



BSI Standards Publication

Health software and health IT systems safety, effectiveness and security

Part 5-1: Security — Activities in the product life cycle

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This British Standard is the UK implementation of EN IEC 81001-5-1:2022. It is identical to IEC 81001-5-1:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2022

ISBN 978 0 539 02449 4

ICS 11.040.01; 35.240.80

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2022.

Amendments/corrigenda issued since publication

Date	Text affected
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 81001-5-1

February 2022

ICS 11.040.01; 35.240.80

English Version

Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle (IEC 81001-5-1:2021)

Logiciels de santé et sécurité, efficacité et sûreté des systèmes TI de santé - Partie 5-1 : Sûreté - Activités du cycle de vie du produit (IEC 81001-5-1:2021)

Gesundheitssoftware und Gesundheits-IT-Systeme Sicherheit, Effektivität und Security - Teil 5-1: Security - Aktivitäten im Produktlebenszyklus (IEC 81001-5-1:2021)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

European foreword

The text of document 62A/1458/FDIS, future edition 1 of IEC 81001-5-1, 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 approved by CENELEC as EN IEC 81001-5-1:2022.

The following dates are fixed:

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

IEC 62304:2006	NOTE Harmonized as EN 62304:2006 (not modified)
IEC 62443-3-2	NOTE Harmonized as EN IEC 62443-3-2
IEC 62443-3-3	NOTE Harmonized as EN IEC 62443-3-3
IEC 62443-4-1:2018	NOTE Harmonized as EN IEC 62443-4-1:2018 (not modified)
IEC 62443-4-2:2019	NOTE Harmonized as EN IEC 62443-4-2:2019 (not modified)
IEC 62740:2015	NOTE Harmonized as EN 62740:2015 (not modified)
IEC 82304-1:2016	NOTE Harmonized as EN 82304-1:2017 (not modified)
ISO/TS 14441	NOTE Harmonized as CEN ISO/TS 14441
ISO 14971:2019	NOTE Harmonized as EN ISO 14971:2019 (not modified) +A11:2021
ISO/IEC 27000:2018	NOTE Harmonized as EN ISO/IEC 27000:2020 (not modified)
ISO 27789	NOTE Harmonized as EN ISO 27789
ISO 27799	NOTE Harmonized as EN ISO 27799
ISO/IEC 29147	NOTE Harmonized as EN ISO/IEC 29147
ISO/IEC 30111	NOTE Harmonized as EN ISO/IEC 30111

ISO 13485:2016	NOTE Harmonized as EN ISO 13485:2016 (not modified) +A11:2021
IEC 62366-1:2015	NOTE Harmonized as EN 62366-1:2015 (not modified)
IEC/TR 63069	NOTE Harmonized as CLC IEC/TR 63069
ISO 9000:2015	NOTE Harmonized as EN ISO 9000:2015 (not modified)



IEC 81001-5-1

Edition 1.0 2021-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Health software and health IT systems safety, effectiveness and security –
Part 5-1: Security – Activities in the product life cycle**

**Logiciels de santé et sécurité, efficacité et sûreté des systèmes TI de santé –
Partie 5-1: Sûreté – Activités du cycle de vie du produit**

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