

# SABS

## *Permit to Apply Certification Mark*

Subject to the provisions of the Standards Act, 2008  
(Act 8 of 2008), the relevant regulations made thereunder and the permit  
conditions contained in the under mentioned schedules, this permit authorizes

**AKACIA MEDICAL (PTY) LTD  
(TRADING AS CLINISUT)  
Co Reg. 1997/014984/07  
PORT ELIZABETH**

to apply the certification mark



in respect of the mark specification

**SANS 494-1:2011  
TO: SURGICAL MEDICAL DEVICES USED FOR WOUND  
CLOSURE  
PART 1: STERILE SUTURES AND LIGATURES**

This permit, including the schedules 1 to 3 which form an integral part thereof:

- is issued without alteration;
- is identified by the applicable permit number;
- is subject to any condition or limitation contained therein;
- is valid subject to ongoing compliance with permit conditions;
- bears the embossed SABS Commercial seal. In the absence of the seal, the permit and the schedules shall be invalid; and
- the permit may be authenticated by referring to the register of "Certified Clients" on the SABS Commercial website ([www.sabs.co.za](http://www.sabs.co.za))
- Scheme Type 5 permit applies to products that have been tested.

Permit Number **11058/17357**

Effective Date **01 September 2022**

Expiry Date **05 August 2025**

Date of Original Registration **06 August 2019**

Chief Executive Officer

A handwritten signature in black ink, appearing to be "S. S. S.", written over a horizontal line.



C07a

SABS COMMERCIAL SOC Ltd.  
1 Dr Lalagan Rd, Greenkloof, Pretoria,  
Republic of South Africa

AAA1005377

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## SCHEDULE TO PERMIT TO APPLY CERTIFICATION MARK

This permit is only applicable in respect of the permit holder, the factory, the mark specification, the commodity and the trade name or trade mark referred to in this schedule

**Schedule 1**

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<b>1. Permit holder</b> 1.1 Name 1.2 Name under which the business is conducted 1.3 Registration or the identity number	Akacia Medical (Pty) Ltd Clinisut 1997/014984/07
<b>2. Street address of factory at which the commodity is manufactured</b>	25 Harrower Road North End PORT ELIZABETH
<b>3. Mark Specification with which the commodity is required to comply</b>	SANS 494-1 Surgical medical devices used for wound closure Part 1: Sterile sutures and ligatures
<b>4. Description of commodity to which the certification mark may be applied, and Brand name or Trade mark which may be used in conjunction with the certification mark</b>	Sterile sutures and ligatures Sutures CliniMonoQ - Sterile beige monofilament synthetic Poly (Glycolide-Co-Caprolactone) absorbable sutures Sutures CliniTro - Sterile Monofilament Non - Absorbable Polyvinylidene Fluoride Sutures CliniLene √ Synthetic monofilament polypropylene non absorbable sutures Sutures CliniLon - Sterile monofilament nylon Non-absorbable sutures Sutures CliniSolv √ Sterile monofilament Synthetic Poly (P-Dioxanone) Absorbable Sutures CliniEster - Sterile Braided Polyester non-absorbable sutures Sutures & Ligatures CliniSorb - Sterile Braided Polyglycolic Acid Absorbable Sutures & Ligatures Sutures & Ligatures CliniSorbQ - Sterile Braided Polyglycolic Acid Synthetic Rapid Absorbable Sutures & Ligatures CliniSilk - Sterile Black Braided Silk non-absorbable sutures and ligatures Sutures & Ligatures CliniGut Plain √ Sterile Plain Catgut Absorbable Sutures and Ligatures Sutures & Ligatures CliniLin - Sterile Linen non-absorbable sutures and ligatures Sutures & Ligatures CliniGut Chromic - Sterile Chromic Catgut absorbable sutures and Ligatures CliniStern- Sterile Stainless steel monofilament non-absorbable suture
<b>5. Quality management system with which consistent compliance is required</b>	

**SCHEDULE TO PERMIT TO APPLY CERTIFICATION MARK**Schedule 1  
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The quality management system relating to the production of the commodities identified in section 3 and 4 of this schedule must consistently meet the requirements of the nominated product specification, the requirements for a product certification system 5 certification scheme as per ISO 17067 and requirements of the general and specific permit conditions as detailed in schedules 2 and 3 of the permit



**SCHEDULE TO PERMIT TO APPLY CERTIFICATION MARK**

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**Schedule 1**

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**Record of amendments to permit**

Original date of issue : 2019-08-06

**Amendments**

2022-03-30	CliniStern- Sterile Stainless steel monofilament non-absorbable suture
2022-09-01	a) Permit reissued with a new triennial expiry date b) Post permit audit date 26 July 2022 c) Last permit expiry date 05 August 2022