



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Columbo Australia Pty Ltd**

for approval to supply

## **Columbo Australia Pty Ltd - MRI system, application program software**

<b>ARTG Identifier</b>	406931
<b>ARTG Start Date</b>	28/03/2023
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	40872
<b>GMDN Term</b>	MRI system, application program software
<b>Intended Purpose</b>	The purpose of the device is to assist in reading MR lumbar spine images and providing information on detected pathologies and abnormalities, as well as reducing the time to write the report. The results are reviewed and confirmed by a radiologist.

Manufacturer Details	Address	Certificate number(s)
Smart Soft Ltd	113 Gen Kolev Str Suite 7.3 , Varna , 9000 Bulgaria	DV-2022-MC-29362-1

### **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. MRI system, application program software**

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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