ISBN 978-0-626-32335-6

SANS 53795:2015
Edition 1 (incorporating EN amdt 1)
EN 13795:2011
Edition 2 (incorporating amdt 1)

SOUTH AFRICAN NATIONAL STANDARD

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

This national standard is the identical implementation of EN 13795:2011 (which incorporates EN amendment 1), and is adopted with the permission of CEN, Avenue Marnix 17, B-1000 Brussels.

WARNING
This document references other documents normatively.

Published by SABS Standards Division
1 Dr Lategan Road Groenkloof ✉ Private Bag X191 Pretoria 0001
Tel: +27 12 428 7911 Fax: +27 12 344 1568
www.sabs.co.za

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Table of changes

Change No.	Date	Scope
EN amdt 1	2013	Amended to add an annex on the relationship between this European standard and the essential requirements of EU Directive 93/42/EEC on medical devices.

National foreword

This South African standard was approved by National Committee SABS/TC 038/SC 03, *Textiles – Medical textiles*, in accordance with procedures of the SABS Standards Division, in compliance with annex 3 of the WTO/TBT agreement.

This document was approved for publication in December 2015.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13795:2011+A1

February 2013

ICS 11.140

Supersedes EN 13795:2011

English Version

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux pour les patients, le personnel et les équipements - Exigences générales pour les fabricants, les prestataires et les produits, méthodes d'essai, exigences et niveaux de performance

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Allgemeine Anforderungen für Hersteller, Wiederaufbereiter und Produkte, Prüfverfahren und Gebrauchsanforderungen

This European Standard was approved by CEN on 5 February 2011 and includes Amendment 1 approved by CEN on 8 January 2013.

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Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 13795:2011+A1:2013: E

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Foreword

This document (EN 13795:2011+A1:2013) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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This document ⟦A1⟩ supersedes EN 13795:2011 ⟨A1⟧.

This document includes Amendment 1 approved by CEN on 2013-01-08.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟦A1⟩ ⟨A1⟧.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Annex A provides details of significant changes between this European Standard and the previous edition represented by the three parts mentioned above.

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