

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

SYNTHECON SUTURES MANUFACTURING SA CC

Co Reg. 2006/004193/23

JOHANNESBURG

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 schedule 1 to 3 which forms 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 schedule 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)
- Scheme Type 5 permit applies to products that have been tested.

Permit Number

10817/16997

Effective Date

26 February 2024

Expiry Date

22 February 2027

Date of Original Registration

23 February 2018

Chief Executive Officer

A handwritten signature in black ink, consisting of a stylized 'D' followed by a series of loops and a horizontal line.



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

A43 0009962

SABS

Permit number

10817/16997

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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1. Permit holder 1.1 Name 1.2 Name under which the business is conducted 1.3 Registration or the identity number	Synthecon Sutures Manufacturing SA CC Synthecon Sutures Manufacturing SA CC 2006/004193/23
2. Street address of factory at which the commodity is manufactured	1 Power Road Isando JOHANNESBURG
3. Mark Specification with which the commodity is required to comply	SANS 494-1 Surgical medical devices used for wound closure Part 1: Sterile sutures and ligatures
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	Sterile sutures and ligatures Absorbable sutures SYNTHECON, SYNTHABS SYNTHECON PDO SYNTHECON MOCRYL SYNTHECON SYNCRYL Non-Absorbable sutures SYNTHECON SILK SYNTHECON NYLON SYNTHECON SYNCRON SYNTHECON SYNLENE Twisted Absorbable sutures SYNTHECON PLAIN CATGUT SYNTHECON CHROMIC CATGUT
5. Quality management system with which consistent compliance is required	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

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Schedule 1

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Record of amendments to permit

Original date of issue : 2018-02-23

Amendments

- | | |
|------------|---|
| 2021-06-04 | a) Permit reissued with a new triennial expiry date |
| | b) Reissue audit date 17 February 2021 |
| | c) Last Permit expiry date 23 February 2021 |
| 2024-02-26 | a) Permit reissued with a new triennial expiry date |
| | b) Reissue audit date 16 October 2023 |
| | c) Last Permit expiry date 22 February 2024 |
| | d) Removal of brand Medinox |