









The data exposed has research value and not legal value.

Terms	Variant	Complementary	AI Act	
159 Risk management process				30
170 Management				30
156 Risk analysis				30
158 Risk evaluation			Article 009	30
238 Risk estimation				30
154 Residual risk			Article 009	30
239 Market for medical or safety reasons			Article 005	30
214 Safety			Article 001, Article 073	30
240 Safety components of devices				30

OPTIONAL INFORMATION

Name and Surname: \_\_\_\_\_ Affiliation and Qualification: \_\_\_\_\_ LinkedIn ... other: \_\_\_\_\_

Observations: \_\_\_\_\_

**ID 30** **14971** - [ ]

**Specification** Application of risk management to medical devices

**Relationship with AI Act** Article 009 (Residual risk); Article 009 (Risk evaluation); Article 001, Article 073 (Safety); Article 005 (Market for medical or safety reasons)

**Link** <https://www.iso.org/obp/ui/en/#iso:std:iso:14971:ed-3:v1:en>

**Scope** This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of this document are applicable to all phases of the life cycle of a medical device. The process described in this document applies to risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability. The process described in this document can also be applied to products that are not necessarily medical devices in some jurisdictions and can also be used by others involved in the medical device life cycle.

Terms	Variant	Complementary	AI Act	
194 Artificial intelligence			Article 003, Article 001	26
64 Terms related to AI				26
206 Terms related to computer vision				26
201 Terms related to data				26
202 Terms related to machine learning				26
205 Terms related to natural language processing				26
203 Terms related to neural networks				26
204 Terms related to trustworthiness				26
28 Data quality reporting			Article 015	26
215 Cybersecurity			Article 015	26
231 Knowledge			Article 004	26
76 Validation				26

OPTIONAL INFORMATION

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Observations: \_\_\_\_\_

**ID 26** **22989** - [ ]

**Specification** Artificial intelligence concepts and terminology

**Relationship with AI Act** Article 015 (Data quality reporting); Article 003, Article 001 (Artificial intelligence); Article 015 (Cybersecurity); Article 004 (Knowledge)

**Link** <https://www.iso.org/obp/ui/en/#iso:std:iso-iec:22989:ed-1:v1:en>

**Scope** This document establishes terminology for AI and describes concepts in the field of AI. This document can be used in the development of other standards and in support of communications among diverse, interested parties or stakeholders. This document is applicable to all types of organizations (e.g. commercial enterprises, government agencies, not-for-profit organizations).

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Terms	Variant	Complementary	AI Act
101 Risk management			Article 017, Article 009
86 Leadership			Article 017
34 Design			Article 010, Article 017
90 Evaluation			
91 Improvement			
160 Risk treatment			
112 Monitoring			
235 Processes			
236 Products			

**ID 24** **23894** -

**Specification** Guidance on risk management

**Relationship with AI Act** Article 010, Article 017 (Design); Article 017 (Leadership); Article 017, Article 009 (Risk management)

**Link** <https://www.iso.org/obp/ui/en/#iso:std:iso-iec:23894:ed-1:v1:en>

**Scope** This document provides guidance on how organizations that develop, produce, deploy or use products, systems and services that utilize artificial intelligence (AI) can manage risk specifically related to AI. The guidance also aims to assist organizations to integrate risk management into their AI-related activities and functions. It moreover describes processes for the effective implementation and integration of AI risk management. The application of this guidance can be customized to any organization and its context.

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Observations

Terms	Variant	Complementary	AI Act
51 Functional correctness			
16 Characteristics of the data sets may be met at			
14 Bias			
106 Data bias			
34 Design			Article 010, Article 017
49 Lifecycle			Article 015, Article 017, Article 009
107 Software testing			
108 Social responsibility			

**ID 13** **24027** -

**Specification** Bias in AI systems and AI aided decision making

**Relationship with AI Act** Article 010, Article 017 (Design); Article 015, Article 017, Article 009 (Lifecycle)

**Link** <https://www.iso.org/obp/ui/en/#iso:std:iso-iec:tr:24027:ed-1:v1:en>

**Scope** This document addresses bias in relation to AI systems, especially with regards to AI-aided decision-making. Measurement techniques and methods for assessing bias are described, with the aim to address and treat bias-related vulnerabilities. All AI system lifecycle phases are in scope, including but not limited to data collection, training, continual learning, design, testing, evaluation and use.

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Observations







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**ID 25** **25019** -

**Specification** Quality-in-use model

**Relationship with AI Act** **Article 017, Article 005 (Accessibility); Article 017 (Compliance); Article 017 (Post-market); Article 010 (Data quality); Article 004 (Experience)**

**Link** <https://www.iso.org/obp/ui/en/#iso:std:iso-iec:25019:ed-1:v1:en>

**Scope** This document defines a quality-in-use model composed of three characteristics (which are further subdivided into sub-characteristics) that can influence stakeholders when products or systems are used in a specified context of use. This model is applicable to the entire spectrum of information system and IT service system, including both computer systems in use and software products in use. This document provides a set of quality characteristics for specifying, measuring, evaluating and improving quality-in-use. In this document, because context of use is specified as prerequisite of quality-in-use, context of use is necessary to be re-specified to change prerequisite when a product or service intend to fulfill to context of use changes.

Terms	Variant	Complementary	AI Act	
100 Post-market			Article 017	25
112 Monitoring				25
113 Stakeholder				25
90 Evaluation				25
1 Accessibility			Article 017, Article 005	25
97 Usability				25
116 Data quality			Article 010	25
115 Customer				25
117 Information system				25
79 Organization				25
118 Quality-in-use				25
119 Risk				25
120 Society				25
121 Software quality				25
122 System				25
123 Target entity				25
125 Direct user				25
124 User				25
126 Beneficialness				25
128 Freedom from risk				25

## OPTIONAL INFORMATION

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## Observations

**ID 2** **25024** -

**Specification** Measurement of data quality

**Relationship with AI Act** **Article 017, Article 005 (Accessibility); Article 015 (Accuracy); Article 017 (Compliance); Article 010 (Consistency); Article 015 (Measurement and method); Article 010 (Quality criteria); Article 010 (Training, validation, testing datasets)**

**Link** <https://www.iso.org/obp/ui/en/#iso:std:iso-iec:25024:ed-1:v1:en>

**Scope** This International Standard defines data quality measures for quantitatively measuring the data quality in terms of characteristics defined in ISO/IEC 25012. This International Standard contains the following:  
 — a basic set of data quality measures for each characteristic;  
 — a basic set of target entities to which the quality measures are applied during the data-life-cycle;  
 — an explanation of how to apply data quality measures;  
 — a guidance for organizations defining their own measures for data quality requirements and evaluation. It includes, as informative annexes, a synoptic table of quality measure elements defined in this International standard (Annex A), a table of quality measures associated to each quality measure element and target entity (Annex B), considerations about specific quality measure elements (Annex C), a list of quality measures in alphabetic order (Annex D), and a table of quality measures grouped by characteristics and target entities (Annex E).  
 This International Standard does not define ranges of values of these quality measures to rate levels or grades because these values are defined for each system by its nature depending on the system context and users' needs.  
 This International Standard can be applied to any kind of data retained in a structured format within a computer system used for any kinds of applications. People managing data and services including data are the primary beneficiaries of the quality measures. This International Standard is intended to be used by people who need to produce and/or use data quality measures while pursuing their responsibilities.  
 — Acquirer (an individual or organization that acquires or procures data from a supplier).  
 — Evaluator (an individual or organization that performs an evaluation, which can, for example, be a testing laboratory, the quality department of an organization, a

Terms	Variant	Complementary	AI Act	
2 Accuracy	free of errors		Article 015	2
21 Compliance	complete		Article 017	2
1 Accessibility	access		Article 017, Article 005	2
50 Measurement and method			Article 015	2
23 Confidentiality	personal data			2
11 Balance				2
26 Credibility		complementary		2
25 Consistency		complementary	Article 010	2
27 Currentness		complementary		2
76 Validation		complementary		2
40 Eliminate or reduce biased output		complementary		2
57 Quality criteria		complementary	Article 010	2
74 Training, validation, testing datasets		complementary	Article 010	2
56 Precision		complementary		2
60 Relevance		complementary		2
50 Measurement and method			Article 015	2
10 Auditability				2
142 Non-repudiation				2
73 Traceability				2
20 Completeness				2

## OPTIONAL INFORMATION

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## Observations



