



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Key Business Group Pty Ltd

for approval to supply

Key Business Group Pty Ltd - Ozone generator, portable

ARTG Identifier	344041
ARTG Start Date	22/09/2020
Product Category	Medical Device Included Class 1
GMDN	46087
GMDN Term	Ozone generator, portable
Intended Purpose	A portable, mains electricity (AC-powered) device used to create and deliver ozone (O3) - also known as trioxygen. It produces a high electrical voltage between electrodes, to convert oxygen (O2) into O3 when passed through the electrode gap. It is used at the site of application due to the short half life of ozone. Aqueous Ozone is used for various purposes, to disinfect hard non porous surfaces, and is ideal in clinical settings requiring non toxic outcomes.

Manufacturer Details	Address	Certificate number(s)
ENOZO TECHNOLOGIES INC	300 Willow Street North Andover , MA , 0184 5 United States Of America	

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. Ozone generator, portable

Product Specific Conditions

No specific conditions have been recorded against this entry.

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