection set, home-use (38092 )*

*File reference:*

**No Components Located in the Register**

