



Australian Register of Therapeutic Goods Certificate

Issued to

Vesticam

for approval to supply

Vesticam - Vesticam - Camera, video, <specify>

ARTG Identifier	301218
ARTG Start date	23/03/2018
Product Category	Medical Device Included Class 1
GMDN	17001
GMDN Term	Camera, video, <specify>
Intended Purpose	<p>Vesticam is an active, medical device used to assist in the diagnosis of human balance disorders. It does this by taking, displaying, and recording images of a single eye movements in various head positions and conditions. The movements are independent of and not controlled by the device. The direction and quality of eye movement provide information to assist assessment and diagnosis; in particular, whether a condition is central or peripheral in nature. There is no measurement of the eye movement involved.</p> <p>An approved usb camera with low power IR LED illuminator mounted on standard swimming goggles is connected to an android phone via cable (NO WiFi or bluetooth). The usb camera and IR lights are driven by the batteries in the phone and records images via a software application. The device is extracorporeal and does not come into contact with the eye, as the camera is safely enclosed in a cylinder (narrower at the proximal end).</p> <p>Vesticam is not intended to be used with any other medical device. Its purpose is solely to supply video images for the purpose of detecting, assisting in diagnosing, or monitoring balance conditions.</p>

Manufacturer Details	Address	Certificate number(s)
Vesticam	29 Endeavour Drive Bellingen, NSW, 2454 Australia	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Vesticam - Camera, video, <specify>

Product Specific Conditions

Therapeutic Goods Administration
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