



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**AMBU Australia Pty Ltd**

for approval to supply

## **AMBU Australia Pty Ltd - Cervical spine collar, single-use**

<b>ARTG Identifier</b>	391114
<b>ARTG Start Date</b>	22/06/2022
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	45129
<b>GMDN Term</b>	Cervical spine collar, single-use
<b>Intended Purpose</b>	The Ambu Perfit Collar is a one-piece rigid cervical spine immobilisation device designed to assist the rescuer with the maintenance of neutral alignment, prevention of lateral (side to side)sway and anterior-posterior (forward and backward) flexion and extension of the cervical spine during patient transport or movement

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup , , DK-2750 Denmark	

### **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. Cervical spine collar, single-use**

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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