Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Specimen collection swabs

Guidance

All collection swabs are medical devices and must be included in the ARTG.

Last updated: 30 July 2020

A specimen collection swab (collection swab) is used to take a sample for medical testing, for example a swab that takes a sample of a virus. All collection swabs are medical devices, and must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

The TGA prioritises ARTG applications for collection swabs that are related to COVID-19.

Classification of collection swabs

How a collection swab is classified for regulation depends on features such as whether it is sterile, the manufacturer's intended purpose for the product and what type of certification a manufacturer may hold. Medical devices with higher classifications have greater requirements for inclusion in the ARTG under conformity assessment procedures.

Class I

Generally, a non-sterile collection swab intended to be used in an oral or nasal cavity is classified as Class I non-sterile, non-measuring medical device.

Class I sterile

A sterile collection swab intended for use in an oral or nasal cavity is classified as Class I (sterile). A sterile swab with an associated viral transport media may also be regulated as Class I (sterile), but only if the whole pack is sterile. The manufacturer's intended purpose for the product is also a factor in whether it is classified as Class I (sterile)

Class IIa

A swab intended to be surgically invasive (such as a swab for a wound) is classified as Class IIa.

Class 1 (IVD)

A swab with an associated viral transport media may be regulated as a Class 1 in-vitro diagnostic (IVD) medical device, depending on the manufacturer's intended purpose.

For more information on the classifications of medical devices, visit Overview of medical devices and IVD regulation.

3-D printed collection swabs

3-D printed collection swabs supplied as medical devices must meet all relevant regulatory requirements. Manufacturers should be aware that there are known issues with 3-D printed devices such as brittleness that may impact the conformity assessment of the device. For more information, visit 3-D printing (additive manufacturing) of medical devices

How to apply for inclusion of a collection swab on the ARTG

If you are manufacturing or supplying a collection swab, you must ensure that it meets all relevant regulatory requirements. A sponsor must apply to include the product on the ARTG, and satisfy the conformity assessment requirements appropriate to the product's classification. If you are unsure of the product's classification, contact the TGA.

For more information, visit Manufacturing medical devices for COVID-19 including 3-D printing.

Topics: In Vitro Diagnostic medical devices (IVDs)