



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**STERIFLEX PTY LTD**

for approval to supply

## STERIFLEX PTY LTD - Sterilizer, gas, ethylene oxide

<b>ARTG Identifier</b>	341490
<b>ARTG Start Date</b>	13/08/2020
<b>Product Category</b>	Medical Device Included Class IIb
<b>GMDN</b>	13740
<b>GMDN Term</b>	Sterilizer, gas, ethylene oxide
<b>Intended Purpose</b>	To be used to sterilise heat and moisture sensitive medical devices

Manufacturer Details	Address	Certificate number(s)
Andersen Sterilizers Inc	3154 Caroline Drive Health Science Park Haw River , NC , 27258 United States Of America	DV-2020-MC-16028-1

### ARTG Standard Conditions

The above Medical Device Included Class IIb 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. Sterilizer, gas, ethylene oxide

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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