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IEC 62366-1:2015 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS associated with CORRECT USE and USE ERRORS, i.e., NORMAL USE.

IEC 62366-1:2015 - Medical devices -- Part 1: Application ...
This first edition of IEC 62366-1, together with the first edition of IEC 62366-2, cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1 (2014). Part 1 has been updated to include contemporary concepts of USABILITY ENGINEERING, while also streamlining the process.

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This first edition of IEC 62366-1, together with the first edition of IEC 62366-2, cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1 (2014). Part 1 has been updated to include contemporary concepts of USABILITY ENGINEERING, while also streamlining the process.

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IEC 62366-1 - 2015-02 - Beuth.de
Abstract. IEC 62366-1:2015 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use.

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IEC 62366-1 Ed. 1.0 b:2015 - Techstreet
IEC 62366-1 Edition 1.0 2015-02 INTERNATIONAL STANDARD NORME INTERNATIONALE Medical devices – Part 1: Application of usability engineering to medical devices Dispositifs médicaux – Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux IEC 62366-1:201 5-0 2 (en-fr)

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IEC 62366-1:2015. Abstract IEC 62366-1:2015 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e.,...

IEC 62366-1:2015 - IECEE - IEC System of Conformity ...
This standard has been revised by IEC 62366-1:2015 Specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device.

This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use.

IEC 62366:2007 - Medical devices -- Application of ...
IEC 62366-1 Edition 1.0 2015-02 INTERNATIONAL STANDARD NORME INTERNATIONALE Medical devices – Part 1: Application of usability engineering to medical devices – Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux INTERNATIONAL ELECTROTECHNICAL COMMISSION COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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Full Description. BS EN 62366-1:2015 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS associated with CORRECT USE and USE ERRORS, i.e.,...

BS EN 62366-1:2015 - Techstreet -Technical Information ...
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IEC Stdandard - Regulatory Requirements
IEC 62366-1:2015 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use.

IEC 62366-1:2015 - Norsk Standard | standard.no
Manufacturers of medical electrical equipment who comply with IEC 60601-1-6 need to also comply by extension to IEC 62366 as part of IEC 60601-1 Edition 3.1 History of IEC 62366. IEC 62366 was published for the first time in 2007. In February 2015 IEC 62366-1:2015 was published, Medical devices - Part 1: Application of usability engineering to ...

IEC 62366 - Wikipedia
FDA recognition of IEC 62366 Edition 1.1 2014-01 [Rec#5-87] will be superseded by recognition of IEC 62366-1 Edition 1.0 2015-02 [Rec#5-95]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec#5-87] until January 31, 2018. After this transition period, declarations of conformity to [Rec#5-87] will not be ...

Usability Guidance Document Referenced - Ombu Enterprises
February 1, 2015 Medical devices - Part 1: Application of usability engineering to medical devices This part of IEC 62366 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY.

IEC 62366-1 - Medical devices - Part 1: Application of ...
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IEC 62366-1 Edition 1.0 2015-02 INTERNATIONAL STANDARD NORME INTERNATIONALE Medical devices – Part 1: Application of usability engineering to medical devices – Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux INTERNATIONAL ELECTROTECHNICAL COMMISSION COMMISSION ELECTROTECHNIQUE INTERNATIONALE

From a regulatory standpoint the differences between IEC 62366:2007 and IEC 62366 -1:2015 are minimal, with all the same boxes needing to be ticked. However, it is clear from reading the documentation that the whole process has been streamlined, using more familiar language and on the whole a more usable standard.

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