



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Medtronic Australasia Pty Ltd**

for approval to supply

**Medtronic Australasia Pty Ltd - Spirometer, incentive**

<b>ARTG Identifier</b>	294782
<b>ARTG Start date</b>	7/10/2017
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	31266
<b>GMDN Term</b>	Spirometer, incentive
<b>Intended Purpose</b>	The device is intended for exercising the inspiratory muscles only. No other use is intended or implied. The device is not intended for use by persons with reduced physical, sensory or mental capabilities, unless they have been given supervision or instruction concerning the use of the appliance by a person responsible for their safety. The device is not suitable for children under 7; it is intended for children in the age group of 8-16 under adult supervision.

Manufacturer Details	Address	Certificate number(s)
POWERbreathe International Limited UK	Northfield Road Southam, Warwickshire, CV470FG United Kingdom	

### 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. Spirometer, incentive

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
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