



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 355032 Elenium Automation Pty Ltd - Thermography system, infrared

ARTG entry for Medical Device Included Class IIa
Sponsor Elenium Automation Pty Ltd
Postal Address 7 Challenger Court, ESSENDON FIELDS, VIC, 3041
Australia
ARTG Start Date 16/02/2021
Product Category Medical Device Class IIa
Status Active
Approval Area Medical Devices

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.

Manufacturers

Name	Address
Elenium Automation Pty Ltd	7 Challenger Court Essendon Fields, VIC, 3041 Australia

Products

1 . Thermography system, infrared

Product Type	Single Device Product	Effective Date	16/02/2021
GMDN	40803 Thermography system, infrared		
Intended Purpose	The device is a self-serve contactless interactive Desktop kiosk which uses infra-red thermography of the face surface for the purpose of screening potentially FEBRILE individuals.		

Specific Conditions

No Specific Conditions included on Record

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