

## **Australian Government**

# Department of Health and Aged Care

Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry: Suretest - Nitrile examination/treatment glove, non-powdered 366553

ARTG entry for Medical Device Included Class 1

Sponsor Suretest

**Postal Address** 1291 Malvern Road, Malvern, Melbourne, VIC, 3144

Australia

19/05/2021 ARTG Start Date

**Product Category** Medical Device Class 1

Status Active

Medical Devices Approval Area

### 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

**Address** Name

Sri Trang Gloves (Thailand) Public Company Limited

10 Soi 10 Phetkasem Road Hatyai

, Songkhla, 90110

Thailand

### **Products**

# 1. Nitrile examination/treatment glove, non-powdered

**Product Type Effective Date** 19/05/2021 Single Device Product

GMDN 56286 Nitrile examination/treatment glove, non-powdered

**Intended Purpose** Personal protective equiptment, are being labelled for medical/surgical use, and to reduce or prevent the transmission of disease or

micro-organisms such as bacteria or viruses.

## **Specific Conditions**

No Specific Conditions included on Record

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