Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

KD & A Pty Ltd

for approval to supply

KD & A Pty Ltd- Surgical simulation system

ARTG Identifier	335022
ARTG Start Date	24/04/2020
Product Category	Medical Device Included Class IIa
GMDN	61486
GMDN Term	Surgical simulation system
Intended Purpose	ADAS 3D is indicated for use in clinical settings to support the visualization and analysis of MR and CT images of the heart on individual patients with cardiovascular disease. ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease. ADAS 3D processes MR and CT images. The quality and the resolution of the medical images determines the accuracy of the data produced by ADAS 3D. ADAS 3D is indicated to be used only by qualified medical professionals (cardiologists, electrophysiologists, radiologists or trained technicians) for the calculation, quantification and visualization of cardiac images and intended to be used for pre-planning and during electrophysiology procedures. The data produced by ADAS 3D must not be used as an irrefutable basis or a source of medical advice for clinical diagnosis or patient treatment. The data produced by ADAS 3D is intended to be used to support qualified medical professionals for clinical decision making. The clinical significance of using ADAS 3D to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) or risk stratification has not been established.

Manufacturer Details	Address	Certificate number(s)
ADAS3D Medical SL	Rambla Catalunya 53 4-H , Barcelona , 08007 Spain	DV-2021-MC-13006-1

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 simulation system

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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