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## Elektrisk utrustning för medicinskt bruk – Del 1-9: Allmänna fordringar beträffande säkerhet och väsentliga prestanda – Tilläggsstandard: Miljöhänsyn vid konstruktion och utveckling

*Medical electrical equipment –*

*Part 1-9: General requirements for basic safety and essential performance –*

*Collateral Standard: Requirements for environmentally conscious design*

Som svensk standard gäller europastandarden EN 60601-1-9:2008. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-9:2008.

### Nationellt förord

Europastandarden EN 60601-1-9:2008

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-1-9, First edition, 2007 - Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design**

utarbetad inom International Electrotechnical Commission, IEC.

Denna standard utgör ett tillägg till SS-EN 60601-1, Elektrisk utrustning för medicinskt bruk –  
Del 1: Allmänna fordringar beträffande säkerhet och väsentliga prestanda.

Standarden ska användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

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ICS 11.040; 13.020

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Denna standard är fastställd av SEK Svensk Elstandard,  
som också kan lämna upplysningar om **sakinnehållet** i standarden.  
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### *Standarder underlättar utvecklingen och höjer elsäkerheten*

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

### *SEK är Sveriges röst i standardiseringsarbetet inom elområdet*

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

### *Stora delar av arbetet sker internationellt*

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

### *Var med och påverka!*

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

### **SEK Svensk Elstandard**

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**Medical electrical equipment -  
Part 1-9: General requirements  
for basic safety and essential performance -  
Collateral Standard:  
Requirements for environmentally conscious design  
(IEC 60601-1-9:2007)**

Appareils électromédicaux -  
Partie 1-9: Exigences générales  
pour la sécurité de base  
et les performances essentielles -  
Norme collatérale: Exigences  
pour une conception éco-responsable  
(CEI 60601-1-9:2007)

Medizinische elektrische Geräte -  
Teil 1-9: Allgemeine Festlegungen  
für die Sicherheit einschließlich  
der wesentlichen Leistungsmerkmale -  
Ergänzungsnorm: Anforderungen  
zur Reduzierung  
von Umweltauswirkungen  
(IEC 60601-1-9:2007)

This European Standard was approved by CENELEC on 2008-04-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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

## CENELEC

European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**Central Secretariat: rue de Stassart 35, B - 1050 Brussels**

## Foreword

The text of document 62A/571/FDIS, future edition 1 of IEC 60601-1-9, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-9 on 2008-04-16.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2009-02-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2011-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes Subclauses 4.1, 4.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 4.1, 4.5 and 4.5.1 are all subclauses of Clause 4).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (\*).

Annexes ZA and ZZ have been added by CENELEC.

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### Endorsement notice

The text of the International Standard IEC 60601-1-9:2007 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 14001	NOTE	Harmonized as EN ISO 14001:2004 (not modified).
ISO 14021	NOTE	Harmonized as EN ISO 14021:2001 (not modified).
ISO 14040	NOTE	Harmonized as EN ISO 14040:2006 (not modified).

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## **Annex ZA** (normative)

### **Normative references to international publications with their corresponding European publications**

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006

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**MEDICAL ELECTRICAL EQUIPMENT –**  
**Part 1-9: General requirements for basic safety**  
**and essential performance –**  
**Collateral Standard:**  
**Requirements for environmentally conscious design**

## **1 Scope, object and related standards**

### **1.1 \* Scope**

This International Standard applies to the reduction of adverse ENVIRONMENTAL IMPACTS of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

MEDICAL ELECTRICAL SYSTEMS are excluded from the scope of this collateral standard.

### **1.2 Object**

The object of this collateral standard is to specify general requirements, in addition to those of the general standard, for the reduction of the adverse ENVIRONMENTAL IMPACT of ME EQUIPMENT, and to serve as the basis for particular standards.

### **1.3 Related standards**

#### **1.3.1 IEC 60601-1**

For ME EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-9 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

#### **1.3.2 Particular standards**

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

#### **1.3.3 Environmental standards**

This standard takes into account the ISO 14000 series of environmental standards with particular emphasis on ISO 14062 [8]<sup>1)</sup>.

## **2 Normative references**

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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<sup>1)</sup> Figures in square brackets refer to the Bibliography.