

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:-

**SOUTH AFRICAN CERTIFICATION AND AUDITING
SERVICES (PTY) LTD (SACAS)
Co. Reg. No.: 2013/067785/07**

Facility Accreditation Number: **C59h**

is a South African National Accreditation System accredited facility
provided that all SANAS conditions and requirements are complied with

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

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

The facility is accredited in accordance with the recognised International Standard

ISO/IEC 17021-1:2015

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

**Mr F Osman
Acting Chief Executive Officer**

**Effective Date: 31 January 2025
Certificate Expires: 01 November 2028**

ANNEXURE A

SCOPE OF ACCREDITATION

Facility Number: **C59h**

Permanent Address of Facility:

SACAS-South African Certification and
Auditing Services (Pty) Ltd
6 Rabie Street
Prime Business Park
Unit 14
Vanderbijlpark
1911

Management Signatory:

Mr P du Toit

Postal Address:

P O Box 1290
Vanderbijlpark
1900

Nominated Representative:

Mr P du Toit

Tel: (016) 931 2001

Fax: 086 655 7255

E-mail: pedru@sacas.co.za

Issue No.:

07

Date of Issue:

31 January 2025

Expiry Date:

01 November 2028

South African Certification and Auditing Services (Pty) Ltd complies with the accreditation criteria for certification bodies as laid down in ISO/IEC 17021-1:2015 and authorised to certify organisations to ISO 13485:2016 (Medical Devices Quality Management Systems-Requirements) in the following industrial sector:

IAF MD 9: 2017 Scope Reference	Technical/Area
1.1 Non-active medical devices (Non-active implants)	General non-active, non implantable medical devices Devices for wound care Non-active implants
1.2 Active (non-implantable) medical devices	General active medical devices
1.4 In Vitro Diagnostic medical devices	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology), Haematology/ Haemostasis/Immunohematology, Microbiology, Infectious Immunology, Histology/Cytology, Genetic Testing
1.5 Sterilization Methods for medical devices	Ethylene oxide gas sterilization -EOG Moist heat
1.7 Parts and services	Distribution services, Maintenance services and transportation services Packaging services

Original date of Accreditation: 22 November 2019

ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

Accreditation Manager