



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

LotusTech Pty Ltd

for approval to supply

LotusTech Pty Ltd - Sterilization process indicator, biological

ARTG Identifier	465729
ARTG Start Date	24/10/2024
Product Category	Medical Device Included Class 1
GMDN	13732
GMDN Term	Sterilization process indicator, biological
Intended Purpose	Biological Indicators are designed for use in medical and industrial facilities to monitor critical sterilization parameters. They provide an indication of exposure to a specified range of sterilization conditions, including steam sterilization and dry heat sterilization cycles.

Manufacturer Details	Address	Certificate number(s)
Wenzhou MicroDome Technologies Co Ltd	601 Binhai Fifteenth Road Binhai Park Economic and Technological Development Zone Wenzhou , Zhejiang , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 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 4-5, 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.

Products Covered by This Entry

1. Sterilization process indicator, biological

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

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