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Health software — Software life cycle processes

Logiciels de santé — Processus du cycle de vie du logiciel

ICS: 11.040.01; 35.240.80

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This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HEALTH SOFTWARE –

SOFTWARE LIFE CYCLE PROCESSES

FOREWORD

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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, in cooperation with ISO Technical Committee 215, Health informatics. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and systems engineering.

It is published as a dual logo standard.

This second edition cancels and replaces the first edition published in 2006 and Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) the scope of this document has been expanded to HEALTH SOFTWARE;

144 b) Clause 4 related to general requirements has been updated to assure that this document would
145 meet the state of art of the use-environment and the way that HEALTH SOFTWARE is being used.

146 The text of this International Standard is based on the following documents:

| | |
|-------------|------------------|
| FDIS | Report on voting |
| 62A/XX/FDIS | 62A/XX/RVD |

147
148 Full information on the voting for the approval of this International Standard can be found in the
149 report on voting indicated in the above table.

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

151 In this document, the following print types are used:

- 152 – requirements and definitions: roman type;
- 153 – informative material appearing outside of tables, such as notes, examples and references: smaller type.
154 Normative text of tables is also in a smaller type;
- 155 – TERMS USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN DEFINED IN CLAUSE 3: SMALL CAPITALS.

156 The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC
157 Directives, Part 2:2018. For the purposes of this document, the verb:

- 158 – "shall" means that compliance with a requirement is mandatory for compliance with this document;
- 159 – "should" means that compliance with a requirement is recommended but is not mandatory for
160 compliance with this document;
- 161 – "may" is used to describe a permissible way to achieve compliance with a requirement;
- 162 – "establish" means to define, document and implement.

163 Where this document uses the term "as appropriate" in conjunction with a required PROCESS, ACTIVITY,
164 TASK or output, the intention is that the MANUFACTURER shall use the PROCESS, ACTIVITY, TASK or output
165 unless the MANUFACTURER can document a justification for not so doing.

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

168 The committee has decided that the contents of this document will remain unchanged until the
169 stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to
170 the specific document. At this date, the document will be

- 171 • reconfirmed,
- 172 • withdrawn,
- 173 • replaced by a revised edition, or
- 174 • amended.

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

180

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.

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183

INTRODUCTION

184 Software is becoming increasingly important in healthcare. The use of software can help
185 contribute to more efficient and safe care of patients. Thus, HEALTH SOFTWARE needs to be
186 developed with appropriate controls to ensure its safe, effective and secure use.

187 Users of software in the care environment have expanded from clinical users (nurses,
188 technicians, dieticians, physicians, etc.) to include non-clinical users (patients, consumers,
189 laypersons, family care givers, etc.). IEC 62304:2006 and IEC 62304:2006/AMD1:2015 focused
190 on software life cycle activities for MEDICAL DEVICE SOFTWARE that was primarily used by clinical
191 users. For this reason, the scope of this document has been expanded to HEALTH SOFTWARE.

192 As software becomes more dependent on network connectivity and integral to clinical workflows,
193 additional considerations need to be made for SECURITY and USABILITY. HEALTH SOFTWARE is
194 being used more commonly in the home and outside of the hospital, so it becomes even more
195 important to develop these products with the user and use environment in mind. For these
196 reasons, Clause 4 related to general requirements has been updated to assure that this
197 document would meet the state of art of the use-environment and the way that HEALTH SOFTWARE
198 is being used.

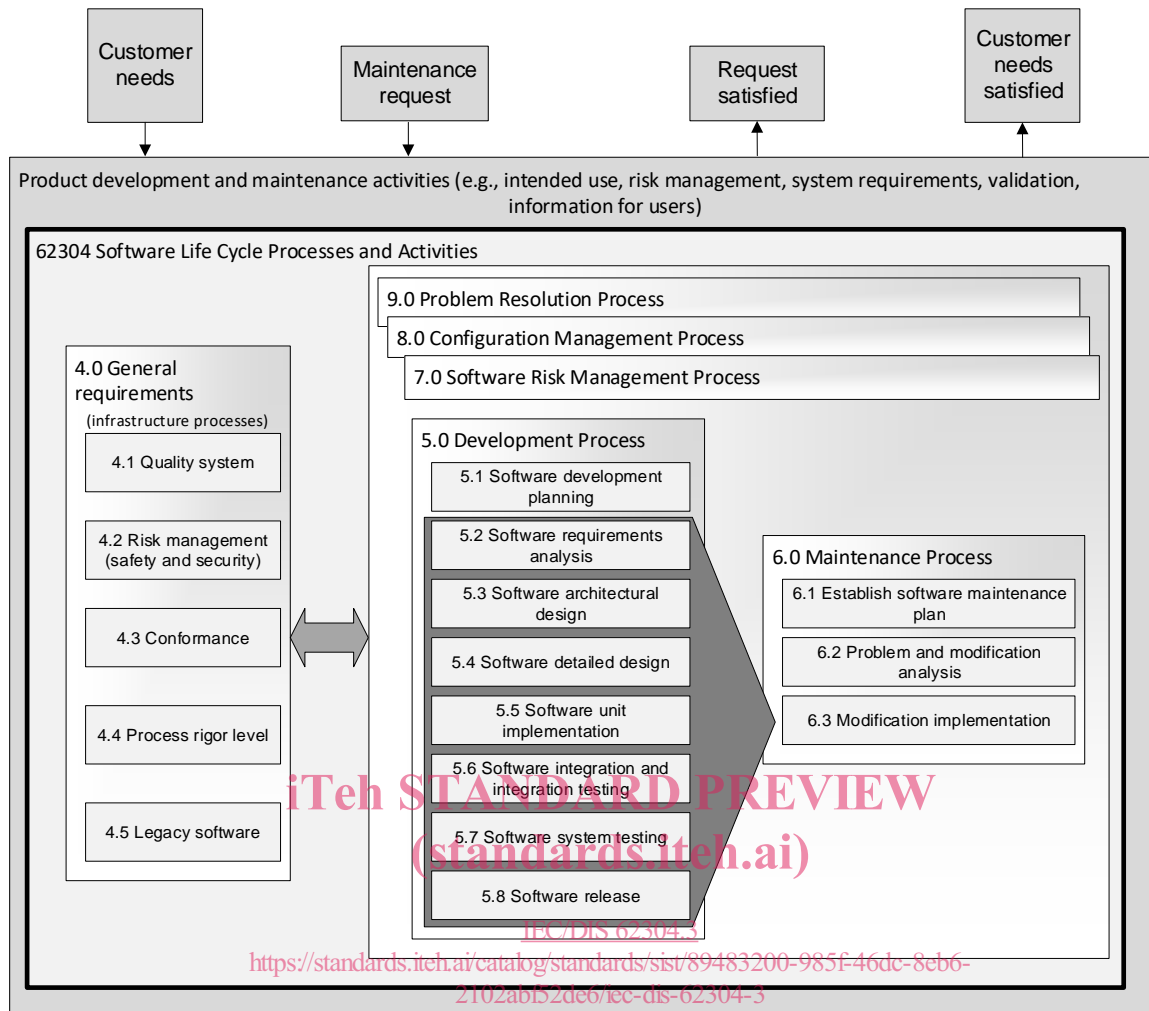
199 This document does not duplicate well-established requirements from standards for USABILITY
200 and SECURITY.

201 Establishing the SAFETY and EFFECTIVENESS of HEALTH SOFTWARE requires knowledge of what
202 the HEALTH SOFTWARE is intended to do and demonstration that the use of the HEALTH SOFTWARE
203 fulfils those intentions without causing any unacceptable RISKS. To demonstrate the
204 EFFECTIVENESS, software VALIDATION is required, which is outside of the scope of this document.

205 The MANUFACTURER of HEALTH SOFTWARE is responsible for determining and complying with the
206 appropriate SAFETY, SECURITY, environmental, health, and interference protection practices.
207 Many laws, regulations, and other rules from authorities having jurisdiction have a direct impact
208 on the way SOFTWARE SYSTEMS are developed, tested, and maintained. From a software
209 development perspective, MANUFACTURERS consider these laws, regulations, and other rules as
210 inputs into the requirements that the HEALTH SOFTWARE supports. This means that the
211 requirements of some laws or regulations can translate into specific HEALTH SOFTWARE product
212 requirements. For example, if HEALTH SOFTWARE is going to send or share health data to a doctor,
213 hospital, or other covered entity, it has an obligation to adhere to privacy and SECURITY rules.
214 This can involve authentication and SECURITY mechanisms to protect patient information saved
215 in an electronic format. Other requirements of the laws or regulations can impact the PROCESS
216 used during the development of the HEALTH SOFTWARE product. For example, many national
217 regulations and quality systems standards have design control requirements that translate into
218 specific procedures to confirm that the product is designed, verified, and validated in a
219 systematic manner and per proven software engineering practices.

220 This document specifies that MANUFACTURERS develop and maintain HEALTH SOFTWARE within a
221 quality management SYSTEM (see 4.1) and a RISK MANAGEMENT SYSTEM (4.2).

222 This document provides a framework for a life cycle PROCESS. It defines the ACTIVITIES and
223 TASKS necessary for the safe design, development and maintenance of HEALTH SOFTWARE. The
224 development and maintenance life cycle ACTIVITIES are shown in Figure 1 and described in
225 Clause 5 and Clause 6. Some incidents in healthcare delivery are related to HEALTH SOFTWARE
226 SYSTEMS, including failures that can occur or be injected when software is modified.



227

228

Figure 1 – Overview of software development and maintenance PROCESSES and ACTIVITIES

229 This document identifies two additional supporting PROCESSES considered essential for
 230 developing safe HEALTH SOFTWARE. They are the software configuration management PROCESS
 231 (Clause 8) and the software problem resolution PROCESS (Clause 9).

232 This document does not specify a specific organizational structure nor responsibilities within
 233 the organization of the MANUFACTURER to perform PROCESSES, ACTIVITIES, and TASKS. This
 234 document specifies planning of software development, maintenance and supporting PROCESS
 235 ACTIVITIES, and the completion of the ACTIVITIES or TASKS for conformance with this document.

236 This document does not prescribe the name, format, or explicit content of the documentation to
 237 be produced. This document calls for adequate evidence of required ACTIVITIES and TASKS by
 238 documentation. Regardless how content is structured and packaged, it is expected that a
 239 controlled documentation PROCESS is in place. This document does not prescribe a specific life
 240 cycle model. The users of this document are responsible for selecting a life cycle model for the
 241 software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this document onto
 242 that model. Annex A provides rationale for the clauses of this document. Annex B provides
 243 guidance on the provisions of this document.

244

245

HEALTH SOFTWARE –

246

SOFTWARE LIFE CYCLE PROCESSES

247

248 **1 Scope**249 **1.1 * Purpose**

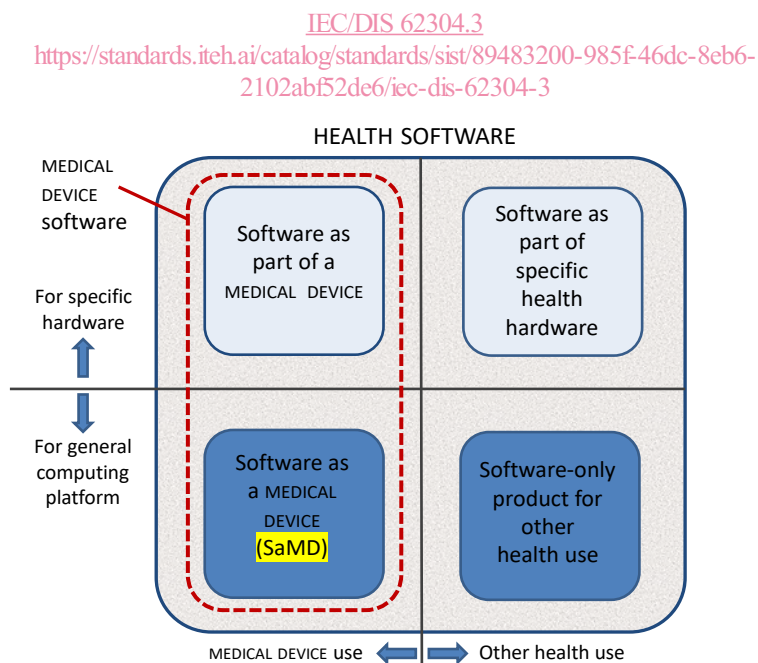
250 This document defines the development and maintenance life cycle requirements for HEALTH
 251 SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this document establishes
 252 a common framework for HEALTH SOFTWARE life cycle PROCESSES.

253 **1.2 * Field of application**

254 This document applies to the development and maintenance of HEALTH SOFTWARE by a
 255 MANUFACTURER. MEDICAL DEVICE SOFTWARE is a subset of HEALTH SOFTWARE (see Figure 2).
 256 Therefore, this document applies to:

- 257 – software as part of a MEDICAL DEVICE;
- 258 – software as part of specific health hardware;
- 259 – software as a MEDICAL DEVICE (SaMD);
- 260 – software-only product for other health use.

261 Figure 2 provides a graphical representation of the health software this document applies to.



262

263 **Figure 2 – HEALTH SOFTWARE field of application**

264 NOTE 1 Examples of HEALTH SOFTWARE include the following:

- 265 1) software as a part of a MEDICAL DEVICE: software that is an integral part of a device such as an infusion pump or dialysis
 266 machine.
- 267 2) software as part of specific health hardware: patient wristband printer software, healthcare scanner software, health app on
 268 specific wearable hardware (i.e. watch, wristband, chestband).

269 3) software as a MEDICAL DEVICE (SaMD): software that is itself a MEDICAL DEVICE, such as a software application that performs
270 diagnostic image analysis for making treatment decisions. A definition of software as a MEDICAL DEVICE is provided in [46]¹.

271 4) software-only product for other health use: hospital information systems, electronic health records, electronic medical
272 records, mobile applications running on devices without physiologic sensors or detectors, software as a service, i.e.
273 software executed in an external environment, providing calculation-results that fulfil the definition of a MEDICAL DEVICE.

274 NOTE 2 This document can be used in the development and maintenance of HEALTH SOFTWARE. Before any type of
275 software can be placed into service, activities are necessary before the software product is integrated into the
276 SYSTEM. These SYSTEM activities are not covered by this document (see Figure 1), but can be found in related
277 product standards (e.g., IEC 60601-1 [1] or IEC 82304-1 [15]). For software as a MEDICAL DEVICE (SaMD) additional
278 guidance on ACTIVITIES at a system level (e.g. clinical EVALUATION) can be found in regulatory authority guidance
279 documents.

280 This document describes PROCESSES that are intended to be applied to software which executes
281 on a processor or which is executed by other software (for example an interpreter) which
282 executes on a processor.

283 This document applies regardless of the persistent storage device(s) used to store the software
284 (for example: hard disk, optical disk, permanent or flash memory).

285 This document applies regardless of the method of delivery of the software (for example:
286 transmission by network or email, EEPROM, Smart Drive, Cloud). The method of software
287 delivery itself is not considered HEALTH SOFTWARE.

288 This document does not cover the means of VALIDATION, even when the product consists entirely
289 of software. It also does not cover software life cycle steps after release for INTENDED USE of
290 the product, including implementation, configuration, integration (with other systems), go-live,
291 clinical use, operations, decommissioning or disposal, other than ACTIVITIES involving
292 maintenance of the software.

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293 This document does not cover the VALIDATION of software tools used in the design of medical
294 devices (e.g. computer aided design (CAD) software), software used in MEDICAL DEVICE quality
295 systems or software for regulated processes (see ISO/TR 80002-2 [20] and AAMI TIR 36 [40]).

296 NOTE 3 If a product incorporates embedded software intended to be executed on a processor, the requirements of this
297 document apply to the software, including the requirements concerning SOFTWARE OF UNKNOWN PROVENANCE (SOUP) – see
298 8.1.2).

299 Data quality and VALIDATION of emergent characteristics or functionality of artificial intelligence
300 (AI) HEALTH SOFTWARE are not within the scope of this document.

301 NOTE 4 Users of this document may need to utilize other standards and technical sources to supplement this document in
302 addressing the unique performance characteristics of their AI HEALTH SOFTWARE. As AI is a rapidly developing field and as
303 further insights are gained, new updates may need to be incorporated into IEC 62034 via an amendment or a future new edition.

304 1.3 Relationship to other standards

305 This HEALTH SOFTWARE life cycle document is written in a way that it can be used together with
306 referencing standards when developing and maintaining a product that includes HEALTH
307 SOFTWARE (see Annex C).

308 2 * Normative references

309 The following documents are referred to in the text in such a way that some or all of their content
310 constitutes requirements of this document. For dated references, only the edition cited applies.

¹ Numbers in square brackets refer to the Bibliography.

311 For undated references, the latest edition of the referenced document (including any
312 amendments) applies.

313 **3 * Terms and definitions**

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

315 ISO and IEC maintain terminological databases for use in standardisation at the following
316 addresses:

- 317 • IEC Electropedia: available at <http://www.electropedia.org/>
- 318 • ISO Online browsing platform: available at <https://www.iso.org/obp>

319 **3.1** 320 **ACTIVITY**

321 set of one or more interrelated or interacting TASKS

322 **3.2** 323 **ANOMALY**

324 condition that deviates from expectations based on requirements specifications, design documents,
325 standards, etc. or from someone's perceptions or experiences

326 [SOURCE: ISO/IEC 25051:2014, 4.1.2] [\(standards.iteh.ai\)](https://standards.iteh.ai/)

327 **3.3** [IEC/DIS 62304.3](https://standards.iteh.ai/catalog/standards/sist/89483200-985f-46dc-8eb6-2102abf52de6/iec-dis-62304-3) 328 **ARCHITECTURE** <https://standards.iteh.ai/catalog/standards/sist/89483200-985f-46dc-8eb6-2102abf52de6/iec-dis-62304-3>

329 [SYSTEM] fundamental concepts or properties of a SYSTEM in its environment embodied in its elements,
330 relationships, and in the principles of its design and evolution

331 [SOURCE: ISO/IEC/IEEE Std 24765-2017, 3.216, definition 1]

332 **3.4** 333 **CHANGE REQUEST**

334 documented specification of a change to be made to HEALTH SOFTWARE

335 **3.5** 336 **CONFIGURATION ITEM**

337 entity that can be uniquely identified at a given reference point

338 **3.6** 339 **DELIVERABLE**

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

341 **3.7** 342 **EVALUATION**

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

344 **3.8**
345 **EFFECTIVENESS**

346 ability to produce the intended result

347 [SOURCE: ISO 81001-1:—², 3.2.5]

348 **3.9**
349 **HARM**

350 injury or damage to the health of people, or damage to property or the environment

351 [SOURCE: ISO 81001-1:—, 3.4.5]

352 **3.10**
353 **HAZARD**

354 potential source of HARM

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

356 [SOURCE: ISO 81001-1:—, 3.4.6, modified – Note 1 to entry has been added.]

357 **3.11**
358 **HAZARDOUS SITUATION**

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359 circumstance in which people, property or the environment is/are exposed to one or more HAZARD(S)

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360 [SOURCE: ISO 81001-1:—, 3.4.7] <https://standards.iteh.ai/catalog/standards/sist/89483200-985f-46dc-8eb6-2102abf52de6/iec-dis-62304-3>

361 **3.12**
362 **HEALTH SOFTWARE**

363 SOFTWARE intended to be used specifically for managing, maintaining, or improving health of individual
364 persons, or the delivery of care, or which has been developed for the purpose of being incorporated
365 into a MEDICAL DEVICE

366 Note 1 to entry: HEALTH SOFTWARE fully includes what is considered software as a MEDICAL DEVICE.

367 [SOURCE: ISO 81001-1:—, 3.3.9]

368 **3.13**
369 **INTENDED USE**

370 use for which a product, PROCESS or service is intended according to the specifications, instructions
371 and information provided by the MANUFACTURER

372 Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user
373 profile, use environment, and operating principle are typical elements of the INTENDED USE.

374 [SOURCE: ISO 81001-1:—, 3.2.7, modified – The second preferred term "intended purpose" has
375 been deleted.]

² Under preparation. Stage at the time of publication: ISO/DIS 81001-1:2019.

376 **3.14**
377 **LEGACY SOFTWARE**

378 HEALTH SOFTWARE placed on the market before the publication of this document for which the
379 MANUFACTURER seeks conformance retrospectively

380 **3.15**
381 **MANUFACTURER**

382 natural or legal person with responsibility for designing, manufacturing, packaging, or labelling of
383 HEALTH SOFTWARE product, or adapting HEALTH SOFTWARE product before it is placed on the market
384 and/or put into service, regardless of whether these operations are carried out by that person or on
385 that person's behalf by a third party

386 Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of
387 MANUFACTURER.

388 Note 2 to entry: For a definition of "labelling", see ISO 13485:2016, 3.8.

389 Note 3 to entry: "Developer" or "developer organization" are commonly used terms and are synonymous with the term
390 "MANUFACTURER" in the context of health information technology.

391 **3.16**
392 **MEDICAL DEVICE**

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

- 396 – diagnosis, prevention, monitoring, treatment or alleviation of disease,
- 397 – diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- 398 – investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
- 399 – supporting or sustaining life,
- 400 – control of conception,
- 401 – disinfection of MEDICAL DEVICES,
- 402 – providing information by means of in vitro examination of specimens derived from the human body,
- 403 and which does not achieve its primary intended action by pharmacological, immunological or
- 404 metabolic means, in or on the human body, but which may be assisted in its function by such means

405 Note 1 to entry: Products which could be considered to be MEDICAL DEVICES in some jurisdictions but not in others include:

- 406 – disinfection substances,
- 407 – aids for persons with disabilities,
- 408 – devices incorporating animal and/or human tissues,
- 409 – devices for in-vitro fertilization or assisted reproductive technologies.

410 Note 2 to entry: In conjunction with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, the term "MEDICAL DEVICE" assumes
411 the same meaning as ME EQUIPMENT or ME SYSTEM (which are defined terms of IEC 60601-1).

412 [SOURCE: ISO 81001-1:—, 3.3.13, modified – Note 2 to entry has been added.]