



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	455431	LotusTech Pty Ltd - Sterilization process indicator, biological
ARTG entry for	Medical Device Included Class 1	
Sponsor	LotusTech Pty Ltd	
Postal Address	1 Avalon Street, Turramurra, NSW, 2074 Australia	
ARTG Start Date	16/07/2024	
Product Category	Medical Device Class 1	
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 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

Name	Address
Wenzhou MicroDome Technologies Co Ltd	601 Binhai Fifteenth Road Binhai Park Economic and Technological Development Zone Wenzhou, Zhejiang, China

Products

1 . Sterilization process indicator, biological

Product Type	Single Device Product	Effective Date	16/07/2024
GMDN	13732 Sterilization process indicator, biological		
Intended Purpose	A VHP (Vaporized Hydrogen Peroxide) Biological Indicator is used to validate and monitor the effectiveness of VHP sterilization/decontamination processes in healthcare and pharmaceutical settings. It ensures that sterilization/decontamination procedures effectively eliminate microbial life, including highly resistant bacterial spores.		

Specific Conditions

No Specific Conditions included on Record

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