



Classification Recommendation

This document serves to recommend that the following product:

Envisionit Deep AI - RADIFY

GMDN Code: 60724

GMDN term: Medical image management system application software

Has a recommended classification of:

Class A – Medical Device

In terms of Rule 12 of Guideline: 8.05 Classification Medical Devices IVDs Apr17 v2, as issued by the South African Health Products Regulatory Authority

Based on the characteristics of the device being a non-invasive, active device for recording, processing or viewing of diagnostic images.

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Issue Date: 23/04/2020

Valid Until: 23/04/2022

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