



# Australian Register of Therapeutic Goods Certificate

Issued to

**The Weringa Group Pty Ltd**

for approval to supply

**The Weringa Group Pty Ltd - Surgical depth gauge, single-use**

<b>ARTG Identifier</b>	386890
<b>ARTG Start Date</b>	8/04/2022
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	58796
<b>GMDN Term</b>	Surgical depth gauge, single-use
<b>Intended Purpose</b>	A sterile depth gauge measuring device intended for various medical purposes including but not limited to, measuring the depth of a passageway (ie drill hole) in a bone or other tissue to enable insertion of properly sized screws and implants. When the gauge tip makes contact with the bottom of hole a reading is digitally displayed. This is single use device.

Manufacturer Details	Address	Certificate number(s)
Edge Surgical Inc	222 W Merchandise Mart Plz #1230 Chicago , IL , 60654 United States Of America	DV-2022-MC-08239-1

## ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Surgical depth gauge, single-use

## Product Specific Conditions

No specific conditions have been recorded against this entry.