

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:

GENDENT SA (PTY) LTD Co. Reg. No.: 2012/167714/07 DURBAN

Accreditation Number: XRAY0018

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 scope 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 T Baleni

Mr I Baleni
Acting Chief Executive Officer

Effective Date: 13 June 2023 Certificate Expires: 29 October 2026

This certificate does not on its own confer authority to act as an Inspection Body as contemplated in the Hazardous Substance Act. Approval to inspect within the regulatory domain is granted by the South African Health Professions Authority.



ANNEXURE A

SCOPE OF ACCREDITATION

Accreditation Number: XRAY0018

TYPE C

Permanent Address: Gendent SA (Pty) Ltd 30 Michigan Street Monteseel Durban 3670

Postal Address: P O Box 339 Monteseel Durban 3670

Tel: E-mail:

063 476-3407

inspection@gendentsa.co.za

info@gendentsa.co.za

Issue No.:

Date of issue: Expiry date:

13 June 2023 29 October 2026

Nominated Representative:

Mrs G Swart

Quality Manager:

Ms CA Wollentine

Technical Manager:

Mr J Wollentine

Inspectors: Mr J Wollentine Mr G Wollentine Mrs G Swart Mr S Lombard

Technical Signatories:

Mr G Wollentine Mr J Wollentine

Field of Inspection

Service Rendered

Codes and Regulations

Regulatory:

The supply of services as an Inspection Body for the Inspection and Test of Diagnostic X-Ray Imaging Systems as defined in the South African Health Professions Authority (SAHPRA) Licence conditions for Diagnostic X-Ray Imaging Systems

Hazardous Substances Act No.: 15 of 1973 as Amended

Functional test and verification of the following:

Reporting Monitors; (Tests 18, 20, 1. 72-76, 78)

10.1 Dental X-ray equipment (tests 1-8, 10, 11, 12, 15, 16, 17, 21-23, 39, 40-46, 48-52, 66-69.

10.2 Digital Dental X-ray equipment (tests 1-8, 10, 18, 20-23, 32, 33, 36, 38, 39, 40-46, 48-52, 72, 74, 75, 76, 78, 81-87, 94-99)

10.3 Cone Beam CT (tests 1, 18, 20, 24, 28-30, 39, 52, 53-57, 60-65, 72-76)

Inspection methods and procedures as per Inspection Body's field of activity:

MAN - CTPC Procedure Manual

Original date of accreditation: 30 October 2014

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ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

Accreditation Manager