

# **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 (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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