

CERTIFICATE OF ACCREDITATION

In terms of section 22(2) (b) of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), read with sections 23(1), (2) and (3) of the said Act, I hereby certify that:-

TECMED AFRICA (PTY) LTD
Co. Reg. No.: 1998/021499/07
MIDRAND

Facility Accreditation Number: **XRAY0015**

is a South African National Accreditation System Accredited Inspection Body to undertake **TYPE C** inspection provided that all SANAS conditions and requirements are complied with

This certificate is valid as per the scope as stated in the accompanying schedule of accreditation, Annexure "A", bearing the above accreditation number for

THE INSPECTION OF DIAGNOSTIC X-RAY IMAGING SYSTEMS

The facility is accredited in accordance with the recognised International Standard

ISO/IEC 17020:2012

The accreditation demonstrates technical competency for a defined scope and the operation of a management system

While this certificate remains valid, the Accredited Facility named above is authorised to use the relevant SANAS accreditation symbol to issue facility reports and/or certificates

Mr R Josias
Chief Executive Officer

Effective Date: 09 May 2020
Certificate Expires: 08 May 2024

This certificate does not on its own confer authority to act as an Approved Inspection Authority as contemplated in the Hazardous Substances Act. Approval to inspect within the regulatory domain is granted by the Department of Health

ANNEXURE A

SCOPE OF ACCREDITATION

Accreditation Number: XRAY0015

TYPE C

<p><u>Permanent Address:</u> Tecmed Africa (Pty) Ltd Tecmed Centre George Road Erand Gardens Midrand 1685</p> <p>Tel: (011) 653-2000 Fax: (011) 653-2100 E-mail: melaniep@tecmed.co.za</p>		<p><u>Postal Address:</u> P O Box 4229 Halfway House 1685</p> <p>Issue No.: 10 Date of Issue: 22 April 2020 Expiry Date: 08 May 2024</p>
<p><u>Nominated Representative:</u> Ms M Pretorius</p>	<p><u>Quality Manager:</u> Ms M Pretorius</p> <p><u>Technical Managers:</u> Mr MT Fox (Jhb) Mr G Scopel (Jhb) Mr B Naude (PE) Mr S Zondi (Durban) Mr BJ Grove (NC/FS)</p>	<p><u>Technical Signatories:</u> Mr MT Fox (7) Mr W Lipke (7) Mr G Scopel (3, 4, 5 & 6) Mr B Naude (3, 4, 5 & 6) Mr PW Molefe (8 & 9) Mr P Smit (8 & 9) Mr BJ Grove (3, 4, 5 & 7)</p>
Field of Inspection	Service Rendered	Codes and Regulations
<p><u>Regulatory:</u> The supply of services as an Inspection Authority for the Inspection and Test of diagnostic X - Ray Imaging Systems as defined in the Department of Health's License conditions for Diagnostic X-Ray Imaging Systems Hazardous Substances Act No: 15 of 1973 as Amended</p>	<p>Functional test and verification of the Following:</p> <ol style="list-style-type: none"> 1. Reporting Monitors; (tests 29, 31, 32, 119, 119.1, 119.2, 120, 121, 122, 190, 191, 193, 194, 195, 196, 197) 3. X-RAY Tubes and Generators – Conventional Film systems; (tests 1-17, 28, 33-36, 75-89, 115-118) 4. Computerised Radiography Reader - (tests 18-20, 23, 29-35, 90-101, 119-122) 5. Direct Digital Radiography System, (tests 1-8, 24-25, 27, 29-36, 75-84, 102-114, 119-122) 6. Fixed Fluoroscopy Equipment (tests 1-3, 37-42, 75, 79-84, 123-124, 126-139.1, 215, 216) 7. Computed Tomography (tests 1-3, 29-32, 36, 46-49, 75, 119-122, 140-146) 8. Screen film Mammography (tests 1, 10-17, 28, 50-55, 69-75, 116-117, 147-163) 9. Digital Mammography (tests 1, 56-75, 119-122, 164-214) 	<p>Reg-16-0002 - Tecmed IB Test Procedure Register QP-26-0001 – Inspection Procedure</p>

Original Date of Accreditation: 09 May 2012

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ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

Accreditation Manager