



HealthGate

PROTECTION | SYMPTOM DETECTION | IDENTITY MANAGEMENT



elenium
AUTOMATION

Elenium Moves You Faster and Safer

Our self-service products are used by millions of people across aviation, healthcare, aged care and government infrastructure. Winner of the Frost & Sullivan 2020 Airport Self-service Technology Innovation Leadership Award, our team has capabilities in robotics, mechanical engineering, physics, machine learning and data science.

HealthGate

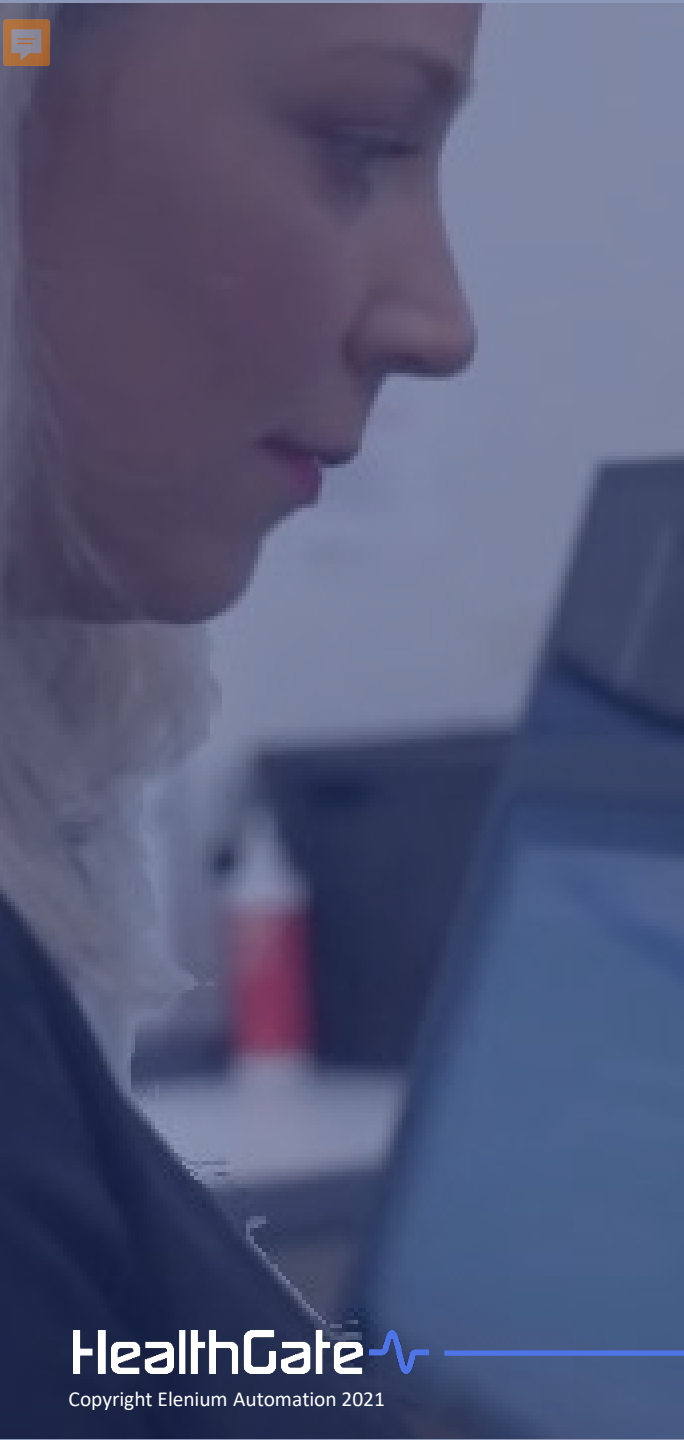
The HealthGate medical device uses touchless fever detection to provide health screening and visitor safety for workplaces and public spaces such as medical centers, transportation hubs and at events.



3 in 1: Safe, Simple and Legal Check-In Device



Government QR Code Check-In
Certified Health Screening
Contact Tracing



Peace of Mind Through Behaviour Change

70%

Of people are more comfortable entering a public space that has **health screening** technology

Want additional health screening in place alongside a vaccine

88%

Will be honest on pre-arrival health screening questions if they knew they would be screened upon arrival

Of people with viral infections have fevers ¹

"People don't do what you expect, they do what you inspect" Lou Gerstner



¹ Source: <https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf>



Tested and Certified Accuracy

HealthGate is tested and certified to make sure you can confidently keep your employees and business safe

14 day sprints of laboratory drift testing, every 5 seconds, proved the accuracy and consistency of HealthGate

9 million test cycles completed as part of our development phase

Globally, one of the few medically certified thermographic fever detection devices

- Entered in the ARTG (355032), Class IIa medical device in Australia
- Class IIa medical device in Europe

HealthGate includes the CDC return to work guidelines for pre-arrival screening

Why Did Elenium Certify HealthGate?

It's the law

In many jurisdictions, including Australia and Europe, Thermal Imaging Systems are classified a **medical device**

Selling or implementing non-certified devices is illegal in these jurisdictions. Organisations which distribute or implement non-certified devices can be fined.

Board directors and senior management are personally liable for the health and safety of their employees under the new workplace legislation in Australia

It's best practice globally

Elenium complies with ISO13485:2016, the globally recognised quality management system requirements for manufacture of medical devices

Elenium received the highest compliance rating (A1) for our quality management system as assessed by the Therapeutic Goods Administration (TGA), Australian regulator for medical devices

People expect it

70% of people are more comfortable entering a public space that has health screening technology and expect it alongside vaccines

More than half of the people surveyed are not confident to return to offices citing health and safety concerns





Traditional Model of Access Control

\$240

Daily cost of minimum wage staff temperature screening at a facility with 3 entrances

\$2,500

Daily cost of nursing staff temperature screening at a healthcare facility with 3 entrances

HealthGate Access Control

\$20

Daily cost of HealthGate deployed at a hospital with 3 entrances in year 1

Value

Keeps staff safe. Trained nurses can focus on essential duties of care.

HealthGate, a touchless certified medical device, proven to protect your customers and business while changing behaviour



Multidimensional Protection

Touchless

Interact at a distance with self-service devices, designed for loud environments.



Certified Medical Device

Accuracy is tested. ARTG, 355032. EC Certified.

Change Behaviour

People tend to respond to health declarations more honestly.



Health Declarations

Enable visitors' self-declaration about symptoms & history.

Biometrics Recognition

Highly accurate, fast and secure facial recognition to authenticate and authorize.



Body Temperature Screening

Audible alarm and notifications for exception cases



Mask Detection

Configurable option prompting visitor for action in line with mandated process.



Integration and Scalability

Simple integration into 3rd party system or access control system

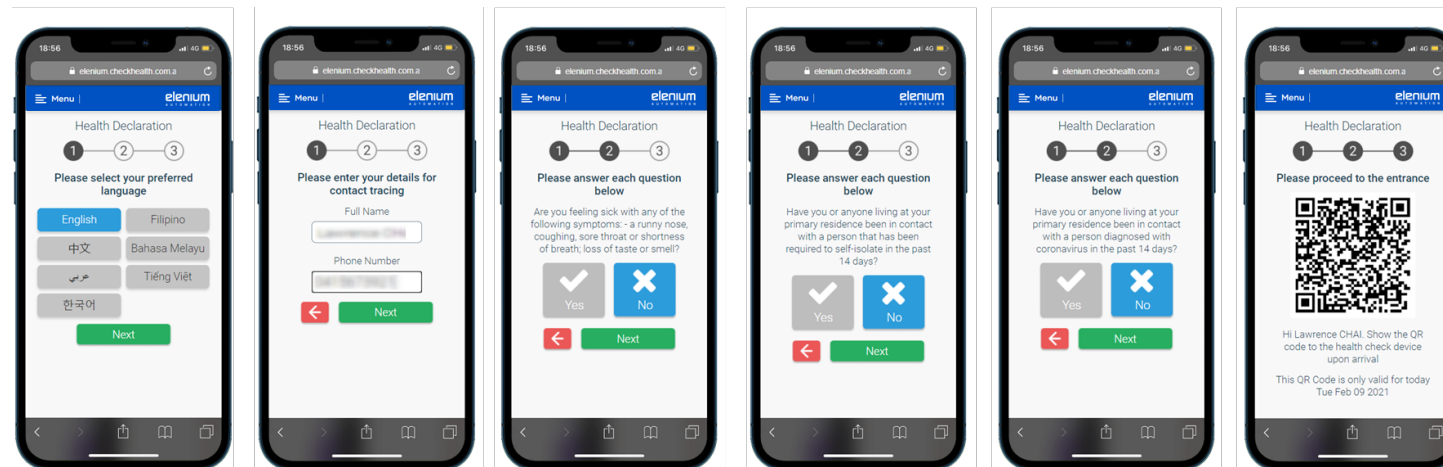


Verify Health Status before Arrival

Register visitors and record health declarations, ensuring they are pre-screened and healthy with HealthGate Declare.

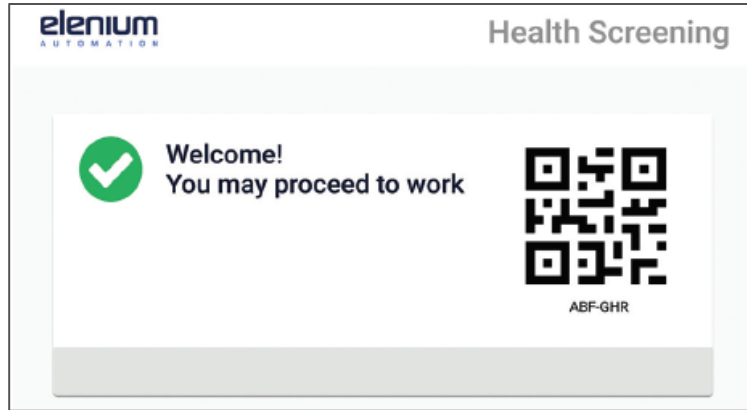
A multi-language online application allowing a user to register their attendance to a site and submit a health declaration to be used with HealthGate device.

HealthGate Declare, based on customisable business rules, will advise the user if they can enter the facility or to seek further advice minimising the risk of transmission and encouraging social responsibility.





Support QR Code and Biometric Check-In



Contact tracing will most likely remain part of our daily lives in a post-pandemic world. Even with a successful distribution of vaccines, contact tracing will deal with outbreaks of variants when international borders re-open.

HealthGate supports the display of government QR Codes.

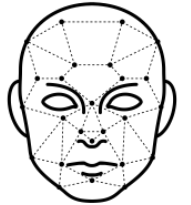
A Seamless Experience

Biometric Recognition enhances the check-in experience by using highly accurate facial recognition.

The entire biometric process takes less than one second. It can be integrated into government systems and can be added to the HealthGate as a software upgrade.

Better for your Staff and Customers

Biometric Recognition enables a simple, secure and authenticated process that will make entry to your premises easier for staff and customers.





Common Use Cases



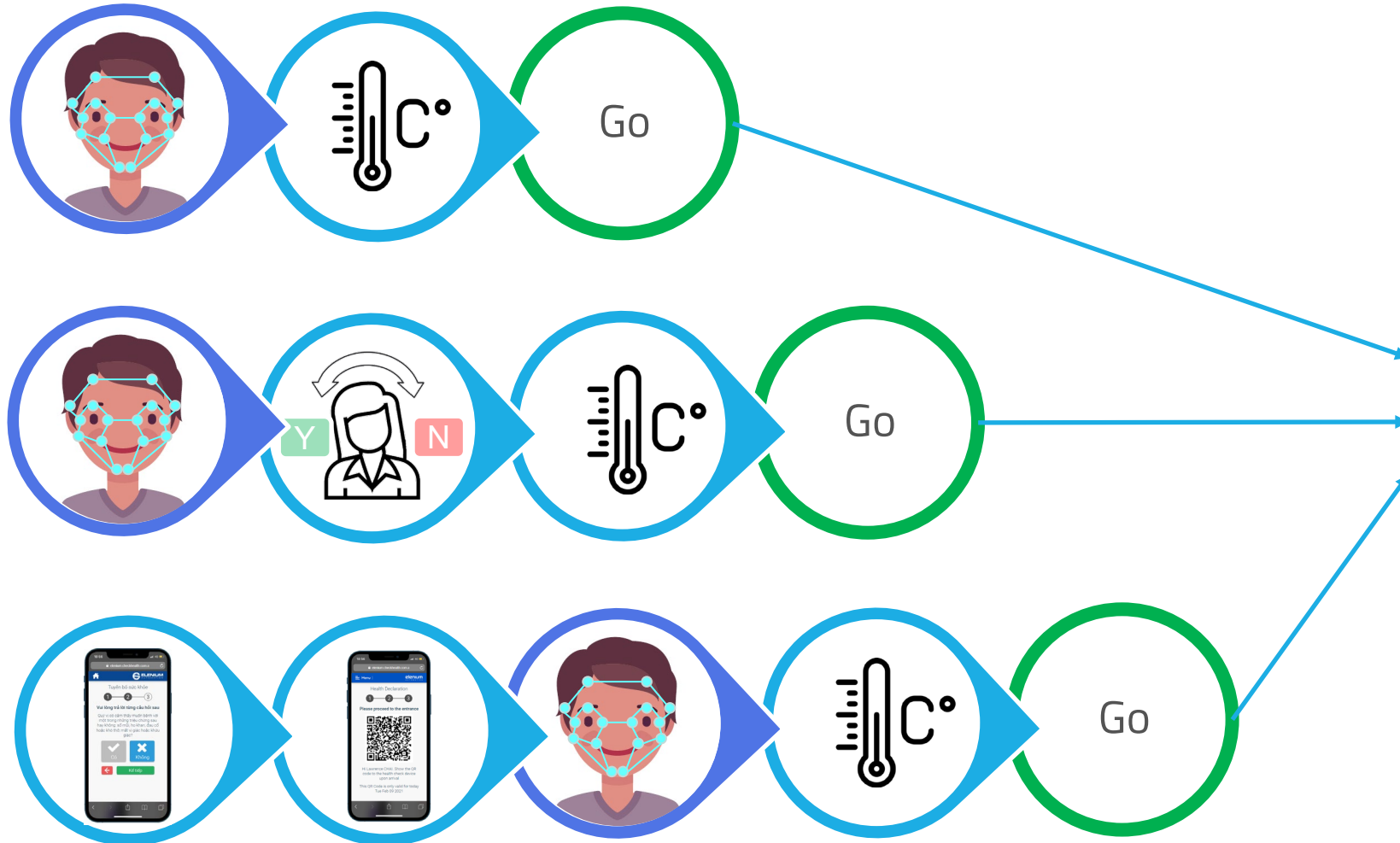


Use Cases with Biometric (Facial Recognition)



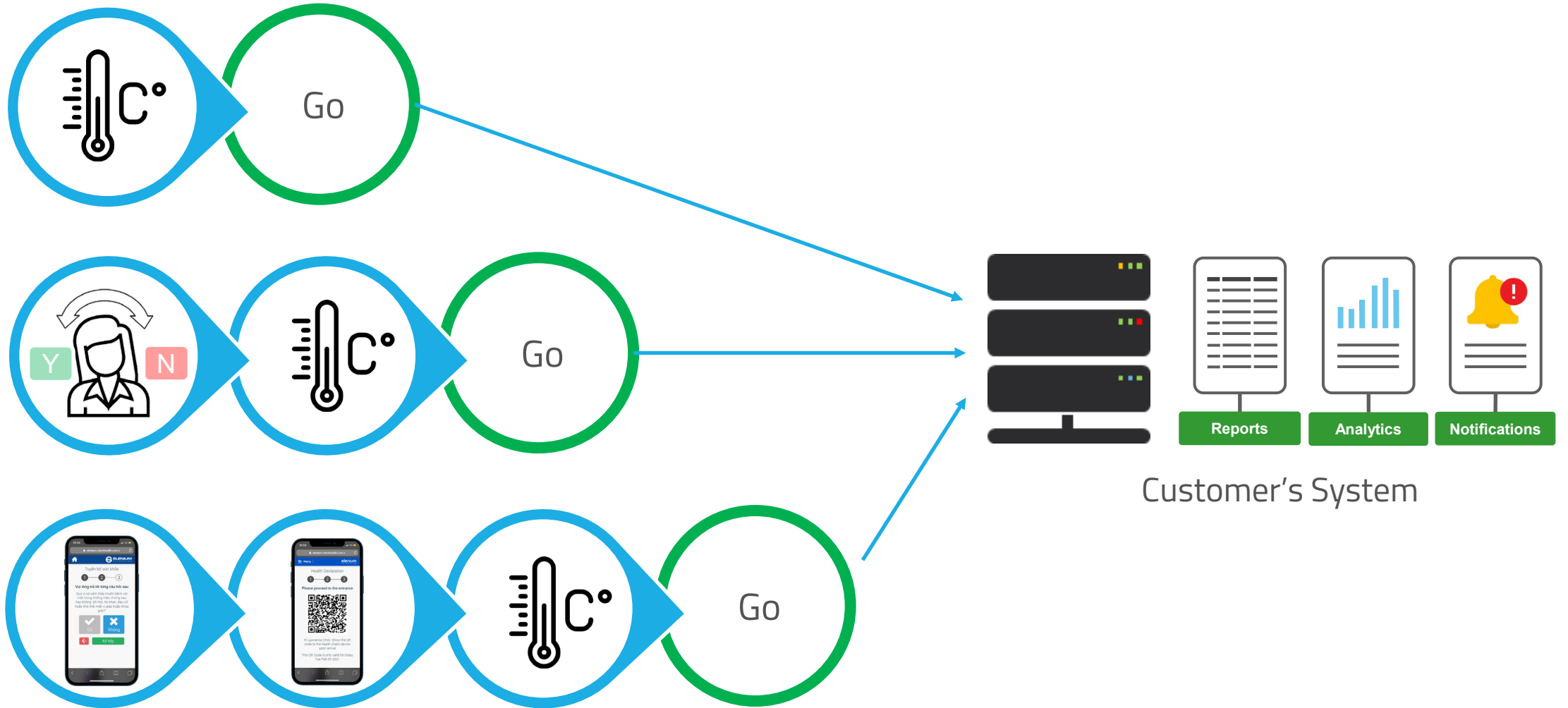


Use Cases with Biometric & Automatic Gov. QR Code Check-In

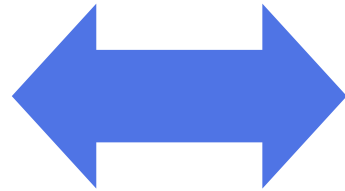




Common Use Cases with Outbound APIs




Accessories



4G WiFi Modem
Provide HealthGate with internet access



Label Printer
Print label sticker with triage outcome



Low Lever Interface
Integrate with a wide range of access control system



Intuitive and Reassuring

"Intuitive to understand and easy to use, even for people with limited technical skills"

Recent State Government trial employee feedback



"HealthGate has already saved us considerable time, but it has also given us and our team great peace of mind, which is priceless"

Retail chain management feedback

Video Links:

<https://www.youtube.com/watch?v=ROSoVZ588M4>

<https://www.youtube.com/watch?v=-c9fQAtHJbA>

<https://www.youtube.com/watch?v=aeMryq4-pV8>



COTTON:ON



intel




sayers



Certified Medical Device

ARTG Certificate


Australian Government
 Department of Health
 Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to
Elenium Automation Pty Ltd
 for approval to supply
Elenium Automation Pty Ltd - Thermography system, infrared

ARTG Identifier: 355032
ARTG Start Date: 16/02/2021
Product Category: Medical Device Included Class Ila
GMDN: 40803
GMDN Term: Thermography system, Infrared
Intended Purpose: The device is a self-serve contactless interactive Desktop kiosk which uses infrared thermography of the face surface for the purpose of screening potentially FEBRILE individuals.

Manufacturer Details	Address	Certificate number(s)
Elenium Automation Pty Ltd	7 Challenger Court Essendon Fields, VIC, 3041 Australia	DV-2021-MC-02674-1

ARTG Standard Conditions
The above Medical Device Included Class Ila 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 4-6, 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. Thermography system, Infrared

Product Specific Conditions
No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia Phone: 1800 020 653 Email: info@tga.gov.au	ARTG Identifier: 355032 ARTG Start Date: 16/02/2021
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ARTG EC Certificate


Australian Government
 Department of Health
 Therapeutic Goods Administration

EC Certificate
Production Quality Assurance Procedures
Annex V of the Council Directive 93/42/EEC on Medical Devices

Notified Body Identification number: 0805
Certificate Number: MRA Q00096

Issued to: Elenium Automation Pty Ltd
Manufacturer Name: Elenium Automation Pty Ltd
Manufacturer Address: 7 Challenger Court
ESSENDON FIELDS VIC 3041
Australia

For the Manufacture and Final Inspection of device categories specified on page two of this certificate.

This is to certify that the quality management system described below conforms to the relevant provisions of Annex V of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for production and final inspection to ensure that each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.


Commencement Date: 11 February 2021
Certificate Expiry Date: 26 May 2024
Associated CA Certificate: AU Q00471

This certificate is issued by:

Jie ZHOU
Signed electronically
Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

TGA Conformity Assessment Certificate Page 1 of 3

HEALTH CANADA IO

 Health Canada
 Santé Canada

Medical Devices Directorate
 Direction des instruments médicaux

COVID-19 Medical Device
Authorization for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19

Authorization Reference Number: 332509
Issue Date: 2021-10-06

Numéro de référence de l'autorisation: 332509
Date de délivrance: 2021-10-06

Device Class/Classe de l'instrument : 1

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to Covid-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Conformément à l'article 5 de l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid-19, réalisé par le ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurer de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Cette autorisation est uniquement valide tant que l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument
ELENIUM AUTOMATION: HEALTHGATE DESKTOP

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation
ELENIUM AUTOMATION PTY LTD.
7 CHALLENGER COURT
ESSENDON FIELDS, VICTORIA
AUSTRALIA
3041

David Bourdram, ing., Director General, Medical Devices Directorate
Directeur général, Direction des instruments médicaux

Application Number: 332509 Numéro de la demande:	Manufacturer ID: 165299 Identificateur du fabricant:
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Feature	Elenium HealthGate
ARTG Entered	Yes (355032)
14 day drift test compliant (-59)	Yes
Sensor Resolution	320 x 240
Sensor Sensitivity	0.7
Accuracy	0.3 – 0.5 degrees
Frame Rate	8.7hz
Elenium Air Shield	Yes
Nvidia GPU	Yes
Client OS	Windows or Android
HD Camera	Yes - 13mp with mechanical focus
Near Infrared Camera	Yes
Touch Screen	Yes
Voice Recognition	Yes (optional SaaS)
Virtual Touch (Head control)	Yes
Barcode reader	Yes
Facial Recognition	Yes (optional SaaS)
Monochrome Printer	Optional
Multilingual support	Yes
Portable	Yes
Operating Environment	Indoors (Ambient Temperature 18°C to 24°C)



The Elenium HealthGate complies with the following standards

Standard	Description
ISO 13485	Medical Device – Quality Management Systems
IEC 62304	Medical Device Software – Software lifecycle Processes
IEC 60601-1	Medical Electrical Equipment – Part 1
IEC 60601-1-2	Medical Electrical Equipment – Part 1-2
IEC 60601-1-6	General requirements for basic safety and essential performance Collateral Standard: Usability
IEC 62366-1	Medical Devices – Part 1: Application of usability to engineering to medical devices
ISO 14971	Application of risk management to Medical Devices.
ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
IEC 80601-2-59	Medical electrical equipment – Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
ISO TR 13154	Medical electrical equipment – Deployment, Implementation and Operational Guidelines for Identifying Febrile Humans Using a Screening Thermograph

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