

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 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)
- Scheme Type 5 permit applies to products that have been tested.

Permit Number **10817/16997**

Effective Date **04 June 2021**

Expiry Date **22 February 2024**

Date of Original Registration **23 February 2018**

Chief Executive Officer

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



C07a

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

AAA1005121

0087M

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

Page 1 of 3

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 Non-Absorbable sutures SYNTHECON SILK Twisted Absorbable sutures SYNTHECON PLAIN CATGUT Absorbable sutures SYNTHECON SYNCRYL Absorbable sutures SYNTHECON MOCRYL Non-Absorbable sutures MEDINOX Twisted Absorbable sutures SYNTHECON CHROMIC CATGUT Non-Absorbable sutures SYNTHECON NYLON Absorbable sutures SYNTHECON PDO Non-Absorbable sutures SYNTHECON SYNCRON Non-Absorbable sutures SYNTHECON SYNLENE
5. Quality management system with which consistent compliance is required	

SCHEDULE TO PERMIT TO APPLY CERTIFICATION MARK**Schedule 1**

Page 2 of 3

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

Page 3 of 3

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