



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	405516	AMBU Australia Pty Ltd - Resuscitator, pulmonary, manual, single use
<b>ARTG entry for</b>	Medical Device Included Class IIb	
<b>Sponsor</b>	AMBU Australia Pty Ltd	
<b>Postal Address</b>	2/1 Prosperity Parade, WARRIEWOOD, NSW, 2102 Australia	
<b>ARTG Start Date</b>	28/02/2023	
<b>Product Category</b>	Medical Device Class IIb	
<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
Ambu AS	Baltorpbakken 13 Ballerup, , DK-2750 Denmark

### Products

#### 1 . Resuscitator, pulmonary, manual, single use

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	28/02/2023
<b>GMDN</b>	36086 Resuscitator, pulmonary, manual, single use		
<b>Intended Purpose</b>	Single use resuscitator intended for manual pulmonary resuscitation and emergency respiratory support for neonates, infants, children and adults.		

### Specific Conditions

No Specific Conditions included on Record

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