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**Medicinska električna oprema - 2-75. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za fotodinamično terapijo in fotodinamično diagnostično opremo - Dopolnilo A1 (IEC 60601-2-75:2017/AMD1:2023)**

Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment (IEC 60601-2-75:2017/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-75: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von photodynamischen Therapie- und photodynamischen Diagnosegeräten (IEC 60601-2-75:2017/AMD1:2023)

Appareils électromédicaux - Partie 2-75: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique (IEC 60601-2-75:2017/AMD1:2023)

**Ta slovenski standard je istoveten z: EN IEC 60601-2-75:2019/A1:2024**

**ICS:**

11.040.55      Diagnostična oprema      Diagnostic equipment

**SIST EN IEC 60601-2-75:2019/A1:2024    en**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN IEC 60601-2-75:2019/A1**

September 2024

ICS 11.040.01

English Version

**Medical electrical equipment - Part 2-75: Particular requirements  
for the basic safety and essential performance of photodynamic  
therapy and photodynamic diagnosis equipment  
(IEC 60601-2-75:2017/AMD1:2023)**

Appareils électromédicaux - Partie 2-75: Exigences  
particulières pour la sécurité de base et les performances  
essentielles des appareils de thérapie photodynamique et  
de diagnostic photodynamique  
(IEC 60601-2-75:2017/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-75: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von photodynamischen  
Therapie- und photodynamischen Diagnosegeräten  
(IEC 60601-2-75:2017/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 60601-2-75:2019; it was approved by CENELEC on 2024-07-31. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CEN-CENELEC Management Centre or to any CENELEC member.

This amendment 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

**EN IEC 60601-2-75:2019/A1:2024 (E)****European foreword**

The text of document 62D/2006/FDIS, future edition 1 of IEC 60601-2-75/AMD1, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-75:2019/A1:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2025-05-01 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-07-31 document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

**Endorsement notice**

The text of the International Standard IEC 60601-2-75:2017/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

ISO 13694:2018	NOTE	Approved as EN ISO 13694:2018 (not modified)
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
ISO 11554:2017	NOTE	Approved as EN ISO 11554:2017 (not modified)
ISO 11145:2018	NOTE	Approved as EN ISO 11145:2018 (not modified)
IEC 62304:2006/A1:2015	NOTE	Approved as EN 62304:2006/A1:2015 (not modified)

## Annex ZA (normative)

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

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cencenelec.eu](http://www.cencenelec.eu).

Replace EN 60601-1, EN 60601-2-22 and their amendments with :

<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
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020	<a href="https://standards.iteh.ai/catalog/standards/sist/10e07fbf-68c4-4431-9f1e-7b92ba0e7e38/iec-60601-2-75-2019-a1-2024">SIST EN IEC 60601-2-75:2019/A1:2024</a>	+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC 60601-2-22	2019	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	EN IEC 60601-2-22	2020

