

# **Australian Government**

# Department of Health and Aged Care

Therapeutic Goods Administration

# **Public Summary**

Summary for ARTG Entry: 337424 Veratemp - Thermometer, infrared, skin

ARTG entry for Medical Device Included Class IIa

Sponsor Veratemp

Postal Address PO Box 18, Keilor, VIC, 3036

Australia

4/06/2020 ARTG Start Date

**Product Category** Medical Device Class IIa

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

4F BaiShiDa High-Tech Park XiangDong Hetaida Technology Co Ltd

Industrial Area DaLingShan Town DongGuan City, Guangdong, China

# **Products**

## 1. Thermometer, infrared, skin

**Product Type Effective Date** 4/06/2020 Single Device Product

**GMDN** 17888 Thermometer, infrared, skin

**Intended Purpose** A hand-held, battery powered measuring device for determining the patient's body temperature. It is used to estimate the

temperature of a site on the skin, e.g. axilla or forehead by measurement of body infrared emissions at this particular point.

# **Specific Conditions**

No Specific Conditions included on Record

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