SLOVENSKI STANDARD
SIST EN 1789:2007/kprA1:2010

01-januar-2010

Medicinska vozila in pripadajoļ a oprema - Reģevalna vozila

Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Ta slovenski standard je istoveten z: **EN 1789:2007/FprA1**

ICS:

11.160	Prva pomoļ	First aid
43.160	Vozila za posebne namene	Special purpose vehicles

SIST EN 1789:2007/kprA1:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
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English Version

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 239.

This draft amendment A1, if approved, will modify the European Standard EN 1789:2007. 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

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Foreword

This document (EN 1789:2007/FprA1:2009) has been prepared by Technical Committee CEN/TC 239 “Rescue systems”, 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 EU Directive(s).

For relationship with EU 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 Union 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
6.3.2	7.3, 9.2	These relevant Essential Requirements are only partly addressed in this European Standard.
6.3.3	7.6	
6.3.4	9.2, 12.7.1, 12.7.2	These relevant Essential Requirements are only partly addressed in this European Standard.
6.3.5	9.2	This relevant Essential Requirement is only partly addressed in this European Standard.
6.3.6	4, 9.1, 9.2, 12.6	These relevant Essential Requirements are only partly addressed in this European Standard.
6.3.7	10.3	
6.3.8	7.1, 7.3, 7.5, 9.1, 9.2, 9.3, 10.1, 10.2, 10.3, 12.3	These relevant Essential Requirements are only partly addressed in this European Standard.
6.3.9	13	

General note: Ambulances are not considered to be medical devices. However, ambulances are designed to accommodate medical devices and some clauses of this standard specify requirements for devices carried and used in ambulances. Compliance with the clauses listed above and subsequent presumption of conformity with the corresponding ERs of the directive only applies to these medical devices.

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