



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

KD & A Pty Ltd

for approval to supply

KD & A Pty Ltd - X-ray image interpretive software

ARTG Identifier	329185
ARTG Start date	28/01/2020
Product Category	Medical Device Included Class IIa
GMDN	63386
GMDN Term	X-ray image interpretive software
Intended Purpose	The Oxipit ChestEye software is intended to support trained radiologists when reporting on chest X-ray images. The final report must be approved by a trained radiologist. The software is a fully automatic computer assisted diagnosis solution. Based on collected data (deep neural network) the software analyses a given chest X-ray image. By function, ChestEye consists of three parts: ChestEye CAD, ChestEye Queue, and ChestEye Search. The software detects 75 radiological findings.

Manufacturer Details	Address	Certificate number(s)
Oxipit UAB	Sauletekio al 15 , Vilnius, 10224 Lithuania	DV-2019-MC-20900-1

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. X-ray image interpretive software

Product Specific Conditions

No specific conditions have been recorded against this entry.

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