



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	354076	Scott Airway Management - Endoscopic bite block, oxygenating
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	Scott Airway Management	
<b>Postal Address</b>	42 Beeston Street, Teneriffe, QLD, 4005 Australia	
<b>ARTG Start Date</b>	2/02/2021	
<b>Product Category</b>	Medical Device Class 1	
<b>Status</b>	Active	
<b>Approval Area</b>	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
Suzhou GZM Medical Co Ltd	Room 1612 Building 8 Shi Shan Tian Jie Living Plaza New District Suzhou, Jiang Su, 215011 China

**Products**

1 . Endoscopic bite block, oxygenating			
Product Type	Single Device Product	Effective Date	2/02/2021
<b>GMDN</b>	47162 Endoscopic bite block, oxygenating		
<b>Intended Purpose</b>	A dual-purpose device that is inserted into a patient's mouth to maintain patency during an endoscopic or bronchoscopic procedure to primarily protect the endoscope or bronchoscope being introduced via the mouth; this is due to some patient's natural reflex to resist and bite down on the endoscope, thereby causing damage. It will also assist to protect the tongue and teeth of the patient during the procedure, assist in guiding the endoscope or bronchoscope and simultaneously provide the patient with an uninterrupted flow of oxygen (O2) during the procedure, and after the endoscopy, if necessary. It has a gas sample line that enables monitoring of the expired carbon dioxide (CO2) during the procedure. The device may include an airway, one-way valve or other component. This is a single-use device.		

**Specific Conditions**  
No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary