# SLOVENSKI STANDARD
# SIST EN 13795-3:2006/kprA1:2009

**01-april-2009**

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**Operacijska pokrivala, pregrinjala in plaģļ i ter ļ ista oblaļ ila, ki se uporabljajo kot medicinski pripomoļ ki za paciente, zdravstveno osebje in opremo - 3. del: Zahtevane lastnosti in zahtevane stopnje**

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 3: Performance requirements and performance levels

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 3: Gebrauchsanforderungen und Leistungsstufen

Champs chirurgicaux, casaques et tenues de bloc utilisés en tant que dispositifs médicaux pour les patients, le personnel et les équipements - Partie 3 : Exigences et niveaux de performance

**Ta slovenski standard je istoveten z:** **EN 13795-3:2006/FprA1**

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**ICS:**

| | | |
|---|---|---|
| 11.140 | Oprema bolnišnic | Hospital equipment |

**SIST EN 13795-3:2006/kprA1:2009** **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# FINAL DRAFT
# EN 13795-3:2006

## FprA1

February 2009

ICS 11.140

English Version

# Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 3: 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 - Partie 3 : Exigences et niveaux de performance

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 3: Gebrauchsanforderungen und Leistungsstufen

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 13795-3:2006. 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

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# Foreword

This document (EN 13795-3:2006/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 (incl. Tables 1, 2, 3) | 1, 3, 4, 5, 7.1, 8.1, 8.5 | EN 13795-3 is intended to be used in conjunction with EN 13795-1 and EN 13795-2 |

For devices intended by the manufacturer to be for dual use in accordance with Article 1(6) of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 89/686/EC on Personal Protective Equipment and their corresponding clauses of this European Standard. Table ZA.2 however, does not imply any citation in the OJEU under the PPE directive and thus does not provide presumption of conformity for the PPE directive.

**Table ZA.2 — Relevant Essential Requirements from Directive 89/686/EEC on Personal Protective Equipment that are addressed by this European Standard**
(according to article 1 (6) of amended Directive 93/42/EEC)

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 89/686/EEC | Qualifying remarks/Notes |
|---|---|---|
| 4 (incl. Tables 1, 2, 3) | 3.10.2 | Other basic health and safety requirements are not specifically addressed. |

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