



SLOVENSKI STANDARD
SIST EN 13795-2:2005/kprA1:2009
01-april-2009

CdYfUMY'g_Udc_fj UŁdfY[f]b'UU]b'd'Uy]'hYf']gHJcV'U]UŁ_]gYi dcfUV'Uc' _ch
a YX]W]bg_]df]dca c _]nUdUMY]bHYZnXfUj ghj Ybc`cgYV'Y']b'cdfYa c'!'&"XY.
DfYg_i gbY'a YfcXY

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 2: Test methods

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 2: Prüfverfahren

Champs chirurgicaux, casaques et tenues de blocs, utilisés comme dispositifs médicaux, pour les patients, le personnel médical et les équipements - Partie 2: Méthodes d'essai

Ta slovenski standard je istoveten z: EN 13795-2:2004/FprA1

ICS:

11.140 Oprema bolnišnic Hospital equipment

SIST EN 13795-2:2005/kprA1:2009 en,fr

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
EN 13795-2:2004

FprA1

February 2009

ICS 11.140

English Version

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This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A1, if approved, will modify the European Standard EN 13795-2:2004. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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EN 13795-2:2004/FprA1:2009 (E)

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Foreword

This document (EN 13795-2:2004/FprA1:2009) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

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

1 Modification to Annex ZA

Replace the existing Annex ZA with the following:

"

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on Medical Devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1	7.1	EN 13795-2 is intended to be used in conjunction with EN 13795-1 and EN 13795-3
5.1	8.1, 8.5	
5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9	1, 3, 4, 5, 7.1, 8.1	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."