



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

## Public Summary

**Summary for ARTG Entry:** 353365 A R Medicom Australia Pty Ltd - Sterilization packaging, single-use

**ARTG entry for** Medical Device Included Class 1

**Sponsor** A R Medicom Australia Pty Ltd

**Postal Address** PO Box 226, THORNLEIGH, NSW, 2120  
Australia

**ARTG Start Date** 20/01/2021

**Product Category** Medical Device Class 1

**Status** Active

**Approval Area** 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
Medicom Asia-Pacific Holdings Limited Taiwan Branch	11 Sec 2 Ligong 1st Road Wujie Township Yilan County, , 26841 Taiwan

### Products

#### 1 . Sterilization packaging, single-use

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	20/01/2021
<b>GMDN</b>	13735 Sterilization packaging, single-use		
<b>Intended Purpose</b>	This is a device that is intended to be used to enclose (Wrap) medical devices that are to be sterilized. It is designed to allow sterilization of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device.		

### Specific Conditions

No Specific Conditions included on Record

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