



Classification Recommendation

This document serves to recommend that the following product:

Envisionit Deep AI - RADIFY

GMDN Code: 63386

GMDN Term: X-ray image interpretive software

Has a recommended classification of:

Class A – MEDICAL DEVICE

In terms of Rule 12 of Guideline: 8.05 Classification Medical Devices IVDs August21_v5, 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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Authorised Representative

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