



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	414815	BES Group (AUST) Pty Ltd - Medical device cleaning agent
ARTG entry for	Medical Device Included Class 1	
Sponsor	BES Group (AUST) Pty Ltd	
Postal Address	Unit 5 / 2 Denmark Stret, Kew, VIC, 3101 Australia	
ARTG Start Date	28/07/2023	
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
BES Group Yantai United Ozonetec Corporation	4F 1 Wuzhishan Road Yantai Intelligent Manufacturing Industrial Park ETDZ , Yantai Shandong Province, 264006 China

Products

1 . Medical device cleaning agent

Product Type	Single Device Product	Effective Date	28/07/2023
GMDN	63385 Medical device cleaning agent		
Intended Purpose	This is a water based substance that contains ozone generated within a tumbler that is intended to be used to clean soiled medical, dental and/or surgical instruments/devices as a pre-cleaning and/or cleaning to remove blood proteins and other organic compounds (decontamination) prior to disinfection or a sterilization process.		

Specific Conditions

No Specific Conditions included on Record

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