



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

BES Group (AUST) Pty Ltd

for approval to supply

BES Group (AUST) Pty Ltd - Medical device cleaning agent

ARTG Identifier	414815
ARTG Start Date	28/07/2023
Product Category	Medical Device Included Class 1
GMDN	63385
GMDN Term	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.

Manufacturer Details	Address	Certificate number(s)
BES Group Yantai United Ozonetec Corporation	4F 1 Wuzhishan Road Yantai Intelligent Manufacturing Industrial Park ETDZ , Yantai Shandong Province , 264006 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. Medical device cleaning agent

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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