Department of Health

Radiation Control

LICENCE TO PERFORM MAINTENANCE TESTS ON DIAGNOSTIC X-RAY IMAGING SYSTEMS HAZARDOUS SUBSTANCES ACT (ACT 15 OF 1973)

Licence Number: 1015 SANAS Acreditation Number: XRAY0015

LICENCE HOLDER

Tecmed Africa (Pty) Ltd
Tecmed Centre, George Road, Erand Gardens
Midrand

QUALITY MANAGER: Ms M Pretorius

This licence is subject to the following conditions and replaces the licence dated 19 January 2018 and all previous licences.

a. Acceptance and/or routine quality control tests must be performed in accordance with the requirements as listed in table 2 of document DIAGNOSTIC QC or DIAGNOSTIC ACCEPTANCE DENTAL. (https:/sites.google.com/site/radiationcontroldoh/);

a.1. Results of the acceptance and/or routine quality control tests must be documented and a copy of these results must be handed to the licence holder of the diagnostic x-ray imaging equipment for filing on the Individual Equipment Record;
a.2. The copy of the results must at least include the measurements (raw data), Date of test(s), Summary of the results (pass or fail), Identification of product, Details of the person(s) that performed the tests, and Details of the Inspection Body, including Department of Health licence number and SANAS reference number.

b. Should any of the tests indicate non-compliance, the licence holder must be informed that corrective maintenance (repairs) should immediately be implemented, followed by re-testing;

c. The Inspection Body must verify evidence during routine inspections that the licence holder has performed the routine quality control tests in section III.1. of table 2 of document DIAGNOSTIC QC;

d. The Inspection Body must submit to the Director: Radiation Control on a monthly basis all QC and repair tests which were performed during the preceding month. Acceptance tests must immediately be submitted after completion. Document: Electronic submission of Acceptance & QC tests must be used for this purpose and in electronic format be submitted to electronic.submissions@gmail.com;

d.1 Diagnostic Reference Levels listed in table 5 (section III.2.15.) must be included on the document Electronic submission of Acceptance & QC tests.

d.1.1. Results for section III.2.15.1, section III.2.15.2 and section III.2.15.3 must be reported from February 2015;
d.1.2. Results for section III.2.15.4 must be reported from March 2015, and
d.1.3. Results for section III.2.15.4.1 must be reported from October 2015.

e. The Department of Health, as the regulatory body, gives permission that an individual person from a Type C Inspection Body may undertake the design and/or manufacture and/or supply and/or installation and/or servicing and/or maintenance as well as the inspection (acceptance and QC tests) of a diagnostic x-ray imaging system;

f. The Inspection Body must comply with all the requirements of the latest TR78 document of SANAS and ISO17020;

g. The Inspection Body must ensure that they obtain accreditation status from SANAS within the prescribed timescale and must maintain their accreditation with SANAS.

h. The Inspection Body must keep a detailed record of all technical work performed in the regulatory domain under
their accreditation application. In the event that the facility fails to demonstrate their technical competence, all work performed in the regulatory domain will be deemed as un-accredited work. The facility will be responsible to ensure that all work performed in the regulatory domain is redone by an appropriately accredited facility, at the cost of the Inspection Body, to ensure that the health and safety of the public is not compromised.

i. In terms of section 4(1)(b) of the Hazardous Substances Act, 1973 (act 15 of 1973) the licence holder is licenced to perform the following:

i.1. Maintenance tests (Acceptance and routine quality control tests)

X-Ray tubes and generators (3)
CR Readers (4)
DDR System (5)
Fluoroscopy systems - Mobile and Fixed (6)
Computed tomography systems (7)
Mammography - screen film systems (8)
Mammography - digital systems (9)

i.2. By these personnel:

TECHNICAL SIGNATORIES	Functional tests
Fox M	7
Scopel G	3,4,5 & 6
Lipke W	7
Naude B	3,4,5,6 & 7
Molefe PW	8 & 9
Smit P	8 & 9

INSPECTORS	Functional tests
Nieuwoudt E	3 & 6
Molefe W	3,4,5 & 6
Meintjies J	3,5 & 6
Bera A	4
van Huyssteen W	3,4,5 & 6
Grove B	3, 4, 5 & 7
Dirker P	3, 4 & 5
Snyman J	3 & 6
Truter H	3, 4 & 5
Marais W	3, 4, 5 & 6
van Niekerk G	7
du Toit F	7
Smit P	3, 4 & 5

j. Should any of the information contained in this licence change, a new completed IB scope form must be submitted.

k. From the 1st July 2012 acceptance and routine quality control tests may only be performed by the following personnel;

k.1 Technical Signatories, OR
k.2 Technical Signatories and Inspectors provided that a medical physicist is employed (full time or part time)

by the Inspection Body and the competence of the Inspectors is verified by the Medical Physicist on a regular basis and such evaluations are documented. The Inspection Body may only permit an Inspector to perform a functional test after the Medical Physicist declares that the Inspector is competent to perform the functional test.

Signed at Bellvile on **23 July 2018**

for DIRECTOR-GENERAL: HEALTH