

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical device software – Software life cycle processes

Logiciels de dispositifs médicaux – Processus du cycle de vie du logiciel

[IEC 62304:2006](#)

<https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006>



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2006 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: csc@iec.ch
Tél.: +41 22 919 02 11
Fax: +41 22 919 03 00



IEC 62304

Edition 1.0 2006-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical device software – Software life cycle processes

Logiciels de dispositifs médicaux – Processus du cycle de vie du logiciel

[IEC 62304:2006](https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006)

<https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006>

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

XC

ICS 11.040

ISBN 2-8318-8637-6

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	9
1.1 * Purpose	9
1.2 * Field of application	9
1.3 Relationship to other standards.....	9
1.4 Compliance	9
2 * Normative references	10
3 * Terms and definitions.....	10
4 * General requirements.....	14
4.1 * Quality management system.....	14
4.2 * RISK MANAGEMENT.....	15
4.3 * Software safety classification.....	15
5 Software development PROCESS	16
5.1 * Software development planning	16
5.2 * Software requirements analysis	18
5.3 * Software ARCHITECTURAL design	20
5.4 * Software detailed design	21
5.5 * SOFTWARE UNIT implementation and verification	21
5.6 * Software integration and integration testing	22
5.7 * SOFTWARE SYSTEM testing	24
5.8 * Software release	25
6 Software maintenance PROCESS	26
6.1 * Establish software maintenance plan	26
6.2 * Problem and modification analysis.....	26
6.3 * Modification implementation	27
7 * Software RISK MANAGEMENT PROCESS	28
7.1 * Analysis of software contributing to hazardous situations	28
7.2 RISK CONTROL measures	29
7.3 VERIFICATION of RISK CONTROL measures.....	29
7.4 RISK MANAGEMENT of software changes	30
8 * Software configuration management PROCESS.....	30
8.1 * Configuration identification	30
8.2 * Change control.....	31
8.3 * Configuration status accounting.....	31
9 * Software problem resolution PROCESS.....	31
9.1 Prepare PROBLEM REPORTS.....	31
9.2 Investigate the problem.....	32
9.3 Advise relevant parties	32
9.4 Use change control process.....	32
9.5 Maintain records	32
9.6 Analyse problems for trends	32
9.7 Verify software problem resolution	33
9.8 Test documentation contents	33

Annex A (informative) Rationale for the requirements of this standard.....	34
Annex B (informative) Guidance on the provisions of this standard	37
Annex C (informative) Relationship to other standards.....	53
Annex D (informative) Implementation	74
 Bibliography	 76
 Index of defined terms.....	 77
 Figure 1 – Overview of software development PROCESSES and ACTIVITIES.....	 7
Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES.....	7
Figure B.1 – Example of partitioning of SOFTWARE ITEMS	42
Figure C.1 – Relationship of key MEDICAL DEVICE standards to IEC 62304	54
Figure C.2 – Software as part of the V-model	56
Figure C.3 – Application of IEC 62304 with IEC 61010-1.....	66
 Table A.1 – Summary of requirements by software safety class	 36
Table B.1 – Development (model) strategies as defined at ISO/IEC 12207	38
Table C.1 – Relationship to ISO 13485:2003	54
Table C.2 – Relationship to ISO 14971:2000	55
Table C.3 – Relationship to IEC 60601-1	58
Table C.4 – Relationship to IEC 60601-1-4:2006	62
Table C.5 – Relationship to ISO/IEC 12207	68
Table D.1 – Checklist for small companies without a certified QMS.....	75

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 62304 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice and ISO Technical Committee 210, Quality management and corresponding general aspects for MEDICAL DEVICES. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

It is published as a dual logo standard.

The text of this standard is based on the following documents:

FDIS	Report on voting
62A/523/FDIS	62A/528/RVD

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 23 P-members out of 23 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- requirements and definitions: in roman 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 used throughout this standard that have been defined in Clause 3 and also given in the index: in small capitals.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under “<http://webstore.iec.ch>” in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[IEC 62304:2006](#)

<https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006>

INTRODUCTION

Software is often an integral part of MEDICAL DEVICE technology. Establishing the SAFETY and effectiveness of a MEDICAL DEVICE containing software requires knowledge of what the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable RISKS.

This standard provides a framework of life cycle PROCESSES with ACTIVITIES and TASKS necessary for the safe design and maintenance of MEDICAL DEVICE SOFTWARE. This standard provides requirements for each life cycle PROCESS. Each life cycle PROCESS is further divided into a set of ACTIVITIES, with most ACTIVITIES further divided into a set of TASKS.

As a basic foundation it is assumed that MEDICAL DEVICE SOFTWARE is developed and maintained within a quality management system (see 4.1) and a RISK MANAGEMENT system (see 4.2). The RISK MANAGEMENT PROCESS is already very well addressed by the International Standard ISO 14971. Therefore IEC 62304 makes use of this advantage simply by a normative reference to ISO 14971. Some minor additional RISK MANAGEMENT requirements are needed for software, especially in the area of identification of contributing software factors related to HAZARDS. These requirements are summarized and captured in Clause 7 as the software RISK MANAGEMENT PROCESS.

Whether software is a contributing factor to a HAZARD is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. HAZARDS that could be indirectly caused by software (for example, by providing misleading information that could cause inappropriate treatment to be administered) need to be considered when determining whether software is a contributing factor. The decision to use software to control RISK is made during the RISK CONTROL ACTIVITY of the RISK MANAGEMENT PROCESS. The software RISK MANAGEMENT PROCESS required in this standard has to be embedded in the device RISK MANAGEMENT PROCESS according to ISO 14971.

[IEC 62304:2006](#)

<https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-6e7cc487984/iec-62304-2006>

The software development PROCESS consists of a number of ACTIVITIES. These ACTIVITIES are shown in Figure 1 and described in Clause 5. Because many incidents in the field are related to service or maintenance of MEDICAL DEVICE SYSTEMS including inappropriate software updates and upgrades, the software maintenance PROCESS is considered to be as important as the software development PROCESS. The software maintenance PROCESS is very similar to the software development PROCESS. It is shown in Figure 2 and described in Clause 6.

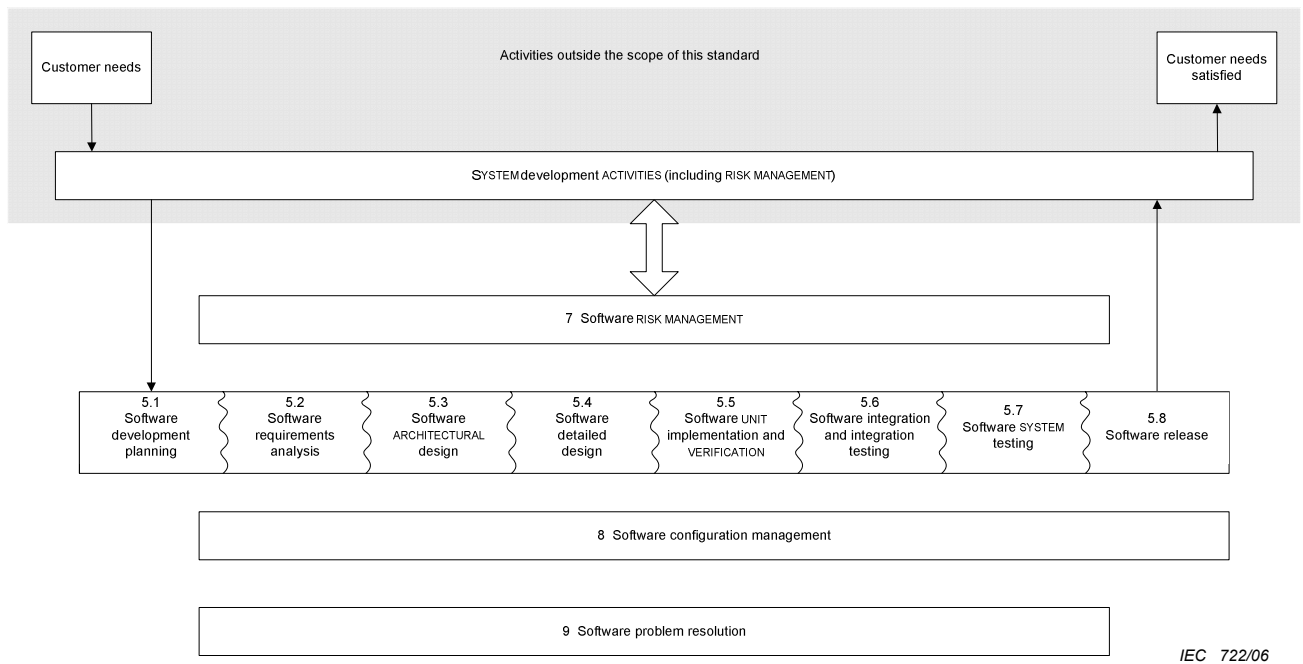


Figure 1 – Overview of software development PROCESSES and ACTIVITIES

iTeh STANDARD PREVIEW

(standards.iteh.ai)

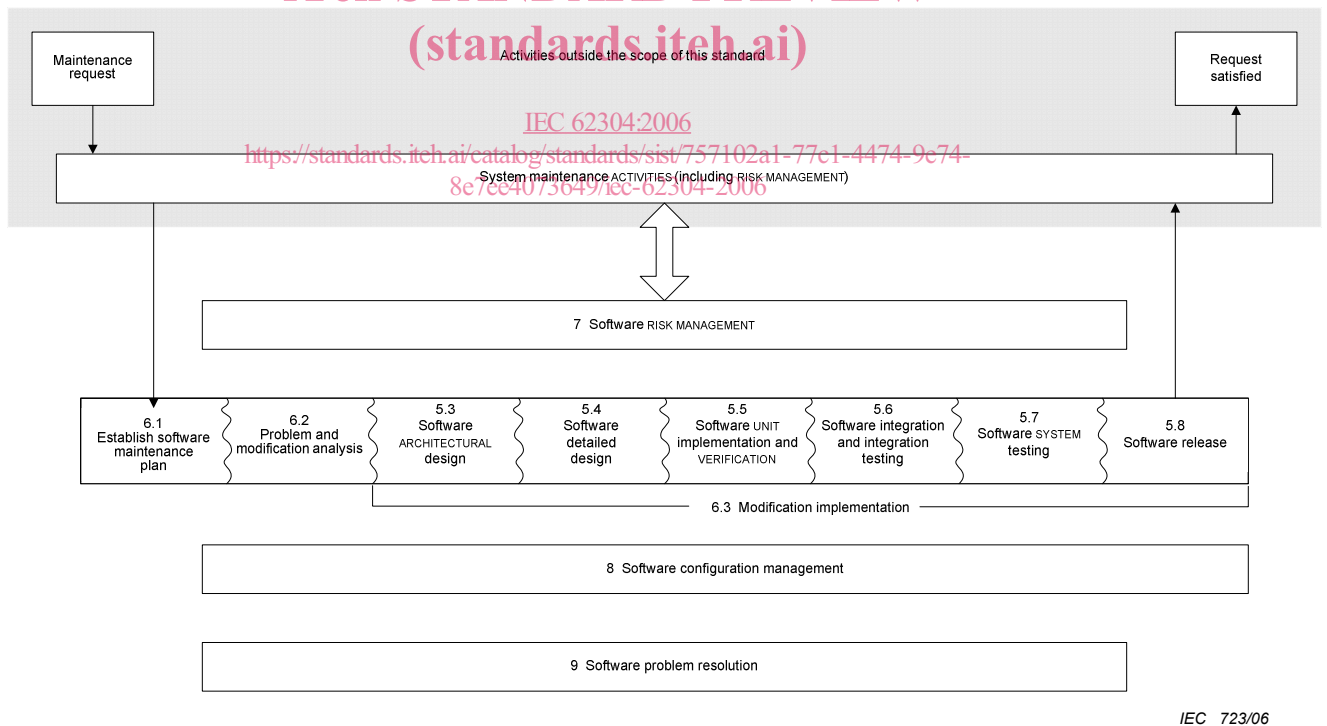


Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES

This standard identifies two additional PROCESSES considered essential for developing safe MEDICAL DEVICE SOFTWARE. They are the software configuration management PROCESS (Clause 8) and the software problem resolution PROCESS (Clause 9).

This standard does not specify an organizational structure for the MANUFACTURER or which part of the organization is to perform which PROCESS, ACTIVITY, or TASK. This standard requires only that the PROCESS, ACTIVITY, or TASK be completed to establish compliance with this standard.

This standard does not prescribe the name, format, or explicit content of the documentation to be produced. This standard requires documentation of TASKS, but the decision of how to package this documentation is left to the user of the standard.

This standard does not prescribe a specific life cycle model. The users of this standard are responsible for selecting a life cycle model for the software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this standard onto that model.

Annex A provides rationale for the clauses of this standard. Annex B provides guidance on the provisions of this standard.

For the purposes of this standard:

- “shall” means that compliance with a requirement is mandatory for compliance with this standard;
- “should” means that compliance with a requirement 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;
- “establish” means to define, document, and implement; and
- where this standard uses the term “as appropriate” in conjunction with a required PROCESS, ACTIVITY, TASK or output, the intention is that the MANUFACTURER shall use the PROCESS, ACTIVITY, TASK or output unless the MANUFACTURER can document a justification for not so doing.

[IEC 62304:2006](https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006)

<https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006>

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

1 Scope

1.1 * Purpose

This standard defines the life cycle requirements for MEDICAL DEVICE SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this standard establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.

1.2 * Field of application

This standard applies to the development and maintenance of MEDICAL DEVICE SOFTWARE.

This standard applies to the development and maintenance of MEDICAL DEVICE SOFTWARE when software is itself a MEDICAL DEVICE or when software is an embedded or integral part of the final MEDICAL DEVICE.

This standard does not cover validation and final release of the MEDICAL DEVICE, even when the MEDICAL DEVICE consists entirely of software.

1.3 Relationship to other standards

This MEDICAL DEVICE SOFTWARE life cycle standard is to be used together with other appropriate standards when developing a MEDICAL DEVICE. Annex C shows the relationship between this standard and other relevant standards.

1.4 Compliance

Compliance with this standard is defined as implementing all of the PROCESSES, ACTIVITIES, and TASKS identified in this standard in accordance with the software safety class.

NOTE The software safety classes assigned to each requirement are identified in the normative text following the requirement.

Compliance is determined by inspection of all documentation required by this standard including the RISK MANAGEMENT FILE, and assessment of the PROCESSES, ACTIVITIES and TASKS required for the software safety class. See Annex D.

NOTE 1 This assessment could be carried out by internal or external audit.

NOTE 2 Although the specified PROCESSES, ACTIVITIES, and TASKS are performed, flexibility exists in the methods of implementing these PROCESSES and performing these ACTIVITIES and TASKS.

NOTE 3 Where any requirements contain “as appropriate” and were not performed, documentation for the justification is necessary for this assessment.

NOTE 4 The term “conformance” is used in ISO/IEC 12207 where the term “compliance” is used in this standard.

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.

ISO 14971, *Medical devices – Application of risk management to medical devices*.

3 * Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

ACTIVITY

a set of one or more interrelated or interacting TASKS

3.2

ANOMALY

any condition that deviates from the expected based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experiences. ANOMALIES may be found during, but not limited to, the review, test, analysis, compilation, or use of SOFTWARE PRODUCTS or applicable documentation

[IEEE 1044:1993, definition 3.1]

3.3

ARCHITECTURE

organizational structure of a SYSTEM or component

[IEEE 610.12:1990]

3.4

CHANGE REQUEST

a documented specification of a change to be made to a SOFTWARE PRODUCT

3.5

CONFIGURATION ITEM

entity that can be uniquely identified at a given reference point

NOTE Based on ISO/IEC 12207:1995, definition 3.6.

3.6

DELIVERABLE

required result or output (includes documentation) of an ACTIVITY or TASK

3.7

EVALUATION

a systematic determination of the extent to which an entity meets its specified criteria

[ISO/IEC 12207:1995, definition 3.9]

iteh STANDARD PREVIEW
(standards.iteh.ai)

IEC 62304:2006

https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8e7ee4073649/iec-62304-2006

3.8**HARM**

physical injury, damage, or both to the health of people or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.3]

3.9**HAZARD**

potential source of HARM

[ISO/IEC Guide 51:1999, definition 3.5]

3.10**MANUFACTURER**

natural or legal person with responsibility for designing, manufacturing, packaging, or labelling a MEDICAL DEVICE; assembling a SYSTEM; or adapting a MEDICAL DEVICE before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or by a third party on that person's behalf

[ISO 14971:2000, definition 2.6]

3.11**MEDICAL DEVICE**

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
- supporting or sustaining life,
- control of conception,
- disinfection of MEDICAL DEVICES,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

NOTE 1 This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15] (in ISO 13485:2003).

[ISO 13485:2003, definition 3.7]

NOTE 2 Some differences can occur in the definitions used in regulations of each country.

3.12**MEDICAL DEVICE SOFTWARE**

SOFTWARE SYSTEM that has been developed for the purpose of being incorporated into the MEDICAL DEVICE being developed or that is intended for use as a MEDICAL DEVICE in its own right

3.13**PROBLEM REPORT**

a record of actual or potential behaviour of a SOFTWARE PRODUCT that a user or other interested person believes to be unsafe, inappropriate for the intended use or contrary to specification

NOTE 1 This standard does not require that every PROBLEM REPORT results in a change to the SOFTWARE PRODUCT. A MANUFACTURER can reject a PROBLEM REPORT as a misunderstanding, error or insignificant event.

NOTE 2 A PROBLEM REPORT can relate to a released SOFTWARE PRODUCT or to a SOFTWARE PRODUCT that is still under development.

NOTE 3 This standard requires the MANUFACTURER to perform extra decision making steps (see Clause 6) for a PROBLEM REPORT relating to a released product to ensure that regulatory actions are identified and implemented.

3.14

PROCESS

a set of interrelated or interacting ACTIVITIES that transform inputs into outputs

[ISO 9000:2000, definition 3.4.1]

NOTE The term "ACTIVITIES" covers use of resources.

3.15

REGRESSION TESTING

the testing required to determine that a change to a SYSTEM component has not adversely affected functionality, reliability or performance and has not introduced additional defects

[ISO/IEC 90003:2004, definition 3.11]

3.16

RISK

combination of the probability of occurrence of HARM and the severity of that HARM

[ISO/IEC Guide 51:1999 definition 3.2]

3.17

RISK ANALYSIS

systematic use of available information to identify HAZARDS and to estimate the RISK

[ISO/IEC Guide 51:1999 definition 3.10]

<https://standards.iteh.ai/catalog/standards/sist/757102a1-77c1-4474-9e74-8c7cc4073649/iec-62304-2006>

ITEH STANDARD PREVIEW
(standards.iteh.ai)

3.18

RISK CONTROL

PROCESS in which decisions are made and RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2000 definition 2.16, modified]

3.19

RISK MANAGEMENT

systematic application of management policies, procedures, and practices to the TASKS of analyzing, evaluating, and controlling RISK

[ISO 14971:2000 definition 2.18]

3.20

RISK MANAGEMENT FILE

set of records and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS

[ISO 14971:2000 definition 2.19]

3.21**SAFETY**

freedom from unacceptable RISK

[ISO/IEC Guide 51:1999 definition 3.1]

3.22**SECURITY**

protection of information and data so that unauthorized people or SYSTEMS cannot read or modify them and so that authorized persons or SYSTEMS are not denied access to them

[ISO/IEC 12207:1995 definition 3.25]

3.23**SERIOUS INJURY**

injury or illness that directly or indirectly:

- a) is life threatening,
- b) results in permanent impairment of a body function or permanent damage to a body structure, or
- c) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

NOTE Permanent impairment means an irreversible impairment or damage to a body structure or function excluding trivial impairment or damage.

3.24**SOFTWARE DEVELOPMENT LIFE CYCLE MODEL**

conceptual structure spanning the life of the software from definition of its requirements to its release for manufacturing, which:

- identifies the PROCESS, ACTIVITIES and TASKS involved in development of a SOFTWARE PRODUCT,
- describes the sequence of and dependency between ACTIVITIES and TASKS, and
- identifies the milestones at which the completeness of specified DELIVERABLES is verified.

NOTE Based on ISO/IEC 12207:1995, definition 3.11

3.25**SOFTWARE ITEM**

any identifiable part of a computer program

[ISO/IEC 90003:2004, definition 3.14, modified]

NOTE Three terms identify the software decomposition. The top level is the SOFTWARE SYSTEM. The lowest level that is not further decomposed is the SOFTWARE UNIT. All levels of composition, including the top and bottom levels, can be called SOFTWARE ITEMS. A SOFTWARE SYSTEM, then, is composed of one or more SOFTWARE ITEMS, and each SOFTWARE ITEM is composed of one or more SOFTWARE UNITS or decomposable SOFTWARE ITEMS. The responsibility is left to the MANUFACTURER to provide the definition and granularity of the SOFTWARE ITEMS and SOFTWARE UNITS.

3.26**SOFTWARE PRODUCT**

set of computer programs, procedures, and possibly associated documentation and data

[ISO/IEC 12207:1995 definition 3.26]

3.27**SOFTWARE SYSTEM**

integrated collection of SOFTWARE ITEMS organized to accomplish a specific function or set of functions