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BSI Standards Publication

Health Software

Part 1: General requirements for product safety

bsi.

EUROPEAN STANDARD

NORME EUROPÉENNE

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English Version

Health Software - Part 1: General requirements for product safety (IEC 82304-1:2016)

Logiciels de santé - Partie 1: Exigences générales pour la sécurité des produits (IEC 82304-1:2016)

Gesundheitssoftware - Teil 1: Allgemeine Anforderungen für die Produktsicherheit (IEC 82304-1:2016)

This European Standard was approved by CENELEC on 2016-12-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

The text of document 62A/1140/FDIS, future edition 1 of IEC 82304-1, prepared by IEC/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 82304-1:2017.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2018-03-01
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2020-09-01

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.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 82304-1:2016 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 standards indicated:

IEC 60601 (series)	NOTE	Harmonized as EN 60601 (series).
IEC 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006.
IEC 61907:2009	NOTE	Harmonized as EN 61907:2010.
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015.
IEC 80001-1:2010	NOTE	Harmonized as EN 80001-1:2011.
ISO 9000:2015	NOTE	Harmonized as EN ISO 9000:2015.
ISO 13485:2015	NOTE	Harmonized as EN ISO 13485:2016.
ISO 14971:2007	NOTE	Harmonized as EN ISO 14971:2012.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 62304	2006	Medical device software - Software life-cycle processes	EN 62304	2006
-	-		+ corrigendum Nov.	2008
+ A1	2015		+ A1	2015

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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HEALTH SOFTWARE –

Part 1: General requirements for product safety

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.
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International Standard IEC 82304-1 has been prepared by 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 215: Health informatics.

It is published as a double logo standard.

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

FDIS	Report on voting
62A/1140/FDIS	62A/1151/RVD

Full information on the voting for the approval of this part of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 21 P members out of 22 having cast a vote.

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

Terms defined in Clause 3 of this standard are printed in SMALL CAPITALS.

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; and
– “establish” means to define, document, and implement.

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

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

NOTE The attention of National Committees is drawn to the fact that manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

HEALTH SOFTWARE PRODUCTS, within the context of this document, are software-only products. These products are intended to be used with computing equipment not explicitly developed for running the software. HEALTH SOFTWARE PRODUCTS may require specified platforms.

HEALTH SOFTWARE PRODUCTS are intended by their MANUFACTURER for managing, maintaining or improving health of individual persons, or the delivery of care. Some HEALTH SOFTWARE can contribute to a HAZARDOUS SITUATION. Accordingly, Clause 5 requires a RISK MANAGEMENT process for all HEALTH SOFTWARE. For HEALTH SOFTWARE that can contribute to a HAZARDOUS SITUATION, RISK CONTROL is needed to prevent HARM or reduce the likelihood of HARM occurring. Testing of the finished product is not, by itself, adequate to address the SAFETY of HEALTH SOFTWARE. Therefore, requirements for the processes by which the HEALTH SOFTWARE is developed are necessary. This document relies heavily on IEC 62304:2006 and IEC 62304:2006/AMD1:2015 for the software development process which can be applied to HEALTH SOFTWARE PRODUCTS.

Whether a HEALTH SOFTWARE PRODUCT has to meet regulatory requirements is a matter of national legislation. This document makes no attempt to determine whether a HEALTH SOFTWARE PRODUCT is or should be regulated.

This document aims to provide requirements for the SAFETY and SECURITY of HEALTH SOFTWARE PRODUCTS; it can only provide such requirements for software-only products. Situations where HEALTH SOFTWARE is a part of—or embedded in— a physical device are outside the scope of this document as these combined products are considered separately in, for example, IEC 60601-1 and associated collateral and particular standards.

This document understands health in a meaning similar to the WHO definition: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 1946). This definition appears not highly suitable for practical purposes: ”a state of complete well-being” or the inclusion of social well-being could be interpreted more widely than seems reasonable. For example dating software, games, or flight simulator software could be considered within the scope of the standard. That is clearly not the intent. However, a precise definition – or even delineation – of “health” for practical use in “HEALTH SOFTWARE” is not available.

HEALTH SOFTWARE refers to software that contributes to the health of individual people as observed and/or demonstrated using measurable health parameters or clinical expertise. This is a subset of “health” as defined by the WHO. The requirements of the standard apply to the software that impacts such health parameters, and/or to software where SECURITY violations would undermine privacy or confidentiality of health and wellbeing information.

The reader is kindly referred to the Table A.1 for examples of what is in the scope and what is outside the scope of this document.

HEALTH SOFTWARE –

Part 1: General requirements for product safety

1 Scope

1.1 Purpose

This Part of 82304 applies to the SAFETY and SECURITY of HEALTH SOFTWARE PRODUCTS designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, and its primary focus is on the requirements for MANUFACTURERS.

1.2 Field of application

This document covers the entire lifecycle including design, development, VALIDATION, installation, maintenance, and disposal of HEALTH SOFTWARE PRODUCTS.

In each referenced standard, the term “medical device” or “medical device software” is to be substituted by the term “HEALTH SOFTWARE” or “HEALTH SOFTWARE PRODUCT”, as appropriate.

Where the term “patient” is used, either in this document or in a referenced standard, it refers to the person for whose health benefit the HEALTH SOFTWARE is used.

IEC 82304-1 does not apply to HEALTH SOFTWARE which is intended to become part of a specific hardware designed for health use. Specifically, IEC 82304-1 does not apply to:

a) medical electrical equipment or systems covered by the IEC 60601/IEC 80601 series;

b) in vitro diagnostic equipment covered by the IEC 61010 series; or

c) implantable devices covered by the ISO 14708 series.

NOTE This document also applies to HEALTH SOFTWARE PRODUCTS (e.g. medical apps, health apps) intended to be used in combination with mobile computing platforms.

1.3 Compliance

Compliance with this document is determined by inspection of all documentation required by this document.

Assessment of compliance is carried out and documented by the MANUFACTURER. Where the HEALTH SOFTWARE PRODUCT is subject to regulatory requirements, external assessment may take place.

Where this document normatively references parts or clauses of other standards focused on SAFETY or SECURITY, the MANUFACTURER may use alternative methods to demonstrate compliance with the requirements of this document. These alternative methods may be used if the process results of such alternative methods, including traceability, are demonstrably equivalent and the RESIDUAL RISK remains acceptable.

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

2 Normative references

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.

IEC 62304:2006, *Medical device software – Software life cycle processes*
IEC 62304:2006/AMD1:2015

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
ACCOMPANYING DOCUMENT
document accompanying HEALTH SOFTWARE containing information for the RESPONSIBLE ORGANIZATION or USER, particularly regarding SAFETY and/or SECURITY

[SOURCE: IEC 60601-1:2005, 3.4, modified – Replace "ME EQUIPMENT, ME SYSTEM, equipment and accessory" by "HEALTH SOFTWARE" and replace "OPERATOR" by "USER" and added “and/or SECURITY”.]

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.

Note 1 to entry: ANOMALIES can be found during, but not limited to, the review, test, analysis, compilation, or use of HEALTH SOFTWARE or applicable documentation.

[SOURCE: Based on IEEE 1044:1993, 3.1]

3.3
HARM
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.4
HAZARD
potential source of HARM

Note 1 to entry: Potential sources of HARM include breach of SECURITY and reduction of effectiveness.

[SOURCE: ISO/IEC Guide 51:2014, 3.2, modified – Note 1 to entry has been added.]

3.5
HAZARDOUS SITUATION
circumstance in which people, property or the environment is/are exposed to one or more HAZARDS

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.6
*** HEALTH SOFTWARE**
software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

Note 1 to entry: HEALTH SOFTWARE fully includes what is considered software as a medical device (see rationale in A.1).

Note 2 to entry: The scope of this document refers to the subset of HEALTH SOFTWARE that is intended to run on general computing platforms.

3.7
HEALTH SOFTWARE PRODUCT
combination of HEALTH SOFTWARE and ACCOMPANYING DOCUMENTS

3.8
INTENDED USE
INTENDED PURPOSE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: ISO 14971:2007, 2.5]

3.9
IT-NETWORK
INFORMATION TECHNOLOGY NETWORK
a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

Note 1 to entry: The scope of the IT-NETWORK in this document is defined by the RESPONSIBLE ORGANIZATION based on where the HEALTH SOFTWARE in the IT-NETWORK is located and the defined use of the IT-NETWORK. It can contain IT infrastructure, home health, or general computing components or systems not intended by design to be used in a healthcare setting. See also 7.2.3.2.

[SOURCE: IEC 61907:2009, 3.1.1, modified – The definition has been rephrased and Note 1 to entry has been added.]

3.10
MANUFACTURER
natural or legal person with responsibility for the design, development, packaging, or labelling of a HEALTH SOFTWARE PRODUCT, or adapting a HEALTH SOFTWARE PRODUCT before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: For a definition of labelling, see ISO 13485:2016, 3.8.

Note 2 to entry: Developer" or "developer organization" are commonly used terms instead of MANUFACTURER in the context of health information technology.

3.11
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[SOURCE: ISO 14971:2007, 2.15]

3.12
RESPONSIBLE ORGANIZATION
entity accountable for the use and proper operation of a HEALTH SOFTWARE PRODUCT

Note 1 to entry: An accountable entity is, for example, a hospital, a healthcare provider, or a telehealth organization.

[SOURCE: IEC 60601-1:2005, 3.101, modified – Replaced " maintenance of an ME EQUIPMENT or an ME SYSTEM" by " proper operation of a HEALTH SOFTWARE PRODUCT".]

3.13
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

Note 1 to entry: The probability of occurrence includes the exposure to a HAZARDOUS SITUATION and the possibility to avoid or limit the HARM

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified – Note 1 to entry updated to remove the reference to hazardous event.]

3.14
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

3.15
RISK ASSESSMENT
overall process comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.16
RISK CONTROL
process in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2012, 2.12]

3.17
RISK EVALUATION
process of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO/IEC Guide 63:2012, 2.14]

3.18
RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and MONITORING RISK

[SOURCE: ISO/IEC Guide 63:2012, 2.15]

3.19
SAFETY
freedom from unacceptable RISK

[SOURCE: ISO/IEC Guide 63:2012, 2.16]

3.20
SECURITY
protection of information and data so that unauthorized persons or systems cannot read or modify them and authorized persons or systems are not denied access to them

[SOURCE: ISO 12207:2008, 4.39]

3.21
SOFTWARE MAINTENANCE
modification of HEALTH SOFTWARE PRODUCT after release for INTENDED USE, for one or more of the following reasons:

a) corrective, as fixing faults;

b) adaptive, as adapting to new hard- or software platform;

c) perfective, as implementing new requirements;

d) preventive, as making the product more maintainable

Note 1 to entry: See also ISO/IEC 14764:2006.

3.22
USER
person interacting with the HEALTH SOFTWARE PRODUCT

Note 1 to entry: In general, a USER is not considered to be a RESPONSIBLE ORGANIZATION, except for consumer type HEALTH SOFTWARE PRODUCTS, e.g., for personal health applications, or products to be used by lay persons.

3.23
VALIDATION
confirmation, through the provision of objective evidence, that the requirements for a specific INTENDED USE or application have been fulfilled

Note 1 to entry: The objective evidence needed for a VALIDATION is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for VALIDATION can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

3.24
VERIFICATION
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a VERIFICATION can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for VERIFICATION are sometimes called a qualification process.

Note 3 to entry: The word “verified” is used to designate the corresponding state.

[SOURCE: ISO 9000:2015, 3.8.12]

4 * HEALTH SOFTWARE PRODUCT requirements

4.1 General requirements and initial RISK ASSESSMENT

The MANUFACTURER shall determine and document:

a) the INTENDED USE for the HEALTH SOFTWARE PRODUCT, including the intended USER profile and the intended operational environment;

b) the characteristics related to the SAFETY and/or SECURITY of the HEALTH SOFTWARE PRODUCT, identification of HAZARDS and estimation of the associated RISK(S). As applicable, this includes situations where the HEALTH SOFTWARE PRODUCT can be configured and/or supports interfaces to other products;

c) the need for RISK CONTROL measures for estimated RISKS that are considered unacceptable.

NOTE 1 Subclause 4.1 does not require a formal and full RISK MANAGEMENT as, for example, per ISO 14971. However, performing the initial steps of that process is considered good practice.

NOTE 2 RISK CONTROL measures can be hardware, an independent software system, health care procedures, or other means.

NOTE 3 Sources of information on SECURITY vulnerabilities include publicly available reports from authorities, as well as publications by suppliers of, for instance, operating systems and third party software.

4.2 HEALTH SOFTWARE PRODUCT use requirements

The MANUFACTURER shall determine and document:

a) requirements that address the INTENDED USE;

b) interface requirements, including USER interface requirements where applicable;

NOTE 1 In contrast to the USER interface specification as part of the HEALTH SOFTWARE PRODUCT system requirements, USER interface requirements do not describe technical (realization) requirements. They describe the purpose of the technical requirements.

EXAMPLE "The displayed information shall be readable from a distance of 3 m in an emergency unit."

NOTE 2 IEC 62366-1:2015 provides a process to establish USER interface requirements.

c) requirements for immunity from or susceptibility to unintended influence by other software using the same hardware resources;

d) privacy and SECURITY requirements addressing areas such as authorised use, person authentication, health data integrity and authenticity, and protection against malicious intent;

NOTE 3 See 7.2.3.1 and IEC TR 80001-2-2 (list of SECURITY capabilities) for further information on SECURITY aspects.

e) requirements for ACCOMPANYING DOCUMENTS such as instructions for use (see 7.2.2);

f) requirements to support:

   1) upgrades from previous versions, including maintaining data integrity, and compatibility with prior versions,

   2) rollback to the previous version after upgrade,

   3) timely SECURITY patches and updates,

   4) software distribution mechanism that ensures integrity of installation,

   5) decommissioning, irreversible deletion, transfer and/or retention of data;

g) requirements derived from applicable regulation, including rules for protected information.

NOTE 4 In some jurisdictions, data protection regulations (e.g. European data protection directive 95/46/EC, revised in 2016) mandate citizens to maintain control over their personal data such as to delete or export data. European directive 95/46/EC will be replaced by the European General Data Protection Regulation (2016/679) on 25 May 2018.

4.3 VERIFICATION of HEALTH SOFTWARE PRODUCT use requirements

The MANUFACTURER shall verify that the HEALTH SOFTWARE PRODUCT use requirements are:

a) defined and documented as input for system requirements;

b) such that the MANUFACTURER is able to meet the defined use requirements.

The results of the VERIFICATION shall be recorded.

4.4 Updating HEALTH SOFTWARE PRODUCT use requirements

The MANUFACTURER shall ensure that the HEALTH SOFTWARE PRODUCT use requirements are updated as appropriate, e.g. as a result of HEALTH SOFTWARE PRODUCT use requirements VERIFICATION (see 4.3) or as a result of VALIDATION.

4.5 System requirements

The MANUFACTURER shall specify and document the system requirements for the HEALTH SOFTWARE PRODUCT. These requirements shall include the functionality for INTENDED USE and, as applicable:

a) inter-operability;

b) localization and language support;

c) RISK CONTROL measures that have to be implemented in the HEALTH SOFTWARE PRODUCT at system level, based on the initial RISK ASSESSMENT of 4.1;

d) USER interface specification;

e) requirements on the software and hardware platforms for the HEALTH SOFTWARE PRODUCT to function as expected under expected load, and with required performance levels;

f) features that allow for SECURITY compromises to be detected, recognized, logged, timed, and acted upon during normal use;

g) features that protect essential functions, even when the software SECURITY has been compromised;

h) methods for retention and recovery of product configuration by an authenticated privileged USER.

The HEALTH SOFTWARE PRODUCT system requirements shall meet the HEALTH SOFTWARE PRODUCT use requirements (see 4.2).

NOTE 1 The website http://www.himss.org/library/interoperability-standards/what-is-interoperability provides one source of information on inter-operability.

NOTE 2 Technical requirements for the USER interface can include display colour, character size, or placement of the controls.

NOTE 3 The typical software platform includes, but is not limited to: operating system, device drivers, software libraries, and other USER application(s).

NOTE 4 There is not necessarily a difference between SOFTWARE SYSTEM requirements of IEC 62304:2006, 5.2.1 and and HEALTH SOFTWARE PRODUCT system requirements.

4.6 VERIFICATION of system requirements

The MANUFACTURER shall verify that the system requirements:

a) do not contradict each other;

b) are expressed in terms that avoid ambiguity;

c) are stated in terms that permit the establishment of test criteria and performance of tests to determine that test criteria have been met; and

d) can be uniquely identified.

The results of the VERIFICATION shall be recorded.

4.7 Updating HEALTH SOFTWARE PRODUCT system requirements

The MANUFACTURER shall ensure that the HEALTH SOFTWARE PRODUCT system requirements are updated as appropriate, e.g. as a result of modification on the HEALTH SOFTWARE PRODUCT use requirements, as a result of system requirement VERIFICATION (see 4.6), or as a result of

applying 5.2 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015 (software requirements analysis).

5 * HEALTH SOFTWARE – Software life cycle processes

The system requirements for the HEALTH SOFTWARE PRODUCT established in 4.5 shall be used as primary design input for the life cycle process of the HEALTH SOFTWARE PRODUCT.

The requirements in 4.2, 4.3, Clause 5, Clause 6, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 and IEC 62304/AMD1:2015 shall apply to the HEALTH SOFTWARE in addition to the other requirements of this document.

IEC 62304:2006 and IEC 62304/AMD1:2015 normatively references ISO 14971:2007. It is recognized that the MANUFACTURER might not be able to follow all the process steps identified in ISO 14971:2007 for each constituent component of the HEALTH SOFTWARE, such as proprietary components, subsystems of non-healthcare origin, and legacy software. In this case, the MANUFACTURER shall take account of the RESIDUAL RISKS and implement RISK CONTROLS around those found to be unacceptable.

6 * HEALTH SOFTWARE PRODUCT VALIDATION

6.1 VALIDATION plan

The MANUFACTURER shall establish a VALIDATION plan addressing all HEALTH SOFTWARE PRODUCT use requirements established in 4.2.

In the VALIDATION plan, the MANUFACTURER shall:

a) identify the VALIDATION scope and the corresponding VALIDATION activities;

b) identify the constraints that potentially limit the feasibility of VALIDATION activities;

c) select appropriate VALIDATION methods, input information, and associated acceptance criteria for successful VALIDATION;

d) identify the enabling systems or services such as operating environment(s), including hardware and software platforms, needed to support VALIDATION;

e) specify the required qualification of the VALIDATION personnel; where training is required, this shall be completed before starting the VALIDATION;

f) define the appropriate level of independence of the VALIDATION team from the design team.

NOTE 1 Constraints include: technical feasibility, cost, time, availability of VALIDATION enablers or qualified personnel, contractual constraints, criticality of the mission, etc.

NOTE 2 VALIDATION methods include: inspection, analysis, analogy/similarity, demonstration, simulation, peer-review, testing or certification. Relevant information: reference to standards and other publications such as compatibility standards, regulatory authority guidance documents, and clinical literature.

6.2 Performing VALIDATION

The MANUFACTURER shall confirm readiness for VALIDATION once:

a) the VALIDATION plan has been established;

b) the VALIDATION team has been set up with the appropriately qualified personnel; and

c) as appropriate, development life cycle phases as required by Clause 5 have been completed for those parts of the HEALTH SOFTWARE PRODUCT subject to VALIDATION.

The VALIDATION team shall perform the VALIDATION activities in the intended operational environment(s) according to the VALIDATION plan of 6.1. Where deviations from the VALIDATION plan are deemed necessary, they shall be justified in the VALIDATION report.

When ANOMALIES are found in the HEALTH SOFTWARE PRODUCT during VALIDATION, these shall be resolved through a problem resolution process according to Clause 9 of IEC 62304/AMD1:2015. Where this problem resolution process results in modification of the HEALTH SOFTWARE PRODUCT, the affected part of the VALIDATION shall be repeated, taking into account the extent of the modification.

6.3 VALIDATION report

The VALIDATION team shall develop the VALIDATION report for the HEALTH SOFTWARE PRODUCT subject to VALIDATION.

The VALIDATION report shall provide evidence that:

a) the VALIDATION results are traceable to the HEALTH SOFTWARE PRODUCT use requirements, taken as input;

b) the HEALTH SOFTWARE PRODUCT meets the use requirements established in 4.2; and

c) the RESIDUAL RISK of the HEALTH SOFTWARE PRODUCT remains acceptable.

The VALIDATION report shall document the VALIDATION conditions and the results of the VALIDATION activities. If, during VALIDATION, ANOMALIES were identified in the HEALTH SOFTWARE PRODUCT, these shall be listed in the VALIDATION report.

The VALIDATION report shall list the members of the VALIDATION team (name, affiliation, function).

The VALIDATION report shall include a summary of the VALIDATION results, and the conclusion that the HEALTH SOFTWARE PRODUCT is validated for the INTENDED USE, based on the use requirements.

7 HEALTH SOFTWARE PRODUCT identification and ACCOMPANYING DOCUMENTS

7.1 * Identification

A HEALTH SOFTWARE PRODUCT shall be identified with the name or trademark of the MANUFACTURER, a product name, or type reference, and a unique version identifier such as a revision level or date of release/issue.

NOTE 1 In some jurisdictions, a Unique Device Identification (UDI) is mandatory.

The identification of the HEALTH SOFTWARE PRODUCT shall be accessible to the USER when using the HEALTH SOFTWARE.

NOTE 2 Including the identification in the opening page or log-in screen is considered good practice.

7.2 ACCOMPANYING DOCUMENTS

7.2.1 General

The MANUFACTURER shall make available ACCOMPANYING DOCUMENTS for the HEALTH SOFTWARE to allow the USER and/or RESPONSIBLE ORGANIZATION to implement and use the HEALTH SOFTWARE PRODUCT as intended.

The ACCOMPANYING DOCUMENTS shall include:

a) the name and contact information, including the website, of the MANUFACTURER;

b) the HEALTH SOFTWARE PRODUCT identification (see 7.1);

c) the version identifier(s) of the HEALTH SOFTWARE PRODUCT(S)) such as revision level(s) or date(s) of release/issue, necessary to identify the HEALTH SOFTWARE PRODUCT(S) to which it applies;

d) the version identifier of the ACCOMPANYING DOCUMENTS such as revision level or date of release/issue;

e) the instructions for use (see 7.2.2); and

f) the technical description (see 7.2.3).

The ACCOMPANYING DOCUMENTS may include software release notes and an indication of typical installation environments.

The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended USER or the RESPONSIBLE ORGANIZATION, any restrictions on locations or environments in which the HEALTH SOFTWARE PRODUCT can be used, and, as applicable, any system interface, software platforms and tools, and hardware requirements or restrictions.

The ACCOMPANYING DOCUMENTS shall be provided at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

NOTE Providing ACCOMPANYING DOCUMENTS in electronic format can improve usability. Regulatory authorities can specify a particular format for ACCOMPANYING DOCUMENTS, or parts thereof, when provided electronically.

7.2.2 Instructions for use

7.2.2.1 General

The instructions for use shall document all that is necessary for proper operation of the HEALTH SOFTWARE PRODUCT, including installation instructions where appropriate.

If applicable, the instructions for use shall specify restrictions on an IT-NETWORK on which the HEALTH SOFTWARE PRODUCT is intended to be used (see 7.2.3.2).

NOTE The instructions for use are intended for the USER and the RESPONSIBLE ORGANIZATION and contain only the information useful to the USER or RESPONSIBLE ORGANIZATION. Additional details can be contained in the technical description. See also 7.2.3.

7.2.2.2 HEALTH SOFTWARE description

The instructions for use shall contain:

a) the INTENDED USE of the HEALTH SOFTWARE PRODUCT as defined by the MANUFACTURER;

b) a brief description of the HEALTH SOFTWARE PRODUCT, including the essential functions of the HEALTH SOFTWARE PRODUCT;

c) any operational SECURITY options for the use of the HEALTH SOFTWARE; and

d) any known technical issues, limitations, disclaimer, or contraindication(s) to the use of the HEALTH SOFTWARE PRODUCT.

7.2.2.3 Warnings and notices for SAFETY and/or SECURITY

The instructions for use shall list all warnings and notices for SAFETY and/or SECURITY related to the use of the HEALTH SOFTWARE PRODUCT and explain or expand them when they are not self-explanatory.

General warnings and notices for SAFETY and/or SECURITY should be placed in a specifically identified section of the instructions for use. A warning or a notice for SAFETY or for SECURITY

that applies only to a specific instruction or action should precede the instruction to which it applies.

7.2.2.4 Installation

The instructions for use shall contain:

a) a statement whether the installation can be done by the USER or shall be done by or with the assistance of the MANUFACTURER, or by an authorised person;

b) the system requirements for the software and hardware platforms intended to execute the HEALTH SOFTWARE;

c) operational SECURITY options for the HEALTH SOFTWARE to be set at installation time;

d) any critical dependencies on other applications;

e) the configuration requirements;

f) the system interface requirements (both required and optional);

g) the details of the supported software platforms; and

h) the installation instructions or a reference to where the installation instructions are to be found.

7.2.2.5 Start-up procedure

The instructions for use shall contain the necessary information for the USER to bring the HEALTH SOFTWARE into operation.

7.2.2.6 Shutdown procedure

The instructions for use shall contain the necessary information for the USER to safely shut down the operation of the HEALTH SOFTWARE.

7.2.2.7 Operating instructions

The instructions for use shall contain all information necessary to operate the HEALTH SOFTWARE. This shall include explanation of the function of controls, displays and signals and the sequence of operation.

The instructions for use shall explain the meanings of figures, symbols, warning statements and abbreviations.

7.2.2.8 Messages

The instructions for use shall list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory.

NOTE These messages can be identified in groups.

The list shall include an explanation of messages including important causes, and possible action(s) by the USER, if any, that are necessary to resolve the situation indicated by the message.

7.2.2.9 Decommissioning and disposal of HEALTH SOFTWARE

The instructions for use shall contain all information necessary for the USER or the RESPONSIBLE ORGANIZATION to safely decommission and dispose of the HEALTH SOFTWARE. This shall include, where appropriate, safeguarding personal and health-related data in connection with SECURITY and privacy.

NOTE Regulatory authorities can specify requirements when dealing with personal and health-related data.

7.2.2.10 Reference to the technical description

The instructions for use shall contain the technical description (see 7.2.3) or a reference to where the technical description can be found.

7.2.3 Technical description

7.2.3.1 General

The technical description shall provide all data that is essential for safe and secure operation, transport and storage, and measures or conditions necessary for installing the HEALTH SOFTWARE, and preparing it for use. This shall include:

a) the system requirements for the software and hardware platforms intended to execute the HEALTH SOFTWARE;

b) the details of the supported software platforms;

c) the permissible environmental conditions for transport and storage of the media containing the HEALTH SOFTWARE;

d) all characteristics of the HEALTH SOFTWARE, including range(s), accuracy, and precision of the displayed values or an indication where they can be found;

e) any special installation requirements or restrictions;

f) any maintenance requirements, such as log files to be checked and possibly cleared, database maintenance, and change of storage media;

g) any technical SECURITY options that can be configured within the HEALTH SOFTWARE PRODUCT, and that are available to the RESPONSIBLE ORGANIZATION. Such SECURITY may include:

   1) configuration options, e.g. minimum list of network ports and computer services that are required.

   2) software options, e.g. turn on encryption settings, change default login credentials.

   3) operational options, e.g. auditing and logging management settings.

h) a description of what the software does when a failure to maintain SECURITY is detected. The description shall include any impact to patient care, data or clinical workflow.

NOTE Due to the multiple, variable hardware and software platforms where HEALTH SOFTWARE typically runs, in some cases a detailed description of a successful implementation or documentation of typical characteristics and constraints can provide effective help.

The MANUFACTURER shall provide instructions in the technical description for the USER and/or the RESPONSIBLE ORGANIZATION on how to deal with changes of the hardware and software platforms (e.g., with patches/updates of antivirus/firewall software, system libraries, firmware, and others), and how to select appropriate platform settings to support the SECURITY goals and SECURITY capabilities.

7.2.3.2 * HEALTH SOFTWARE intended to be used in an IT-NETWORK

The scope of the IT-NETWORK may include supporting IT infrastructure or systems not explicitly intended to be used in a healthcare setting. See 3.9.

If the HEALTH SOFTWARE is intended to be used in an IT-NETWORK that is outside the control of the HEALTH SOFTWARE MANUFACTURER, the MANUFACTURER shall provide, as part of the technical description, instructions necessary for this use, including but not limited to the following:

a) the characteristics and configuration of the IT-NETWORK required for the HEALTH SOFTWARE to achieve its purpose;

b) the technical specifications of the IT-NETWORK necessary for the HEALTH SOFTWARE to achieve its purpose, including SECURITY specifications and protection against malware (short for malicious software) or similar;

c) the intended information flow between the HEALTH SOFTWARE and other software or systems using the IT-NETWORK.

The MANUFACTURER shall include in the technical description a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics and services required for the purpose of the HEALTH SOFTWARE when using that IT-NETWORK.

In the technical description, the MANUFACTURER shall inform the RESPONSIBLE ORGANIZATION that:

a) execution of the HEALTH SOFTWARE on an IT-NETWORK could result in previously unidentified RISKS to patients, USERS or third parties;

b) the RESPONSIBLE ORGANIZATION is advised to identify, analyze, evaluate and control these RISKS;

c) subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis; and

d) changes to the IT-NETWORK include:

   1) changes in IT-NETWORK configuration;

   2) addition of items (hardware and/or software platforms or software applications) to the IT-NETWORK;

   3) removal of items from the IT-NETWORK;

   4) update of hardware and/or software platforms or software applications on the IT-NETWORK; and

   5) upgrade of hardware and/or software platforms or software applications on the IT-NETWORK.

NOTE IEC 80001-1:2010 provides requirements for the HEALTH SOFTWARE MANUFACTURER, the provider of other information technology, and RESPONSIBLE ORGANIZATIONS to address RISKS of modifications to the IT-NETWORK.

8 Post-market activities for the HEALTH SOFTWARE PRODUCT

8.1 General

According to Clause 1, this document covers the entire life cycle of HEALTH SOFTWARE. Within its life cycle, HEALTH SOFTWARE is likely to undergo SOFTWARE MAINTENANCE and, at the end, decommissioning and disposal. Subclause 4.2 addresses use requirements to be implemented and validated prior to making the product available for use; those requirements include decommissioning and disposal of a HEALTH SOFTWARE PRODUCT. When this document is used for compliance purposes, only the post-market aspects that relate to product design and development apply.

8.2 SOFTWARE MAINTENANCE

Where the MANUFACTURER decides that SOFTWARE MAINTENANCE is relevant or necessary, for instance, due to detected errors that can have an impact on SAFETY and/or SECURITY, the MANUFACTURER shall develop the modification of the HEALTH SOFTWARE PRODUCT in compliance with this document (see Clause 5).

NOTE 1 Maintenance can also include changes in the ACCOMPANYING DOCUMENTS, e.g. regarding the platform where the HEALTH SOFTWARE is executed.

NOTE 2 Regulatory requirements can be in place in the case of SOFTWARE MAINTENANCE due to errors detected with an impact on SAFETY and/or SECURITY.

8.3 Re-VALIDATION

The MANUFACTURER shall ensure re-VALIDATION takes place of the parts of the HEALTH SOFTWARE PRODUCT that have been affected by the SOFTWARE MAINTENANCE, taking into account the extent of the modification. The MANUFACTURER shall update the VALIDATION plan accordingly.

The MANUFACTURER shall ensure that the modified version of the HEALTH SOFTWARE functions with any hardware and software platform that is claimed to be supported.

8.4 Post-market communication on the HEALTH SOFTWARE PRODUCT

The MANUFACTURER shall inform USERS of the HEALTH SOFTWARE PRODUCT and impacted RESPONSIBLE ORGANIZATIONS about SECURITY vulnerabilities the MANUFACTURER has become aware of, and of changes in regulatory requirements that impact the use of the HEALTH SOFTWARE PRODUCT.

In the case of SOFTWARE MAINTENANCE, the MANUFACTURER shall make information available to USERS and to the RESPONSIBLE ORGANIZATIONS of the availability of the updated version of the HEALTH SOFTWARE PRODUCT, and provide information about the following, where appropriate:

a) new features;

b) corrected errors or faults;

c) any impact on SAFETY and/or SECURITY of the modified software;

d) updates in the HEALTH SOFTWARE identification (see 7.1);

e) updates in the ACCOMPANYING DOCUMENTS (see 7.2).

The decision of the USER or the RESPONSIBLE ORGANIZATION whether to install the modified version of the HEALTH SOFTWARE should be based on SAFETY and/or SECURITY impacts of the modifications. Where the modified HEALTH SOFTWARE PRODUCT has a positive impact on the SAFETY and/or SECURITY of the HEALTH SOFTWARE, MANUFACTURER may advise the USERS and the RESPONSIBLE ORGANIZATIONS to replace their version in the short term.

8.5 Decommissioning and disposal of the HEALTH SOFTWARE PRODUCT

The USER or the RESPONSIBLE ORGANIZATION shall be able to safely decommission and dispose of the HEALTH SOFTWARE PRODUCT at the end of its useful life, including, where appropriate, safeguarding personal and health-related data in connection with SECURITY and privacy. The HEALTH SOFTWARE shall provide this function consistent with the applicable use requirements as specified in 4.2.

Annex A
(informative)

Rationale

A.1 General

HEALTH SOFTWARE is intended by its MANUFACTURER specifically for health purposes. This includes applications intended to aid in the diagnosis, treatment, or monitoring of a patient, or to aid in compensation or alleviation of disease, injury or disability.

In the early phase of development of this document, the following terms were used to indicate software as part of a (hardware) medical device ("medical device software") and software that is a medical device in itself ("software medical device"). The respective definitions were: medical device software: software intended to be used specifically for incorporation into a physical medical device, and software medical device: software intended to be a medical device in its own right. The combination of the two subcategories was defined as: medical software: software intended to be used specifically for incorporation into a physical medical device or intended to be a software medical device.

HEALTH SOFTWARE, as defined in 3.6: "*software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care*", fully includes "medical software" yet is broader than that. Medical software is closely related to the term medical device, which is a regulatory definition that varies across jurisdictions. For the purpose of this document, the term HEALTH SOFTWARE is considered more appropriate. With the broader scope, this document allows for a common approach for the SAFETY, SECURITY, and performance of all health related software products, regardless whether they are regulated as a medical device.

The International Medical Device Regulators Forum (IMDRF) has published document SaMD WG/N10FINAL: "Software as a Medical Device (SaMD): Key Definitions". Where HEALTH SOFTWARE has a medical purpose and is not intended to run on dedicated hardware, it is identical to a software as a medical device.

Note that this document provides requirements only for HEALTH SOFTWARE PRODUCTS, that is, for HEALTH SOFTWARE made available as a standalone product. HEALTH SOFTWARE that is intended to run on dedicated hardware, sometimes also called "embedded" software, is considered a part of a physical device and not a product in its own right. See also A.2.

HEALTH SOFTWARE includes applications that deal with health, health management, and healthcare resource management. Table A.1 gives examples of software products that are addressed by this document. Gaps in the coverage of HEALTH SOFTWARE by existing standards have been identified in ISO/TR 17791, presenting the landscape of standards for HEALTH SOFTWARE. For standalone health applications, such standards referencing SAFETY, and SECURITY appeared absent. This document aims to fill that void.

Each jurisdiction has to make its own decisions regarding which HEALTH SOFTWARE PRODUCTS are considered to be subject to its medical device regulation or whether, when not regulated as a medical device, other regulations apply. MANUFACTURERS intending to place software-only products within the HEALTH SOFTWARE domain on the market in jurisdictions that have adopted this document are encouraged to investigate which regulatory regime, if any, applies.

Table A.1 – Examples of software (SW) in or not in the scope of this document

In scope	NOT in scope
– SW-only products for health use – Mobile apps running on devices without using specific sensors or detectors [a] – Laboratory information SW – Radiology information SW – SW for individuals in fitness centres – SW for finding best conception moment – Computer-aided diagnosis SW – Analysis SW for medical images – Clinical decision support software used to aid diagnosis, treatment, and health management of individuals – Individual stress relief SW with feedback – Training plan SW for re-validation purposes – SW for stimulating activity by Alzheimer patients – Electronic health record systems, including electronic medical record systems – Hospital information systems – HEALTH SOFTWARE provided as a service hosted by an external organisation	– SW that is not an executable, such as sets of reference values, ... – SW not addressing health issues for individuals – Hospital billing SW – Hospital equipment maintenance scheduling SW – Epidemiological study SW – Nurse training SW – Self-study for medical professionals – Electronic logbook for nursing home Also outside of the scope is software, or their updates, intended to drive (parts of) – Medical electrical equipment or systems covered by IEC 60601/IEC 80601 (all parts) – In vitro diagnostic equipment covered by IEC 61010 (all parts) – Implantable devices covered by ISO 14708 (all parts)
[a] A camera or microphone or other feature commonly found on a smartphone or tablet computer is not considered a specific sensor or detector.	

A.2 Requirements for HEALTH SOFTWARE PRODUCTS

Note that this document provides requirements only for HEALTH SOFTWARE that is made available as a standalone product. Figure A.1 indicates the application domains for HEALTH SOFTWARE and their respective coverage by the related standards, namely this document and IEC 62304:2006 and IEC 62304:2006/AMD1:2015.

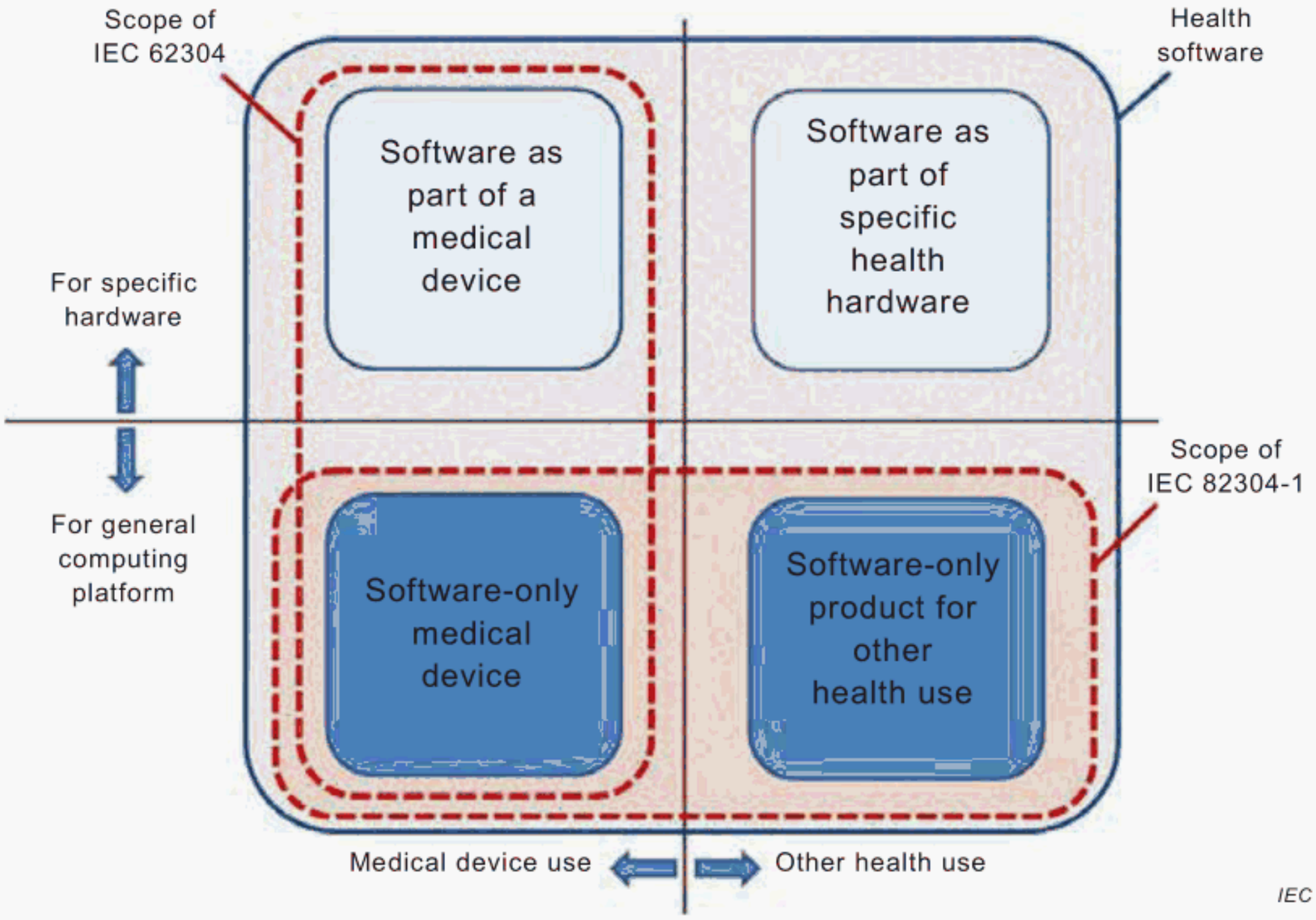


Figure A.1 – HEALTH SOFTWARE application domains and scope of related standards

HEALTH SOFTWARE usually runs on very different platforms, both hardware and software. Examples are: fixed or mobile physical devices, or virtual machines, locally or networked or as a "cloud"-service hosted via the internet. These platforms are often beyond the influence and control of the MANUFACTURER. Therefore, this document also intends to lead the attention of MANUFACTURERS and RESPONSIBLE ORGANIZATIONS to necessary considerations, tasks and documentation to adequately address HAZARDS that might result from the diversity of use and frequently changing platforms.

HEALTH SOFTWARE that is intended to run on dedicated hardware is to be considered as part of a physical device, sometimes also called “embedded” software. Such software is not considered a product in its own right. This holds true for software in a product that is regulated as a medical device as well as for software that is part of a specific physical device which is not regulated as a medical device.

A.3 Rationale for particular clauses and subclauses

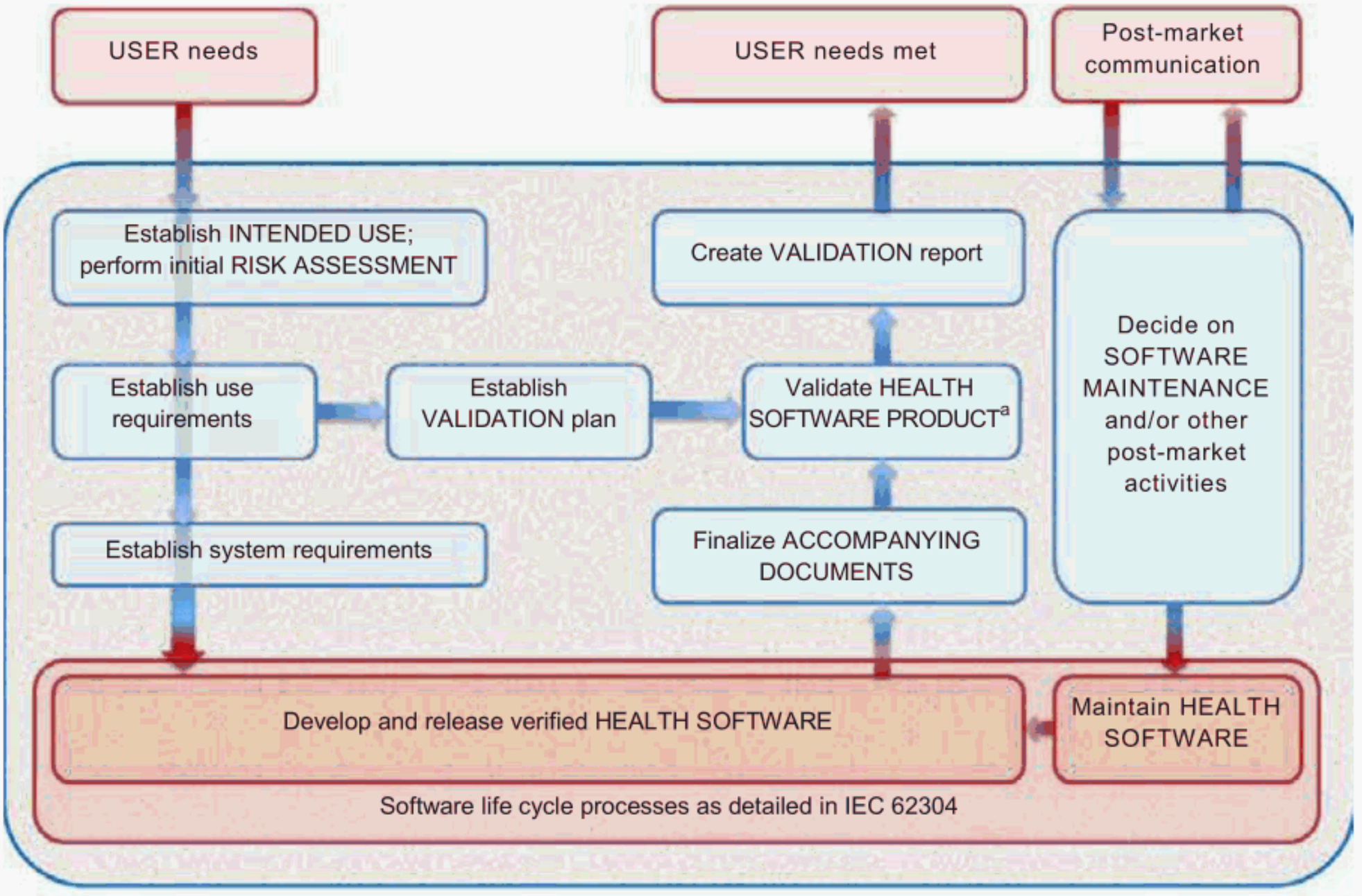
3.6 – Definition of HEALTH SOFTWARE

According to ISO 17791:2013, HEALTH SOFTWARE also includes – in its basic form – systems, software items and software units (see definitions 3.30, 3.25, and 3.28 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015), as well as associated coding systems, inference engines, archetypes and ontologies. Furthermore, it encompasses software that is employed, benefits or applied to any part of the health sector, including all public and private organizations or enterprises as well as consumers, and is commercially and non-commercially available.

The definition of HEALTH SOFTWARE in 3.6 is not in conflict with the definition of the same term in ISO 17791:2013, 2.6.

Clause 4 – HEALTH SOFTWARE PRODUCT requirements

It is common practice that use requirements for a product are established, based on the INTENDED USE, and that criteria to validate the final product are based on these customer or use requirements. The phase in between defining system requirements and VALIDATION of the final product is the product development process. Such a development process is schematically given in Figure A.2. The actual process can follow various schemes, such as the waterfall model or more iterative or incremental development schemes. This document does not require or give preference to a specific process scheme.



[a] HEALTH SOFTWARE PRODUCT: HEALTH SOFTWARE plus ACCOMPANYING DOCUMENTS

IEC

Figure A.2 – IEC 82304-1: HEALTH SOFTWARE PRODUCT processes

The USER needs are input to the development process and flow through a series of processes that interpret these USER needs. The processes described in IEC 62304:2006 and IEC 62304:2006/AMD1:2015 can start once the system requirements have been established. These processes result in the release of verified HEALTH SOFTWARE with documentation. Based on this documentation the ACCOMPANYING DOCUMENTS are then finalized, making the HEALTH SOFTWARE a true HEALTH SOFTWARE PRODUCT that can be subject to VALIDATION.

For VALIDATION of a HEALTH SOFTWARE PRODUCT, this document requires a VALIDATION plan that is based on the use requirements; see 4.2 and 4.3. Following successful VALIDATION, the HEALTH SOFTWARE PRODUCT can be considered to meet the USER needs. It is up to the MANUFACTURER to decide on the release for placing on the market of the HEALTH SOFTWARE PRODUCT; considerations other than successful VALIDATION can influence that decision.

During the post-market phase, the MANUFACTURER may receive -or actively collect- feedback on the HEALTH SOFTWARE PRODUCT. Based on this information or on other considerations, decisions may be made on post-market activities. These activities can include SOFTWARE MAINTENANCE, which has to follow the same processes as the initial development, where applicable. Other post-market activities can be communication to USERS or to authorities, for example on SECURITY vulnerabilities.

HAZARDS associated with HEALTH SOFTWARE can arise from usability issues. When establishing the use requirements, it is advised to consult IEC 62366-1:2015 for the usability engineering process.

IEC 62304:2006 and IEC 62304:2006/AMD1:2015, dealing with lifecycle processes for medical device software, covers the entire software development scheme. IEC 62304 was designed to be referenced from other system safety standards. IEC 82304-1 covers the entire product life cycle, and normatively references IEC 62304:2006 and IEC 62304:2006/AMD1:2015 where applicable.

Clause 5 – HEALTH SOFTWARE – Software life cycle processes

This document incorporates a RISK/benefit based approach. Users of this document are required to establish, maintain and apply a RISK MANAGEMENT process as part of compliance. That requirement, together with other requirements for software life cycle processes, has been documented in IEC 62304:2006 and IEC 62304:2006/AMD1:2015. These requirements apply equally to all HEALTH SOFTWARE and are normatively included in this document by reference.

Clause 6 – HEALTH SOFTWARE PRODUCT VALIDATION

The final phase of any HEALTH SOFTWARE development life cycle model is HEALTH SOFTWARE PRODUCT VALIDATION. The purpose of the VALIDATION process is to provide objective evidence that the HEALTH SOFTWARE PRODUCT fulfils the HEALTH SOFTWARE PRODUCT use requirements (see 4.2) in its intended operational environment. HEALTH SOFTWARE PRODUCT VALIDATION is intended to assure that the right product is built. VALIDATION is important for HEALTH SOFTWARE PRODUCTS because unexpected interactions between functions might occur that can only be discovered by VALIDATION.

HEALTH SOFTWARE PRODUCT VALIDATION can include tests for a high volume of data, heavy loads or stresses, human factors, performance, configuration compatibility, data, environment and system integrity, fault testing, documentation, SAFETY and SECURITY.

Independence is needed, at least strongly recommended, to avoid conflicts of interest and because the assumptions of the designer should not influence or limit the extent of the HEALTH SOFTWARE PRODUCT VALIDATION. Examples of level of independence include:

a) separate person,

b) separate management,

c) separate organization.

7.1 – Identification

Software can be easily updated or upgraded, sometimes without USER involvement. It is important that the specific version of the HEALTH SOFTWARE being used can be identified. The term "version identifier" applies to this specific HEALTH SOFTWARE version, not to an individual copy of the HEALTH SOFTWARE. The identifier used for each version should be sufficiently unique to distinguish the version of HEALTH SOFTWARE in use from a previous version of the same software.

7.2.3.2 – HEALTH SOFTWARE intended to be used in an IT-NETWORK

This document is suggesting IEC 80001-1:2010 and IEC 80001-2-2:2012 for additional information and useful guidance although the scope of the current editions is restricted to medical devices and/or medical device software.

When reading IEC 80001-1:2010 and IEC 80001-2-2:2012 for use with this document, the term “medical device” can be understood as “HEALTH SOFTWARE PRODUCT”; and “medical device MANUFACTURER” as “HEALTH SOFTWARE PRODUCT MANUFACTURER”.

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