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Medical devices - Application of usability engineering to medical devices
(IEC 62366:2007)

Dispositifs médicaux - Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux (CEI 62366:2007)

Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte (IEC 62366:2007)

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

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

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Foreword

The text of document 62A/574/FDIS, future edition 1 of IEC 62366, prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice and ISO/TC 210, Quality management and corresponding general aspects for medical devices, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62366 on 2007-12-01.

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)	2008-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-12-01

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Annexes ZA and ZZ have been added by CENELEC.

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IEC 60601-1	NOTE	Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8:2007 (not modified).
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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices – Application of usability engineering to medical devices

Dispositifs médicaux – Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

IEC 62366:2007

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices – Application of usability engineering to medical devices

Dispositifs médicaux – Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

FOREWORD

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Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 20 P-members out of 20 having cast a vote.

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