



**SLOVENSKI STANDARD**  
**SIST EN 13795-1:2003/kprA1:2009**

**01-april-2009**

---

CdYfUM'g\_Udc\_fj UŁdfY[ f]b'UU]b'd`Uy ]'h'f' ]ghUcV'U ]UŁ\_]gYi dcfUV'Uc'\_ch  
a YX]W]bg\_]df]dca c\_]nUdUM'YbhYžnXfUj ghj Ybc`cgYV'Y']b'cdfYa c`!'%'XY.'Gd`cýbY  
nU h'j Y'nUdfc]nj U'UW'ZdfYXY'cj U'W'j]b']nXY\_Y

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Part 1: General requirements for manufacturers, processors and products

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 1: Allgemeine Anforderungen für Hersteller, Aufbereiter und Produkte

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux, pour les patients, le personnel et les équipements - Partie 1: Exigences générales pour les fabricants, les prestataires et les produits

**Ta slovenski standard je istoveten z: EN 13795-1:2002/FprA1**

---

**ICS:**

11.140      Oprema bolnišnic      Hospital equipment

**SIST EN 13795-1:2003/kprA1:2009      en,fr**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**EN 13795-1:2002**

**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 1: General requirements for manufacturers, processors and products**

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux, pour les patients, le personnel et les équipements - Partie 1: Exigences générales pour les fabricants, les prestataires et les produits

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 1: Allgemeine Anforderungen für Hersteller, Aufbereiter und Produkte

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 13795-1:2002. 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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

**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

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

**EN 13795-1:2002/FprA1:2009 (E)**

## **Foreword**

This document (EN 13795-1:2002/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 the Introduction

*Replace the 2<sup>nd</sup> paragraph with the following:*

"Surgical drapes, including the intended use as a sterile field, gowns and clean air suits are used to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent post-operative wound infections (see Annex C)."

## 2 Modification to Clause 2

*Add the following new definition 2.15 and renumber the subsequent definitions accordingly:*

"

### 2.15

#### **sterile field**

area created by sterile surgical drape material where aseptic technique is practised

NOTE A sterile field can be practised e.g. on a back table."

## 3 Modification to 5.1

*Add the following 2<sup>nd</sup> paragraph:*

"If the intended purpose of a medical device specifies the use as sterile field, the requirements for surgical drapes and equipment covers apply."

## 4 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
3.1	8.7, 13.1, 13.3*, 13.6**	EN 13795-1 is intended to be used in conjunction with EN 13795-2 and EN 13795-3
3.2, Tables 1, 2, 3	1, 3, 4, 5, 7.1, 8.1	
4	1, 2, 3, 4, 5, 7.1, 7.2, 8.1, 8.3, 8.4, 8.5	
5	3, 4, 8.1	
*) Not addressed: 13.3 subclause a, 13.3 subclause f		
**) Only partly addressed: 13.6 subclause h; not addressed: 13.6 subclause q		

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
3, 4, 5	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."